Year in Review (Case Law) 2013-2014
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antitrust</td>
<td>4</td>
</tr>
<tr>
<td>Arbitration</td>
<td>21</td>
</tr>
<tr>
<td>Disability Issues</td>
<td>30</td>
</tr>
<tr>
<td>Employment and Labor</td>
<td>33</td>
</tr>
<tr>
<td>EMTALA</td>
<td>40</td>
</tr>
<tr>
<td>ERISA</td>
<td>50</td>
</tr>
<tr>
<td>Fraud and Abuse</td>
<td>54</td>
</tr>
<tr>
<td>Healthcare Reform</td>
<td>112</td>
</tr>
<tr>
<td>HIPAA</td>
<td>132</td>
</tr>
<tr>
<td>Hospitals and Health Systems</td>
<td>136</td>
</tr>
<tr>
<td>Insurance</td>
<td>143</td>
</tr>
</tbody>
</table>
Antitrust

U.S. Supreme Court Says “Reverse Payment” Deals Subject to Antitrust Scrutiny Under Rule of Reason

The U.S. Supreme Court held June 17 that “reverse payment settlements” of patent infringement litigation should be analyzed under the “rule of reason” to determine whether they violate the antitrust laws.

At the same time, the majority opinion, written by Justice Breyer, and joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan, declined to find, as the Federal Trade Commission (FTC) urged, that reverse payment (also known as “pay-for-delay”) agreements, which involve brand-name drug companies settling patent disputes by paying or providing value to generic drug manufacturers in exchange for an agreement to delay market entry of the generic drug, are presumptively unlawful.

The Court's 5-3 ruling reverses an Eleventh Circuit decision that dismissed the FTC's challenge to agreements in which Solvay Pharmaceuticals, Inc. paid several generic drug makers to delay generic competition to Solvay’s testosterone-replacement drug AndroGel. See Federal Trade Comm’n v. Watson Pharmaceuticals, No. 1:09-cv-00955-TWT (11th Cir. Apr. 25, 2012).

Instead, the Court said the FTC “must prove its case as in other rule-of-reason cases,” noting the likelihood of reverse payments resulting in anticompetitive effects “depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” Remanding the case, the Court left it to the lower courts to “structur[e] the present rule-of-reason antitrust litigation.”

A dissenting opinion, written by Chief Justice Roberts and joined by Justices Scalia and Thomas, argued a reverse payment settlement should be immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.

Justice Alito took no part in the consideration or decision of the case.

Intersection of Patent, Antitrust Law Debated

The application of antitrust laws to Hatch-Waxman-related patent settlements has divided the federal circuits.

While the Eleventh, Second, and Federal Circuits adopted the “scope of the patent test,” the Third Circuit opted for a “quick look rule of reason analysis” that would treat reverse payment agreements as presumptively unlawful unless rebutted by a showing of procompetitive benefit.

In the majority’s view, even where the anticompetitive effects fall within the scope of the patent, these types of agreements “can sometimes violate the antitrust laws.” Breyer said this conclusion had support in Court precedent.

“It would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well,” the majority concluded.

According to the dissent, however, “a patent holder acting within the scope of its patent does not engage in any unlawful anticompetitive behavior; it is simply exercising the monopoly rights
granted to it by the Government.” The cases cited by the majority, the dissent said, applied antitrust scrutiny to patent settlements only because the patent holder acted outside the scope of the patent. A patent’s scope should be determined only by patent law, Roberts added.

Discourage Settlements?

The dissent said the majority’s approach would discourage settlements of patent litigation, which “is unfortunate because patent litigation is particularly complex and particularly costly.”

While acknowledging this concern, the majority cited a number of reasons the FTC should have been allowed to prove its case—including the “potential for genuine adverse effects on competition” that could “at least sometimes prove unjustified.”

The Court also discounted concerns that an antitrust analysis based on the rule of reason would require litigating the patent’s validity and any question of infringement.

“In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself,” the Court said. A sizable payment, the Court explained, could suggest the patentee has serious doubts about the validity of the patent, which in turn could indicate “the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger. . . .”

The dissent disagreed, however, that the courts could scrutinize a reverse payment settlement under the antitrust laws without considering the validity of the patent.

 “[A]though the question posed by this case is fundamentally a question of patent law . . . the majority declares that such questions should henceforth be scrutinized by antitrust law’s unruly rule of reason,” the dissent wrote. “I would keep things as they were and not subject basic questions of patent law to an unbounded inquiry under antitrust law, with its treble damages and famously burdensome discovery,” Roberts said.


Fourth Circuit Finds North Carolina Dentistry Board Not Entitled to State Action Immunity

The Fourth Circuit refused May 31 to disturb a Federal Trade Commission (FTC) finding that the North Carolina State Board of Dental Examiners (Board) violated antitrust law by attempting to block non-dentists from providing teeth-whitening services in the state.

The Board argued it was immune from antitrust scrutiny under the state action doctrine, which provides a narrow exception to the antitrust laws for anticompetitive conduct if it is an act of government, but the Fourth Circuit disagreed. The appeals court also found substantial evidence that the Board violated the Sherman Act under a “quick look” analysis.

“At the end of the day, this case is about a state board run by private actors in the marketplace taking action outside of the procedures mandated by state law to expel a competitor from the market,” the Fourth Circuit concluded. Without evidence of state oversight, the Board’s actions were subject to the antitrust laws.

Board Composition

The eight-member Board consists of six licensed dentists elected by their peers; one licensed dental hygienist elected by fellow hygienists; and one consumer appointed by the governor. All
Board members, with the exception of the consumer member, must be actively practicing dentistry. Under state law, the practice of dentistry includes “remov[ing] stains, accretions or deposits from the human teeth.”

After receiving a number of complaints from dentists, the Board began investigating teeth-whitening services offered in the state by non-dentists, often at lower prices than those offered by licensed dentists. The Board eventually issued 47 cease-and-desist letters to 29 non-dentist teeth-whitening providers, which “successfully expelled” them from the market, the appeals court said.

In June 2010, the FTC issued an administrative complaint against the Board, charging it with violating the FTC Act. The Board tried to stop the administrative proceedings, but a federal district court denied relief. Meanwhile, an administrative law judge found the Board violated the FTC Act; the agency affirmed, enjoining the Board from issuing cease-and-desist orders to teeth-whitening providers.

The Board petitioned the Fourth Circuit for review of the agency’s final order, arguing it was exempt from antitrust scrutiny under the state action doctrine; that it did not engage in concerted action; and that it did not unreasonably restrain trade.

**No State Action Immunity**

The appeals court noted three instances where state action immunity arises: where the state itself is the actor; where private parties are acting pursuant to a “clearly articulated” state policy and are “actively supervised” by the state; and where “substate governmental entities” are acting pursuant to a clearly articulated state policy.

The FTC treated the Board as a private actor that had to satisfy both the “clearly articulated” and “actively supervised” prongs of the state action immunity analysis. The Board contended, however, it was a substate governmental entity and therefore only needed to show it acted pursuant to a clearly articulated state policy.

Although designated as a state agency, the Fourth Circuit agreed with the FTC that the Board was a private actor because the majority of its members were licensed dentists who were active participants in the regulated market and who were elected by fellow dentists.

The appeals court also found the Board, as a private actor, was not actively supervised by the state and thus did not meet the second prong for finding state action immunity. In particular, the appeals court noted the Board sent the cease-and-desist orders “without state oversight and without the required judicial authorization.” In the appeals court’s view, “good government” provisions in North Carolina law “fall far short of the type of supervision” required to meet this prong.

The Supreme Court also recently sided with the FTC in deciding the state action immunity did not apply to a hospital merger involving a substate governmental entity—a hospital authority. The High Court found no clearly articulated state policy to displace competition in the hospital services market. *Federal Trade Comm’n v. Phoebe Putney Health Sys.*, Inc., No. 11-1160 (U.S. Feb. 19, 2013).

**Antitrust Violation**

The Fourth Circuit found substantial evidence to support the FTC’s conclusion that the Board violated Section 1 of the Sherman Act.
The appeals court held the Board members were capable of conspiring because they continued to operate separate dental practices that included teeth-whitening services. The appeals court also found sufficient evidence of concerted activity—pointing in particular to the cease-and-desist letters, which were sent in several instances after Board votes.

As to whether the actions at issue amounted to an unreasonable restraint of trade, the FTC found a violation of Section 1 under a rule of reason and quick look analysis.

“We affirm the FTC’s mode of analysis and find that its conclusion that the Board’s behavior was likely to cause significant anticompetitive harms is supported by substantial evidence,” the Fourth Circuit wrote.

“It is not difficult to understand that forcing low-cost teeth-whitening providers from the market has a tendency to increase a consumer’s price for that service,” the appeals court reasoned.


U.S. Court in California Dismisses Health Plan Enrollees’ Antitrust Action Against Sutter Health

On June 3, the U.S. District Court for the Northern District of California held enrollees of a licensed healthcare insurance plan could not maintain their antitrust action under Sections 1 and 2 of the Sherman Act against a large regional network of hospitals and physicians because plaintiffs failed to establish a relevant market or predatory conduct resulting in or enhancing monopolization.

Plaintiffs are two individuals and others similarly situated (the putative class) who are enrolled in a licensed healthcare insurance plan that has a contractual relationship with defendant Sutter Health, which owns and operates several hospitals and other healthcare providers throughout Northern California.

Plaintiffs sued Sutter, alleging it engaged in anti-competitive conduct that eliminated competition in the market for healthcare services and resulted in supra-competitive prices. According to plaintiffs, Sutter employed tying arrangements that required health plans to use Sutter’s providers and affiliated physician groups (even when there were lower-priced alternatives) or be denied contracted access to any of them, including areas where Sutter had monopolies.

According to plaintiffs, this "all or none" language in Sutter’s contracts with health plans effectively forced the plans to agree to the tying contracts in order to comply with the state’s Knox-Keene Health Care Service Plan Act of 1975, which requires California health plans to provide enrollees a comprehensive network of a broad spectrum of medical service providers (e.g., primary care physicians, hospitals, ancillary medical services) that must be available within 30 minutes or a 15-mile radius from an enrollee’s residence or workplace. Plaintiffs argued the combination of Sutter’s dominant market presence in Northern California and the Knox-Keene Act’s accessibility requirements meant “anyone who is the only provider in a 15-mile radius of one of the required services has a pure monopoly [and] Sutter possess[ed] many hundreds of such monopolies.”

Plaintiffs also alleged Sutter engaged in tying across regions so that a health plan that needed access to Sutter’s hospitals in one county had to contract with all of Sutter’s hospitals throughout Northern California, including all of Sutter’s affiliated physician groups, laboratories, skilled nursing facilities, home care facilities, device suppliers, etc. These entities were in turn required to refer patients to Sutter hospitals for inpatient care, to Sutter labs for blood work, and so on,
depriving competing hospitals of customers, even in otherwise competitive areas, plaintiffs contended.

Plaintiffs further alleged Sutter imposed exclusive dealing arrangements that effectively forced health plans to require enrollees to obtain all of their healthcare services from Sutter Health providers, affiliated entities, and affiliated physicians’ groups, penalizing members that used non-Sutter Health providers.

Sutter moved to dismiss for lack of antitrust standing and for failure to state a claim. The court granted Sutter’s motion to dismiss without prejudice and with leave to amend and file a second amended complaint.

Sutter argued plaintiffs did not have standing under the Sherman Act as plaintiffs failed to sufficiently allege they were Sutter’s customers and were not parties to the Sutter Health-health insurance plan contracts making them only indirect purchasers of Sutter’s services. As indirect purchasers, plaintiffs lacked standing because any injury to them was indirect, Sutter argued.

Plaintiffs alleged as enrollees of a licensed health plan that contracted with Sutter they incurred higher healthcare expenses in the form of higher premiums, co-pays, and out-of-pocket costs as a result of Sutter’s alleged unlawful conduct. According to the court, plaintiffs’ alleged injuries were sufficient at the pleadings stage to show their injuries were directly related to Sutter’s actions for purposes of their Sherman Act claims for injunctive relief.

While finding plaintiffs had antitrust standing, the court held plaintiffs failed to state a claim under the Sherman Act. Specifically, the court found plaintiffs’ exclusive dealing allegations failed to show substantial foreclosure or a requirement to purchase services only from service providers with an exclusive contract. The court also found plaintiffs’ tying allegations failed to show Sutter required patients to choose only among Sutter providers and that anti-competitive effects resulted “in the form of, for example, an effect on more than an insubstantial volume of commerce.”

Plaintiffs’ argument that Sutter’s conduct destroyed and stifled competition that “dramatically increase[d] price[s]” was conclusory, according to the court, and failed to show predatory conduct resulting in or enhancing monopolization.

The court also found plaintiffs failed to establish market power in a relevant product and geographic market as required by the Sherman Act. Plaintiffs alleged the relevant market was the provision of healthcare and related services in 22 Northern California counties and more importantly, the provision of contracted access to healthcare services through healthcare plans that must comply with the Knox-Keene Act.

The court pointed out plaintiffs’ product market (all of the contracted access to all healthcare services through health plans) and geographic market (an “amorphous region” of 22 counties “that is not tethered to any factual allegations about Sutter’s market power”) were defined too broadly and therefore failed to identify the specific services that competed with each other or the geographic area where the competition took place.

The court also rejected plaintiffs’ claims under California’s Cartwright Act and Unfair Competition Law.


**U.S. Court in California Rejects Antitrust Action Against Kaiser, Labor Union**
On July 25, the U.S. District Court for the Southern District of California held plaintiff, the sole shareholder of corporations that own and operate acute-care hospitals in Southern California, failed to sufficiently allege a competitor's agreements over a 15-year span with a local labor union affiliate resulted in unreasonable restraint of trade and monopolization.

Plaintiff Prime Healthcare (Prime) owns and operates 11 acute-care hospitals located throughout Southern California. Prime provides care on a fee-for-service basis and most of its patients enter hospitals through emergency rooms and emergency care centers, the opinion said. Defendant Kaiser Foundation Hospitals (Kaiser) provides covered services to its members for a fixed monthly premium. Kaiser members can seek emergency care at any hospital, including any of the 11 Prime hospitals, and Kaiser must reimburse the non-member hospital for any services rendered. Defendant Service Employees International Union-United Healthcare Workers West (Union) represents health care workers working in California’s hospitals and clinics.

Prime alleged beginning in 1997, Kaiser and Union entered into a conspiracy through several oral and written agreements between themselves to restrain trade and asserted the following claims for relief: violation of Sections 1 and 2 of the Sherman Act; monopolization; attempted monopolization; and conspiracy to monopolize.

Prime contended written and verbal agreements, circumstantial evidence, and parallel conduct showed a conspiracy existed. Kaiser and Union filed respective motions to dismiss Prime’s First Amended Complaint. The court granted defendants’ motions to dismiss without prejudice.

Prime alleged the 1997, 2000, 2002, 2005, 2010, and 2012 labor partnership agreements between Kaiser and Union were illegal under Section 1 and constituted evidence of a broader conspiracy. Prime contended the agreements’ provisions included “code language” such as “increase[ing] Kaiser’s membership in current and new markets,” “market[ing] Kaiser to new and existing unions,” and “increase[ing] enrollment in the Kaiser Foundation Plan” to disguise their true activities aimed at market domination.

The court disagreed, finding a plain reading of those provisions failed to suggest an anticompetitive motive, objective, or purpose intended to restrain trade. The court also refused to infer that an illegal agreement existed simply because defendants’ agreements may have been “innovative or on a larger-scale than local collective bargaining agreements.”

As to the verbal agreements that Prime alleged helped Kaiser achieve market domination, the court concluded Prime’s reliance on Stanislaus Food Products Co. v. USS-POSCO Industries, No. CV 09-0560-LJO(SMS) (E.D. Cal. July 7, 2011), was distinguishable because Stanislaus involved a specific agreement between competitors that was limited in scope and timeframe and gave one of them market domination. In this case, however, Prime failed to specify dates, locations, or participants at the numerous 1996-1997 meetings that Prime argued resulted in the alleged unlawful conspiracy.

Prime also relied on parallel and independent activities conducted separately by Kaiser and Union as evidence of a conspiracy to restrain trade. But the court found these allegations failed to exclude the possibility of independent action. According to the court, while the allegations “could suggest the existence of a preceding illegal agreement or actions against the Defendants’ self-interests,” they “lack specificity or plausibility” to sustain a Section 1 claim.

Noting Prime would have a chance to amend its complaint, the court went on to address the other prongs of a Section 1 claim requiring a showing of an intent to restrain trade and an injury to competition.

Applying the rule of reason analysis, the court concluded Prime sufficiently pled the relevant service (emergency services, general acute-care hospital services, and services provided by
health care workers at Kaiser and non-Kaiser facilities) and geographic (San Bernardino, San Diego, Los Angeles, and Orange County) markets. However, the court held Prime failed to sufficiently plead facts showing defendants intended to harm trade or that their actions injured competition.

Next, the court rejected Prime’s claims of monopolization, attempted monopolization, and conspiracy to monopolize in violation of Section 2 of the Sherman Act. The court held Prime failed to show sufficient circumstantial evidence that Kaiser owned a dominant share of the relevant market—“a critical element to demonstrate circumstantial evidence of market power”—as Prime provided only conclusory statements with no factual contentions to support them.

The court also held Prime failed to show an attempt to monopolize by defendants as Prime alleged Kaiser “merely had the power to control prices,” not that it in fact controlled prices. Prime’s allegation that there was a “dangerous possibility” that Kaiser would succeed in acquiring, maintaining, or expanding its monopoly power was insufficient to allege specific intent to control prices. The court held because Prime failed to show a conspiracy existed as required for a Section 1 violation, Prime therefore also failed to show defendants conspired to monopolize under Section 2.


U.S. Court in California Dismisses Antitrust, RICO Claims Against Insurers in Price-Fixing Lawsuit

A federal district court in California dismissed again most of the claims in a fourth amended complaint against insurers alleging a conspiracy to artificially reduce and set “usual, customary, and reasonable” (UCR) reimbursement rates for covered out-of-network services using the Ingenix Database.

Since early 2009, subscriber, provider, and association plaintiffs filed lawsuits against WellPoint, Inc. and its subsidiaries, United Health Group (UHG), and Ingenix, which UHG acquired through a wholly owned subsidiary in 1998. The actions eventually were consolidated into the current Multi-District Litigation.

The court in August 2011 and September 2012 dismissed the bulk of plaintiffs’ claims on various grounds.

In its latest decision in the case, the U.S. District Court for the Central District of California dismissed with prejudice plaintiffs’ claims under the Sherman Act, the Employee Retirement Income Security Act of 1974 (ERISA), and the Racketeer Influenced and Corrupt Organization Act (RICO).

The court did allow several, limited state law claims to move forward.

Standing

On the threshold issue of standing, the court found the association plaintiffs lacked standing under ERISA because to litigate their claims would require the participation of individual members in the lawsuit. The court did find the association plaintiffs had standing to seek declaratory and injunctive relief under ERISA Section 1132(a)(1)(B) at this stage of the litigation.
The court also found the subscriber plaintiffs lacked antitrust standing under the Sherman Act because they failed to allege they suffered a direct injury. The court found the subscriber plaintiffs supplied no new allegations to modify its earlier analysis on this issue.

Specifically, plaintiffs “failed to explain that their injuries flow inexorably from Defendants’ efforts to reduce competition in the Data Market”; that they are participants in the Data Market; or that “their injuries are inextricably intertwined with the harm the Insurer Conspirators allegedly sought to inflict on the Data Market.”

Thus, the court dismissed the subscriber plaintiffs’ Sherman Act claim, as well as a similar claim under California antitrust law, with prejudice.

**RICO, ERISA Claims Dismissed**

The court dismissed with prejudice the RICO claims against WellPoint, finding plaintiffs failed to show WellPoint directed the enterprise, rather than “simply being involved” in it.

As the court previously determined, plaintiffs adequately pled UHG conducted the enterprise, but found again they failed to plead the other elements necessary for their RICO claims.

The court also dismissed plaintiffs' ERISA claims, finding they failed to exhaust administrative remedies and refusing to conclude defendants had an obligation to disclose UCR data even in response to a specific inquiry.


**U.S. Court in Illinois Dismisses Antitrust Action Against Hospital Provider, Insurer Alleging Exclusive Dealing**

On August 26, the U.S. District Court for the Southern District of Illinois dismissed a freestanding outpatient surgery center’s antitrust lawsuit against a competing provider and a health insurer alleging claims under the Sherman and Clayton Acts.

In dismissing plaintiff’s claims, the court pointed out Sections 2 and 3 of the Clayton Act apply only to goods, not to services—in this case, inpatient and outpatient medical services. For purposes of the Sherman Act claims, the court held plaintiff could not limit the relevant product market to a single method of payment (commercial insurers) when it could find other acceptable methods of payment (Medicare and Medicaid).

Plaintiff Marion Healthcare (MHC) is a multi-specialty freestanding outpatient surgery center. Defendant Southern Illinois Healthcare (SIH) is a nonprofit corporation that owns several acute-care hospitals that provide both inpatient and outpatient medical services. SIH also wholly or partially owns eight freestanding outpatient surgical providers. The other defendant, Health Care Services Corporation, d/b/a BlueCross and BlueShield of Illinois (BCBSI) is the largest health insurance company in Illinois and the dominant health insurer in the relevant geographic market—two Illinois counties and their surrounding areas.

MCH defined the two relevant markets as the sale of general acute-care inpatient hospital services and the sale of outpatient surgical services to commercial health insurers.

MCH asserted most health insurance companies in the relevant geographic market consider SIH a “must-have” hospital system for health plans as it is the largest hospital system in the region and the only local provider of certain essential services.
According to MHC, SIH demanded exclusionary language that prohibited BCBSI from contracting with competing providers like MHC; SIH coerced BCBSI into an agreement that tied discounts for SIH’s inpatient hospital services with exclusive contracting for in-network coverage of SIH’s outpatient surgical services; and the exclusionary agreements between MHC and SIH substantially foreclosed MHC and other competitors from commercial health insurance contracts for outpatient services in the relevant geographic market.

The court dismissed with prejudice MHC’s claims under Sections 2 and 3 of the Clayton Act because those provisions apply only to goods and not services. In this case, MHC designated the relevant markets as the sale of inpatient and outpatient services. The court found any goods involved in providing those services—such as intravenous medications, implants, and fixation devices—were “mere incidentals” to the dominant nature of the transaction, which was contracts for services.

The court also dismissed MHC’s claims under the Sherman Act. Applying a rule of reason analysis, the court found the relevant markets defined by MHC were deficient because they were limited to inpatient hospital and outpatient surgical services paid for by commercial insurers, and did not include government payers.

In so holding, the court rejected MHC’s argument that government payers like Medicare and Medicaid reimburse at significantly lower rates than do private insurers and therefore they are not interchangeable. Citing an Eighth Circuit case, Little Rock Cardiology Clinic PA v. Baptist Health, 591 F.3d (8th Cir. 2009), the court held MHC could not limit the product market to a single method of payment when there were other methods of payment that MHC would find acceptable. According to the court, MHC should have included in the relevant markets all potential buyers of inpatient and outpatient services, including government plans.

The court therefore dismissed without prejudice MHC’s exclusive dealing and monopolization claims, as well as the tying claim against SHI, saying MHC could amend the complaint to correct the deficiencies in the relevant market alleged. The court dismissed with prejudice MHC’s tying claim against BCBSI as MHC failed to allege BCBSI had market power in the tying and/or tied product, i.e., hospital services.

The court also dismissed MHC’s claims based on state antitrust law, which is substantially similar to federal antitrust law, and therefore the claims suffered the same deficiencies.

Lastly, the court dismissed with prejudice MHC’s claim against BCBSI for tortious interference with a business expectancy as BCBSI took action pursuant to already existing, ongoing contractual relationships with its in-network physicians. Citing Quist v. Board of Trustees of Community College Dist. No. 525, 258 Ill.App.3d 814 (Ill. App. Ct. 1994), the court quoted “in order to maintain a cause of action for tortious interference with a contract or prospective contractual relationship, the tortfeasor must be a third party to the contractual relationship.”


U.S. Court in Illinois Certifies Class in Payer Antitrust Action

The U.S. District Court for the Northern District of Illinois granted December 10 class certification to plaintiffs in their antitrust action against a health system. The case arose from the decade-old merger of Evanston Northwestern Healthcare Corp. with Highland Park Hospital.

Plaintiffs, Amit Berkowitz, Steven J. Messner, Henry W. Lahmeyer, and Painters District Council No. 30 Health & Welfare Fund, brought a class action against defendant NorthShore University HealthSystem (formerly known as Evanston Northwestern Healthcare) on behalf of all end-payers who purchased inpatient and outpatient health care services directly from NorthShore.
The suit alleged NorthShore illegally monopolized the market and caused plaintiffs and the putative class to pay artificially inflated prices for health care services in violation of the Sherman Antitrust Act Section 2, 15 U.S.C. §§ 2 and 18, and Section 7 of the Clayton Antitrust Act.

Plaintiffs moved for class certification but the court denied the motion, holding they had not satisfied the predominance prerequisite in the applicable statute. The Seventh Circuit on interlocutory appeal vacated the district court’s order and remanded for further proceedings consistent with its opinion. Messner v. Northshore University HealthSystem, 669 F.3d 802 (7th Cir. 2012).

On remand, the court noted to be entitled to class certification, a plaintiff must satisfy each requirement of Rule 23(a)—numerosity, commonality, typicality, and adequacy of representation—as well as one subsection of Rule 23(b).

The court adopted the analysis of its previous holding that plaintiffs satisfied the prerequisites of typicality and adequacy of representation. After Messner, which held plaintiffs satisfied the predominance prerequisite, superiority was the only class certification requirement at issue, the opinion said. Under Rule 23(b)(3), a class action must be “superior to other available methods for fairly and efficiently adjudicating the controversy.”

The court first addressed NorthShore’s argument that a class action is not superior to arbitration as a means to resolve the dispute. NorthShore argued it had a right to arbitrate disputes as to both the putative plaintiff managed care organizations (MCOs) and the self-insured subscribers, who allegedly are bound by the arbitration provisions contained in the NorthShore-MCO contracts on equitable estoppel and agency grounds.

Although finding NorthShore did not waive its right to compel arbitration, the court found the MCOs are only proposed class members. The named plaintiffs, as non-parties to the alleged contracts, could not be bound by a judicial order to arbitrate, the court pointed out.

In addition, the court noted substantial issues involving numerous arbitration provisions—for 56 separate contracts—that “cannot easily resolve now without giving the MCOs and others a chance to weigh in.”

“So the sensible course, as the previously assigned judge concluded, is to decide whether to certify the class without considering the possibility of arbitration, bring the MCOs into the case, see what their position is on arbitration, and then decide who must arbitrate,” the court said.

The court also rejected NorthShore’s argument that class litigation was not superior to individual litigation. NorthShore argued a certified class would be unmanageable because any trial would require hundreds of mini-trials analyzing many individual NorthShore-MCO contracts. But in Messner, the Seventh Circuit already rejected NorthShore’s mini-trial argument in finding common issues predominates over individual ones, the court found.


U.S. Court in Idaho Orders Health System to Divest Physician Practice Group

The U.S. District Court for the District of Idaho held January 24 that St. Luke’s Health System, Ltd. must divest Saltzer Medical Group after finding the acquisition of the physician practice violated federal and state antitrust laws.
The court issued the order to unwind the acquisition following a bench trial in October 2013. According to the court, the transaction violated Section 7 of the Clayton Act and the Idaho Competition Act. While ordering St. Luke’s to fully divest itself of Saltzer’s physicians, the court declined to require St. Luke’s to notify the government before acquiring other physician groups in the future.

The Federal Trade Commission (FTC) and the Idaho Attorney General filed an action in March 2013 alleging St. Luke’s acquisition of Saltzer was anticompetitive. A group of health care providers, including St. Alphonsus and Treasure Valley Hospital, also previously had filed an antitrust lawsuit challenging the combination.

According to the joint complaint, the “combination of St. Luke’s and Saltzer would give it the market power to demand higher rates for health care services provided by primary care physicians (PCPs) in Nampa, Idaho and surrounding areas, ultimately leading to higher costs for health care consumers.”

In a statement following the court’s decision, FTC Chairwoman Edith Ramirez called the ruling “an important victory that will benefit both competition and consumers in Nampa, Idaho, and the surrounding areas.”

While noting the acquisition was intended “primarily to improve patient outcomes” as the nation attempts to move away from a quantity-based to a quality-based reimbursement system, the court nonetheless found it “highly likely that health care costs will rise” because the combined entity’s dominate market position would allow it to “negotiate higher reimbursement rates from health insurance plans that will be passed on to consumers” and “raise rates for ancillary services.”

The court “applauded” St. Luke’s “for its efforts to improve the delivery of health care,” but added “there are other ways to achieve the same effect that do not run afoul of the antitrust laws and do not run such a risk of increased costs.”

The court’s seven-page ruling did not include findings of facts and conclusions of law, which it decided to withhold at this time to address any confidentiality concerns the parties may have. The court directed the parties to file any objections to releasing the unredacted findings publicly. 


U.S. Court in Colorado Allows Some Antitrust Claims to go Forward Against Hospital Systems, Dismisses Others

The U.S. District Court for the District of Colorado held February 13 that a group of ambulatory surgery centers may pursue some of their antitrust claims against several competing hospital systems. The court did dismiss, however, the insurer defendants from the case finding plaintiffs failed to demonstrate their conduct was part of the alleged conspiracy.

Plaintiff ambulatory surgery centers perform outpatient surgical procedures and treatments in a non-hospital environment. Plaintiff Kissing Camels provides services in the area of Colorado Springs, CO, and the other three plaintiffs provide services in the Denver, CO metropolitan area.

Defendant HCA, Inc. owns defendant HCA-HealthONE LLC, which operates a system of hospitals and surgery centers in Metro Denver that compete with plaintiffs Cherry Creek, Arapahoe, and Hampden to provide ambulatory surgery services. Defendant Centura Health Corporation owns a system of hospitals and surgery centers in both Metro Denver and Colorado Springs, which compete with plaintiff Kissing Camels to provide ambulatory surgery services and defendant
Audubon Ambulatory Surgery Center, LLC is a joint venture between Centura and several local physicians. Defendant Colorado Ambulatory Surgery Center Association, Inc. (CASCA) is a trade association representing the interests of ambulatory surgery centers.

Plaintiffs alleged that beginning in 2010, Centura and HCA conspired to reduce competition for ambulatory surgery services by not doing business with plaintiffs, and by using their market power to pressure physicians and insurers with whom HCA and Centura have relationships not to do business with plaintiffs.

Plaintiffs sued defendant providers, along with a group of insurers doing business in Colorado and others, alleging a conspiracy to restrain trade in the Metro Denver and Colorado Springs markets for ambulatory surgery services, under both Sections 1 and 2 of the Sherman Act and under the state antitrust laws. Defendants moved for summary judgment.

**Sherman Act Section 1 Claims**

Plaintiffs' claims under Section 1 alleged defendants conspired to put plaintiffs out of business, which unreasonably restrained trade in the Metro Denver and Colorado Springs markets for ambulatory surgery services and damaged plaintiffs.

Each defendant argued plaintiffs insufficiently alleged that it participated in a conspiracy.

The court found plaintiffs sufficiently alleged a conspiracy in restraint of trade between HCA and Centura, Therefore, the court denied Centura's motion with respect to plaintiffs' Section 1 claims.

The court found, however, plaintiffs failed to sufficiently allege a plausible inference that CASCA joined HCA and Centura in conspiring to put plaintiffs out of business and accordingly granted CASCA's motion for dismissal. The court similarly granted Audubon's motion.

As to the insurer defendants, the court described the question before it as whether the allegations in the complaint suggested the insurers agreed with Centura and HCA to participate in the conspiracy, or whether their actions could equally have been independent.

The court concluded after reviewing the complaint “that Plaintiffs' allegations of the Insurers' parallel conduct, which targeted physicians using Plaintiffs' facilities and caused indirect injury to Plaintiffs, are insufficient to reasonably suggest that the parallel conduct was the result of an agreement and not the result of independent factors.” Accordingly, the court also granted the insurer defendants’ motion for summary judgment.

**Sherman Act Section 2 Claims**

Turning next to plaintiffs’ claims under Section 2, the court noted the complaint set forth claims of both attempted monopolization and conspiracy to monopolize against HCA and Centura in the Metro Denver market and against Centura and Audubon in the Colorado Springs market.

Citing the “paucity of Plaintiffs' allegations directly involving Audubon,” the court initially granted Audubon's motion to dismiss. But the court denied Centura's motion with respect to the Colorado Springs market, acknowledging its earlier findings that plaintiffs sufficiently alleged facts linking it to the conspiracy to reduce competition.

However, the court concluded plaintiffs failed to plead sufficient facts to support their Section 2 claims against Centura in the Metro Denver market and accordingly dismissed those claims.

U.S. Court in Rhode Island Refuses to Dismiss Health Care System’s Antitrust Action Alleging Refusal to Deal Against Insurer

A federal district court in Rhode Island rejected February 19 a motion to dismiss a health care system’s complaint alleging Blue Cross & Blue Shield of Rhode Island (Blue Cross) violated federal and state antitrust laws by taking steps to block the system’s acquisition of a community hospital and access to the Rhode Island market.

According to the U.S. District Court for the District of Rhode Island, Massachusetts-based Steward Health Care System, LLC at this stage of the litigation sufficiently alleged facts to state a plausible claim that Blue Cross engaged in anticompetitive conduct and tortiously interfered with existing and prospective contractual relations.

Hospital Deal Falls Through

In May 2011, Steward sought to acquire financially troubled Landmark Medical Center, a 214-bed general acute care community hospital located in Woonsocket, RI. Under its business model, Steward focuses on acquiring financially distressed community hospitals. It also sells health insurance and provides much of the care under those policies within its network of community hospitals, the opinion said.

According to Steward, Blue Cross undertook a series of anticompetitive steps aimed at blocking the Landmark acquisition and Steward’s entrance into the Rhode Island market, including engaging in intense lobbying efforts to block legislation that would have allowed Steward, a for-profit, to acquire other nonprofit community hospitals in the state and filing an application to remove Landmark from its provider network.

During ongoing negotiations, Steward also allegedly offered Blue Cross reimbursement rates for Landmark that were 5% below the average rates the insurer was paying other Rhode Island providers but Blue Cross refused. Steward contended Blue Cross took other actions aimed at further destabilizing Landmark’s financial position. In September 2012, Steward decided to abandon the acquisition of Landmark.

Steward sued Blue Cross for actual and attempted monopolization and monopsonization in violation of Section 2 of the Sherman Act and of the Rhode Island Antitrust Act, as well as for tortious interference with existing and prospective contractual relations. Blue Cross moved to dismiss the claims.

Refusal to Deal

The court rejected Blue Cross’ argument that refusal to deal could not form the basis for an antitrust action. Although “high value” is placed on the right to refuse to deal with other firms, “a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2 of the Sherman Act” under certain circumstances, the court said.

Here, the court found a number of allegations, if true, could give rise to a Section 2 violation, including that Blue Cross sought to terminate its prior course of dealing with Landmark and another hospital owned by Steward to the insurer’s short-term financial detriment and that Blue Cross rejected proposed reimbursement rates that were lower than the statewide average it accepted at other hospitals.

“In this case, Steward has pled facts sufficient to suggest that Blue Cross refused to purchase similar services from Steward that it purchased from other providers, at prices significantly below what Blue Cross was willing to pay to those other providers,” the court said.
Whether Blue Cross had a valid business justification for its alleged refusal to deal was not an issue the court could resolve on a motion to dismiss, the opinion added.

**Antitrust Standing**

The court also was not persuaded by Blue Cross’ contention that Steward lacked antitrust standing. Steward did not argue its injury was a loss of negotiating leverage, as Blue Cross contended, but rather Steward’s alleged injury was “the millions of dollars invested in the Landmark acquisition prior to its abandonment, and the lost profits that would have resulted from entry into the Rhode Island market,” which the court found to be a cognizable antitrust injury.

The court also did not view the alleged damages as too speculative, at least at the pleading stage, noting Steward sufficiently alleged Blue Cross engaged in anticompetitive conduct that proximately caused the demise of the Landmark acquisition.

Finally, even if Steward was a non-market participant and therefore presumptively disfavored as an antitrust plaintiff, the court held there was no party better suited or able to bring the unlawful exclusion claims at issue.

**Relevant Markets**

Next, the court held Steward adequately alleged relevant product and geographic markets.

The court concluded Steward’s exclusion of Medicare and Medicaid from the relevant product market was not in error. “Viewing the product market from the perspective of an aggrieved private purchaser of hospital services, then, it is appropriate to exclude Medicare and Medicaid purchasers because the private purchaser was never competing to purchase those services in the first place,” the court said.

The court also found Steward adequately alleged Rhode Island as the relevant geographic market. While some residents may cross state lines to obtain medical services, “common sense suggests that most consumers” would choose to obtain medical services at closer locations. Moreover, “Steward accurately notes that Rhode Island residents cannot practicably turn to out-of-state insurance providers that do not offer in-network access to hospitals and doctors in Rhode Island.”

Thus, the court refused to dismiss Steward’s antitrust claims. The court also held Steward stated a tortious interference claim.


**Seventh Circuit Finds Physician Failed to Show Antitrust Injury, Standing in Lawsuit Against Hospital**

The Seventh Circuit affirmed March 11 a district court’s decision that a physician failed to state an antitrust injury and lacked standing when he filed suit claiming Aurora Health Care (Aurora) engaged in anticompetitive practices to eliminate independent physicians from its medical staff to cut costs.

Dr. Albert Fisher, a Wisconsin-licensed family practice physician, sued Aurora after it refused to renew his medical staff privileges unless he agreed to be on call at the hospital 24-hours a day, seven days a week or provided equivalent alternate coverage by a physician who was on Aurora’s medical staff.
Fisher claimed “his exclusion from the hospital’s medical staff was part of an anticompetitive conspiracy to exclude independent physicians from the hospital, in violation of Section 1 of the Sherman Act, and that his exclusion denied him access to an ‘essential facility.’” Fisher also alleged Aurora acted with others to stop independent physicians, like himself, from ensuring backup medical coverage for their patients.

On appeal, the Seventh Circuit undertook de novo review, stating Fisher “must not only establish an antitrust injury, but also antitrust standing.”

Relying on the Supreme Court’s decision in Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 542 (1983), and its prior holding in Kochert v. Greater Lafayette Health Servs., Inc., 463 F.3d 710, 718 (7th Cir. 2006), the appeals court determined Fisher lacked standing because “consumers, insurance companies, or even groups of doctors serve as better plaintiffs than individual doctors to enforce potential antitrust violations.”

According to the appeals court, “Fisher is not the plaintiff that can most efficiently vindicate an alleged antitrust violation.”


Sixth Circuit Upholds FTC Ruling That Merger of Ohio Hospitals Was Anticompetitive

The Sixth Circuit upheld April 22 a Federal Trade Commission (FTC) ruling that the consolidation of ProMedica Health System, Inc. and rival St. Luke’s Hospital in Lucas County, OH was anticompetitive and likely to increase prices for general acute-care (GAC) inpatient hospital services and inpatient obstetric services sold to commercial health plans in the area.

“The Commission’s analysis of this merger was comprehensive, carefully reasoned, and supported by substantial evidence,” the appeals court concluded in denying ProMedica’s petition for review.

The appeals court also held FTC did not abuse its discretion in ordering ProMedica to divest St. Luke’s to an FTC-approved buyer, finding no reason to disturb the Commission's conclusion that this was the optimal remedy for preserving competition in the relevant markets.

The transaction closed August 31, 2010 but has been subject to a limited “hold-separate” agreement since then.

“The Sixth Circuit’s decision affirming the Commission's ruling is a victory for the residents of Lucas County, Ohio, and ensures that they will continue to benefit from competition,” said FTC Chairwoman Edith Ramirez in a statement following the ruling. “As this decision demonstrates, the FTC’s vigilant enforcement of the antitrust laws in health care provider markets helps deliver lower cost, higher quality health care to consumers.”

“We are extremely disappointed by the decision and intend to appeal,” according to a statement posted by ProMedica on its website.

Merger Challenge

The FTC filed an administrative complaint January 6, 2011 alleging the merger would reduce competition and allow ProMedica to raise prices for GAC and inpatient obstetrical services, significantly harming patients and local employers and employees, in violation of Section 7 of the Clayton Act.
While the administrative proceedings were pending, FTC filed a separate complaint with a federal district court in Ohio seeking an order requiring ProMedica to preserve St. Luke’s as a separate, independent competitor during the administrative proceeding and appeals process. In a 115-page opinion, the U.S. District Court for the Northern District of Ohio granted the FTC’s motion to temporarily block the consolidation. *Federal Trade Comm’n v. ProMedica Health Sys., Inc.*, No. 3:11 CV 47 (Mar. 29, 2011).

The administrative complaint alleged the acquisition would reduce the number of general acute-care hospital competitors in Lucas County from four to three leaving ProMedica with a market share approaching 60% for general acute-care services in Lucas County.

In the market for inpatient obstetrical services in Lucas County, FTC charged the acquisition would leave only one competitor to ProMedica, increasing ProMedica’s market share to more than 80%.

An administrative law judge (ALJ) in December 2011 found the acquisition eliminated competition and ordered ProMedica to divest St. Luke’s within 180 days.

The Commission largely affirmed the ALJ’s ruling in March 2013, finding ProMedica’s market share after the merger created a presumption of illegality and would have substantial anticompetitive effects.

ProMedica petitioned the Sixth Circuit for review.

**Relevant Markets**

For purposes of analyzing the merger, the Commission clustered primary (excluding obstetrics, which the FTC considered a separate product market) and secondary hospital services. The Commission did not consider tertiary services as part of its merger analysis, reasoning the competitive conditions for tertiary services, which include, for example transplant surgeries, differed from those for primary or secondary services such as hernia surgery or knee replacements.

On appeal, ProMedica argued the FTC got the relevant product markets wrong. ProMedica contended the Commission’s clustering methodology contradicted the 2010 Horizontal Merger Guidelines by focusing on supply rather than demand. But the appeals court disagreed, saying the Guidelines at issue concern the manner of defining a relevant market, not the conditions for clustering admittedly different markets when analyzing a merger’s competitive effects.

ProMedica also advocated another approach to defining the relevant market based on “the package-deal” theory. According to ProMedica, managed care organizations (MCOs) typically bargain for a package of hospital services—primary, secondary, tertiary, and OB—in a single negotiation rather than separately. The appeals court found, however, the record told a different story—i.e., that there was no evidence MCOs were willing to pay a premium to have all the services delivered by either ProMedica or St. Luke’s, which offered few tertiary services, in a single package.

The appeals court therefore affirmed the FTC’s market determinations—a cluster market of primary (but not OB) and secondary inpatient services and a separate market of OB services.

**Market Concentration**

ProMedica also disputed the Commission’s reliance on market-concentration data—specifically the Herfindahl-Hirschman Index (HHI)—to establish a presumption of anticompetitive harm.
According to ProMedica, the FTC should have focused on the extent consumers regard ProMedica and St. Luke’s as their next-best choice for each other, rather than presume the merger illegal based on the HHI data alone.

The appeals court agreed the Guidelines state a “unilateral effects” analysis, which was what was at issue here, will focus more on the extent the products of the merging firms are close substitutes, rather than the HHI numbers.

But the appeals court noted the instant case was “exceptional” in two ways.

First, before the merger ProMedica had the highest GAC market share (46.8%) in the relevant geographic area and already commanded higher average prices, which was not explainable by better quality or underlying costs. The appeals court therefore saw a direct correlation between market share and price.

Thus, the appeals court reasoned, “the Commission had every reason to conclude that, as ProMedica’s dominance in the relevant markets increases, so does the need for MCOs to include ProMedica in their networks—and thus so too does ProMedica’s leverage in demanding higher rates.”

Second, the appeals court said the HHI numbers themselves well-exceeded applicable thresholds. In the GAC market, the merger would increase the HHI by more than five times the increase necessary to trigger the presumption of illegality to a total number that was almost double the threshold for a highly concentrated market. In the OB market, the merger would increase the HHI by almost seven times the necessary trigger to almost triple the threshold for a highly concentrated market.

“On this record, the Commission was entitled to put significant weight upon the market-concentration data standing alone,” the Sixth Circuit said.

Given “the strong correlation between market share and price, and the degree to which this merger would further concentrate markets that are already highly concentrated,” the appeals court found the “Commission was correct to presume the merger substantially anticompetitive.”

**Presumption Not Rebutted**

Next, the appeals court held ProMedica failed to rebut the presumption of illegality—it did not show either that the merger would create efficiencies or enhance consumer welfare. The appeals court found it significant that the testimony of the merging parties themselves “tend[ed] to confirm the presumption rather than rebut it.”

ProMedica attempted to argue that another hospital system in the area, which provided tertiary services, was its closest substitute, not St. Luke’s. But the appeals court said this argument was based on a market definition— one including tertiary services—that already was rejected.

The appeals court also discounted ProMedica’s “weakened competitor” defense, characterizing the argument in general as “the Hail-Mary pass of presumptively doomed mergers.” The appeals court pointed to evidence in the record that St. Luke’s market share was increasing before the merger and other indicators it was not in dire financial straits.

Finally, the appeals court upheld divestiture as the appropriate remedy.

Arbitration/Mediation

U.S. Supreme Court Affirms Arbitrator’s Decision Allowing Class Proceedings

The U.S. Supreme Court said June 10 that an arbitrator’s decision to allow class arbitration of a dispute did not exceed his powers under the Federal Arbitration Act (FAA) so long as the arbitrator based the decision on his interpretation of the contract language, regardless of whether his construction was flawed.

In an opinion written by Justice Kagan, the High Court affirmed a Third Circuit opinion refusing to disturb an arbitrator’s decision that the contract at issue authorized class arbitration. *Sutter v. Oxford Health Plans LLC*, No. 11-1773 (3d Cir. Apr. 3, 2012).

The Court clarified that its decision in *Stolt-Nielson S.A. v. AnimalFeeds Internat’l Corp.*, 130 S. Ct. 1758 (2010), did not allow a court to delve into whether an arbitrator misconstrued a contract as authorizing class proceedings where the parties agreed the arbitrator should make that determination. In *Stolt-Nielson*, the Court found the arbitrators exceeded their powers because the parties stipulated that they had not agreed to class arbitration.

In 1998, John Ivan Sutter, M.D., a pediatrician, entered into a provider agreement with Oxford Health Plans, LLC (Oxford). The agreement stated: “No civil action concerning any dispute under this Agreement shall be instituted before any court” and required arbitration of all such disputes.

Sutter subsequently sued Oxford for underpayment and prompt pay violations. He moved to compel arbitration of the dispute as a class action.

In this case, the arbitrator reasoned the phrase “civil action concerning any dispute” in the contract necessarily includes class actions, and that if class relief is unavailable in court, it is available in arbitration absent an agreement to the contrary. The district court and the Third Circuit both agreed they could not vacate the arbitrator’s decision since it was based on his “good faith attempt” to interpret a contract.

The Court in December 2012 agreed to review the decision to resolve a circuit split on judicial review under Section 10(a)(4) of the FAA, which allows a court to vacate an arbitrator’s decision for exceeding his powers.

The only question a court needs to address in considering cases like this is “whether the arbitrator (even arguably) interpreted the parties’ contract, not whether he got its meaning right or wrong,” Kagan wrote.

If the arbitrator’s decision is based on an interpretation of the parties’ agreement, as clearly was the case here, the court’s review of that decision is at an end, Kagan added.

Oxford argued *Stolt-Nielson* dictated a different result. But the Court disagreed, noting the arbitrators’ decision in that case was set aside not because they misinterpreted the contract, but because they “abandoned their interpretative role” altogether.

“The arbitrator’s construction holds, however good, bad, or ugly,” Kagan said, adding the “potential for those mistakes is the price of agreeing to arbitration.”
In a footnote, Kagan did comment that the “Court has not yet decided whether the availability for class arbitration is a question of arbitrability,” but that this case did not present this issue because Oxford agreed the arbitrator should determine whether the provider contract authorized arbitration.

A concurring opinion, written by Justice Alito and joined by Justice Thomas, seemed to seize on this point, agreeing with the Court’s decision specifically because Oxford conceded the arbitrator should determine whether class arbitration was authorized under the contract.

Absent that concession, Alito suggested, courts may need to consider whether “the availability of class arbitration is a question the arbitrator should decide.”

Alito also noted “absent class members” may not be bound to the arbitrator’s resolution of the instant dispute because they never agreed the contract authorized the arbitrator to decide whether class arbitration was available.

“[A]n arbitrator’s erroneous interpretation of contracts that do not authorize class arbitration cannot bind someone who has not authorized the arbitrator to make that determination,” Alito wrote.


Florida Supreme Court Finds Arbitration Provision Not in Accord with State’s Medical Malpractice Act

The Florida Supreme Court held June 20 that an arbitration agreement between a healthcare provider and a patient was void as against the public policy expressed in the state’s Medical Malpractice Act (MMA) because it did not provide the same incentives as the statutory scheme.

Quashing an appeals court decision compelling arbitration, the high court also held the offending clause limiting damages without providing for a concession of liability by the provider was not severable from the arbitration agreement.

Before receiving medical treatment from Dr. Gary John Bowers and North Florida Surgeons, P.A. (NFS), Joseph Franks signed a four-page financial agreement that required arbitration of any medical malpractice or negligence actions. The agreement capped non-economic damages at $250,000 as permitted by the MMA, but did not require the provider to admit any liability.

Bowers performed surgery on Bowers initially without complications. Bowers subsequently was hospitalized, however, where a scan revealed a vein had been lacerated during the surgery. After Bowers died, his wife, Donna Franks, sued Bowers and NFS alleging medical malpractice and wrongful death. NFS moved to compel arbitration. The trial court granted the motion and the appeals court affirmed.

The Florida Supreme Court held the lower courts erred in compelling arbitration, finding the limitations of damages clause in the agreement was inconsistent with the legislative purpose and public policy in the MMA.

The MMA was intended to address the medical malpractice crisis, the high court explained, by creating “substantial incentives” for claimants to voluntarily submit to arbitration to avoid some of the expense associated with proving their case. The provision at issue, however, “blatantly contravenes” those incentives by instituting a $250,000 damages cap, without requiring the provider to concede liability.
The high court noted under the MMA, Franks could receive a maximum of $1 million if the case went to trial. But without the concession of liability, the agreement “contravenes the intent of the statue and, accordingly the public policy of this state,” the high court concluded.

Next, the high court held the limitations of damages clause was not severable from the arbitration provision. The high court did not address whether the arbitration provision was severable from the financial agreement.

Finally, the high court refused to find the Federal Arbitration Agreement (FAA) preempted the MMA. “Because we find that the MMA does not preclude all arbitration—and, in fact encourages arbitration under the specified guidelines—and that our decision here is fact-specific pertaining only to the particular agreement before us and does not prohibit all arbitration agreements under the MMA, we likewise find that the FAA does not preempt state law or preclude our decision here,” the high court said.

A dissenting opinion disagreed with the majority’s conclusion that the limitations of damages clause violated public policy. Instead, the dissent said, the majority’s invalidation of the agreement “is at odds with the public policy established by the Legislature.”


**New Mexico Supreme Court Holds Party Challenging Arbitration Agreement Must Prove Unconscionability**

On June 27, the New Mexico Supreme Court held the party alleging unconscionability of an arbitration agreement bears the burden of proof because unconscionability is an affirmative defense to contract enforcement.

In June 2008, plaintiff sued defendant nursing home alleging negligent care that resulted in preventable medical complications. The nursing home moved to dismiss plaintiff’s claim and compel arbitration according to the arbitration agreement that plaintiff signed in April 2007. Plaintiff argued the agreement was both substantively and procedurally unconscionable.

The district court found plaintiff’s substantive unconscionability claim lacked merit and that her understanding of the arbitration agreement weighed in favor of contract enforcement as she admitted to understanding the agreement would significantly limit her right to seek legal recourse when she signed the contract.

The appeals court reversed, relying primarily on the contract law principle that the party seeking arbitration has the burden of proof to establish the existence of a valid agreement to arbitrate. The appeals court also found compelling another state supreme court’s declaration that “the realities of nursing home admission render unconscionable all mandatory arbitration clauses in nursing home agreements,” and stated that nursing home admission contracts should be treated differently from mere commercial transactions since they are presented to individuals when they are most vulnerable.

Reversing, the high court held plaintiff bore the burden of proof because under state law, unconscionability is an affirmative contract defense in which the party alleging it must show the contract is unenforceable on the basis of being unconscionable. The high court further held the nursing home’s motion to compel arbitration was a suit for specific performance, not an affirmative defense as plaintiff alleged, and that the parties’ relative bargaining strength could not be used to shift the burden of proof.
The high court said plaintiff’s burden to prove unconscionability was consistent with the Federal Arbitration Act (FAA), which requires a court to enforce a valid arbitration agreement unless it is revocable under established principles of contract law.

In this case, the appeals court created a rule that applied only to nursing home arbitration agreements (i.e., “when a nursing home relies upon an arbitration agreement signed by a patient as a condition for admission to the nursing home, and the patient contends that the arbitration agreement is unconscionable, the nursing home has the burden of proving that the arbitration agreement is not unconscionable”).

According to the high court, the rule created by the appeals court was preempted by the FAA, which Congress enacted “to counteract judicial hostility to arbitration and ensure states place[d] arbitration agreements on equal footing with other contracts.” According to the New Mexico Supreme Court, the appeals court presumption that all nursing home arbitration agreements were unconscionable violated the FAA’s mandate that arbitration agreements be treated like any other contract.


**New Jersey High Court Finds Defendant’s Inaction Waived Arbitration**

A provider of anesthesia services (defendant) who was joined in and actively participated in litigation involving one of its certified registered nurse anesthetists (CRNA) but waited 21 months to file a motion to compel arbitration pursuant to its employment agreement waived its right to arbitrate, a unanimous New Jersey Supreme Court held August 14.

According to the high court, defendant’s behavior before trial justified a finding of waiver.

Plaintiff Karen Cole, a CRNA, had an employment agreement with Liberty Anesthesia Associates, LLC (Liberty) that included an arbitration provision. Liberty contracted with Cole to provide anesthesia services at Jersey City Medical Center (JCMC).

JCMC revoked her work privileges and Liberty subsequently terminated Cole’s employment. Cole sued JCMC, which impleaded Liberty as a third-party defendant. Cole amended her complaint to include Liberty as a direct defendant.

The hospital eventually settled the dispute. Three days before the case was scheduled to go to trial, but 21 months after being joined to the lawsuit, Liberty moved to compel arbitration pursuant to the employment agreement with plaintiff. The trial court granted the motion, excusing Liberty for not filing the motion to compel earlier because a non-signatory to the agreement, JCMC, was the primary defendant in the action. The appeals court reversed based on equitable estoppel.

The high court found Liberty waived its right to arbitrate and remanded for trial.

The high court noted it had not yet addressed the standard necessary to establish a party’s implicit waiver of its right to arbitrate. Surveying federal and state case law, the high court said the determination of waiver in the context of an arbitration agreement must focus on the totality of the circumstances, which “by necessity” requires a “fact-sensitive analysis.”

As set forth by the high court, the factors courts should consider in making this determination, with no one factor being dispositive, are:

(1) the delay in making the arbitration request; (2) the filing of any motions, particularly dispositive motions, and their outcomes; (3) whether the delay in seeking arbitration was part of
the party’s litigation strategy; (4) the extent of discovery conducted; (5) whether the party raised the arbitration issue in its pleadings, particularly as an affirmative defense, or provided other notification of its intent to seek arbitration; (6) the proximity of the date on which the party sought arbitration to the date of trial; and (7) the resulting prejudice suffered by the other party, if any.

Based on those factors, the high court determined “Liberty engaged in litigation conduct that was inconsistent with its right to arbitrate the dispute with its former employee.”

Specifically, the high court noted, among other things, that Liberty was a party to the lawsuit for 21 months before seeking to invoke the arbitration provision; advanced 35 affirmative defenses in its answer but did not include arbitration as one of them; and the motion to compel arbitration was filed three days before the trial was scheduled to begin, after extensive preparation, including discovery, interrogatories, proposed witnesses and exhibit lists, and motion practice.

“A party that intends to invoke its right to arbitrate in a case where another party is a non-signatory to the arbitration agreement may preserve its right by asserting arbitration in its answer as an affirmative defense, moving to compel arbitration in a timely manner, moving to stay the judicial proceeding, or notifying the other party to the arbitration agreement that its litigation conduct should not be considered a waiver of its right to arbitrate the dispute,” the high court observed.


**Tenth Circuit Upholds Nursing Home Arbitration Agreement**

The Tenth Circuit held September 20 that wrongful death beneficiaries of a nursing home resident must arbitrate their dispute with the nursing home based on an admission agreement signed by one of the beneficiaries.

Douglas Spradlin was admitted to THI of New Mexico at Hobbs Center, LLC, a nursing home, for long term care and treatment of his dementia. During the admissions process, Spradlin signed a Durable Power of Attorney appointing his children, Jason and Melissa, as his attorneys in fact. Melissa then signed a six-page “Admission Contract,” which included an arbitration agreement. On the agreement, Melissa checked a box indicating that she was “execut[ing] th[e] Contract in the capacit(y)” of “Immediate Family Member,” rather than “Attorney-in-Fact under validly executed power of attorney.”

After Spradlin passed away, Jason, as the personal representative of his father’s estate, sued THI and other defendants in New Mexico state court for wrongful death. THI filed a complaint in federal district court to compel arbitration, but Jason moved to dismiss THI’s complaint, arguing the arbitration agreement was invalid and unenforceable. The district court found the arbitration agreement was valid and enforceable and dismissed the action.

On appeal, the Tenth Circuit rejected Jason’s argument that his father was not bound to the agreement under a third-party beneficiary theory. The appeals court likewise rejected his argument that the wrongful death beneficiaries were not bound by the agreement.

Noting a split of authority among the states regarding the binding effect of arbitration provisions on nonsignatory, wrongful death heirs, the appeals court concluded the New Mexico wrongful death statute confers upon the beneficiaries those rights that the decedent would have possessed had he lived.
“Consequently, because Mr. Douglas Spradlin was bound by the arbitration clause as a third-party beneficiary, the non-signatory, wrongful-death beneficiaries are likewise bound,” the appeals court held.

The appeals court went on to reject Jason’s remaining arguments that the arbitration clause was procedurally unconscionable; that the nursing home breached a fiduciary duty to Spradlin; and that the lower court should have allowed discovery.

THI of New Mexico at Hobbs Center, LLC v. Spradlin, No. 12-2182 (10th Cir. Sept. 20, 2013).

Massachusetts High Court Says Health Care Agent’s Authority Does Not Extend to Arbitration Agreement

On January 13, the Supreme Judicial Court of Massachusetts held a “health care decision” under the state's health care proxy statute does not include the decision to waive a principal’s right of access to the courts and to trial by jury by agreeing to binding arbitration. Specifically, the high court held that Mass. Gen. Laws ch. 201D § 5 narrowly limits a health care agent’s authority to those decisions that require a principal’s informed consent to medical treatment, medical services, or procedures.

In May 2007, Mr. Dalton Johnson executed a health care proxy naming his wife Barbara Johnson as his health care agent. Four months later, Mr. Johnson was admitted to defendant’s nursing home. Almost a year later, the wife signed an agreement with the nursing home to submit any disputes to mediation and if mediation was unsuccessful, then to arbitration. In March 2009, Mr. Johnson suffered burns at the nursing home and was transported to a hospital, where he died four months later.

Plaintiffs (the administrators of Mr. Johnson’s estate) filed a wrongful death action against the national operator of the nursing home and two of its health care professionals. The nursing home defendants sought to enforce the arbitration agreement.

The trial court held the wife’s decision to enter into the agreement was a “health care decision” that bound Mr. Johnson. The court ordered the wrongful death suit stayed pending conclusion of the mediation or arbitration. Plaintiffs sought leave to pursue an interlocutory appeal, which the appeals court allowed. Thereafter, this court transferred the case to itself on its own motion.

According to the high court, the terms “health care” and “health care decision” as defined by the state’s health care proxy statute (Mass. Gen. Laws ch. 201D, § 1) limited the agent’s health care decisions to those that directly involved the provision of medical services, procedures, or treatment of the principal’s physical or mental condition, and that no language elsewhere in the statute suggested the legislature intended for a health care agent to have the kind of broad decision-making power allowed by a durable power of attorney, guardianship, or conservatorship.

Given the statute’s language, context, history, and purpose, the high court held a health care agent’s narrowly defined decision-making authority was limited to health care decisions and did not include authority to bind the principal to arbitration.

The high court was not persuaded by defendants’ argument that an arbitration agreement was no different from other decisions a health care agent may make on behalf of a nursing home resident, such as decisions regarding billing, access to the resident’s mail and personal property, or decisions about what the resident will eat.
The high court also pointed out that its conclusion that a health care agent does not have the authority to bind the principal to an arbitration agreement is consistent with the view of a majority of courts in other jurisdictions that have considered similar cases.

The high court distinguished this case from the one defendants relied on (Owens v. National Health Corp., 263 S.W.3d 876 (Tenn. 2007)), which involved an attorney in fact acting under a durable power of attorney for health care who signed an arbitration agreement as a precondition for the principal’s admission to a nursing home.


Tenth Circuit Says FAA Preempts New Mexico Case Law Finding Arbitration Agreement Unconscionable

The Tenth Circuit reversed January 28 a lower court decision denying a nursing home’s motion to compel arbitration of a wrongful death action after finding the agreement unconscionable under New Mexico case law.

While the Federal Arbitration Act (FAA) allows a state court to set aside an arbitration agreement as unconscionable, the notion that arbitration is inferior to litigation cannot be the basis for the decision, the appeals court said.

In this case, the Tenth Circuit held a New Mexico appeals court decision, Figueroa v. THI of New Mexico at Casa Arena Blanca, LLC, 306 P.3d 480 (N.M. Ct. App. 2012), cited by the district court in finding the agreement at issue unconscionable, relied on just such a faulty assumption and therefore FAA preemption was triggered.

Plaintiff Lillie Mae Patton’s husband signed an arbitration agreement when he was admitted to a nursing home operated by THI New Mexico, LLC (THI). The agreement required arbitration of any dispute arising out of his care except claims related to guardianship, collection, or eviction actions by THI.

After her husband’s death, plaintiff sued THI for negligence and misrepresentation. THI filed a complaint in the U.S. District Court for the District of New Mexico to compel arbitration of the claims.

The district court initially ordered arbitration. After that ruling, however, a New Mexico appeals court held an identical arbitration agreement unconscionable in Figueroa, prompting the district court to reverse its prior order. THI appealed.

Reversing, the Tenth Circuit agreed the FAA preempted the New Mexico common law on unconscionability, just as it would preempt a state statute with the same underpinnings, because it treated arbitration as inferior to litigation contrary to Supreme Court precedent.

The Tenth Circuit reviewed the state appeals court decision and found its finding of unconscionability rested on the perception that arbitration is inferior to litigation.

For example, in Figueroa, the appeals court concluded the agreement was unconscionable because it “subject[ed] the weaker party to arbitration” for those claims most likely to be brought by residents (i.e., negligence and personal injury actions), while preserving THI’s ability to litigate claims in court that it was most likely to bring (i.e., guardianship, collection, and eviction actions).

“Here, the state law does express the view that arbitration is inferior, and that is ‘impermissible,’” the Tenth Circuit concluded.
South Carolina Supreme Court Says Health Care Surrogate Lacked Authority to Sign Separate Arbitration Agreement

The sister of a patient acting as a health care surrogate under state law lacked the capacity to bind the now deceased patient to an arbitration agreement signed separately from a nursing home admissions contract, the South Carolina Supreme Court held March 12.

Denying the nursing home’s motion to compel arbitration of the wrongful death and survival action, the high court construed a health care surrogate’s authority under the Adult Health Care Consent Act, S.C. Code Ann. §§44-66-10 et seq., as extending primarily to traditional health care decisions, and only secondarily to the financial decisions that accompany care taking responsibilities.

On two occasions, Ann Coleman signed an admissions agreement and a separate arbitration agreement when her sister, who lacked the capacity to sign herself, was admitted to Faith Health Care Center.

“The separate arbitration agreement concerned neither health care nor payment, but instead provided an optional method for dispute resolution between the Facility and Decedent or Sister should issues arise in the future,” the high court said. Therefore, the high court said, Coleman lacked the authority as a health care surrogate to enter into the arbitration agreement.

The high court also held the facility’s equitable estoppel argument failed because there was no merger of the admissions and arbitration agreements, whose terms specified they remain separate.

A dissenting opinion argued the majority missed the mark by implying a power under the Act to make financial decisions that flow from health care decisions, but not similarly implying a power for the surrogate to bind a patient to arbitration.

The dissent opined that both powers—i.e., those related to financial decisions and those related to dispute resolution—should be implied under the Act.

The dissent also raised concerns the majority’s decision would encourage nursing homes to incorporate arbitration clauses into the admissions contract, rather than maintain separate agreements.

“[I]t is inadvisable and undesirable to interpret the statutes in a manner as to encourage nursing homes to utilize adhesive arbitration agreements more frequently than discretionary arbitration agreements,” the dissent said.

Finally, the dissent argued the majority’s interpretation contradicted U.S. Supreme Court precedent, which repeatedly has “emphasized that arbitration agreements must be placed on the same footing as all other contracts.”


Third Circuit Says No Arbitration of Device Providers’ ERISA Claims Against CIGNA
The Third Circuit held May 6 that two providers of medical devices did not have to arbitrate their derivative claims under the Employee Retirement Income Security Act (ERISA) against CIGNA after the insurer began denying coverage of their products and services.

The appeals court also ruled plaintiffs CardioNet, Inc. and LifeWatch Services, Inc., suppliers of outpatient cardiac telemetry (OCT), did not have to arbitrate their direct claims—for harm allegedly resulting from CIGNA’s distribution of a “physician update” that indicated their products and services were “experimental” and “unproven.”

The Third Circuit reversed the U.S. District Court for the Eastern District of Pennsylvania’s decision a year ago that both types of claims should be arbitrated pursuant to the contractual agreement between the parties. CardioNet, Inc. v. Cigna Health Corp., No. 13-191 (E.D. Pa. May 23, 2013).

The reversal stemmed from the appeals court’s narrow construction of the arbitration clause at issue, which it viewed as encompassing only disputes concerning the “performance or interpretation” of the contract. According to the appeals court, none of plaintiffs claims fell within this narrow category of disputes.

**Coverage Dispute**

In 2007, plaintiffs entered into an Administrative Services Agreement with CIGNA to become in-network providers. The agreement included an arbitration provision.

At the time, CIGNA announced a policy of covering OCT, which is an outpatient device typically used by cardiologists to monitor cardiac arrhythmias. CIGNA maintained the policy each year through 2011. In 2012, however, CIGNA reversed the policy and indicated it no longer would cover OCT.

CIGNA subsequently issued “Medical Coverage Policy Updates for Health Care Professionals” (physician update), “to hundreds of thousands of network physicians” announcing its non-coverage of OCT as “experimental, investigational or unproven.”

Plaintiffs sued CIGNA, both on their own behalf and as assignees of the rights and claims of five patients who were denied coverage of OCT by CIGNA. Plaintiffs asserted, among other things, claims to recover benefits due under ERISA Section 502(a)(1)(B) and sought an injunction under ERISA § 502(a)(3) directing CIGNA to withdraw its current coverage policy for OCT and rescind the physician update.

Plaintiffs separately advanced direct challenges to CIGNA’s dissemination of misleading and injurious statements about their products and services through common law and statutory claims for tortious interference with plaintiffs' relations with ordering physicians, violation of Section 43(a) of the Lanham Act, and trade disparagement.

CIGNA filed a motion to compel arbitration, which the trial court granted, both for the derivative and the direct claims.

**Broad Versus Narrow Construction**

Unlike the district court, the Third Circuit applied a narrow construction of the arbitration clause and determined none of plaintiffs’ claims fell within the scope of the agreement.

In particular, the appeals court read the section of the agreement outlining “internal dispute resolution” as limiting the section on “arbitration” to “disputes” regarding the “performance or interpretation” of the agreement.
**Direct Claims**

The Third Circuit found plaintiffs’ direct claims did not fall within the scope of the arbitration clause under this construction of “dispute” because the claims did not relate to the performance and interpretation of the agreement.

Instead, the claims hinged on whether the physician update—which was completely separate from the agreement—was deceptive and misleading and, if so, caused a cognizable injury to plaintiffs.

“[W]hether CIGNA performed its obligations under the Agreement has no bearing on whether it harmed the Providers by providing physicians with misleading information on OCT,” the appeals court observed.

**Derivative Claims**

The appeals court also found the derivative claims were not subject to arbitration, through which plaintiffs sought reimbursement for the cost of the OCT services provided to the five participants and injunctive relief requiring CIGNA to reverse its non-coverage policy.

The participants who assigned their rights under ERISA to plaintiffs were, as CIGNA conceded, not bound by the arbitration clause.

CIGNA argued, and the district court agreed, that plaintiffs could not essentially skirt the arbitration requirement by allowing them to bring the participants’ ERISA claims.

But the appeals court disagreed, noting first the claims did not involve the performance or interpretation of the contractual terms, which said nothing about CIGNA’s duty to cover OCT but instead referred to “the terms or conditions of the applicable Benefit Plan.”

“[C]laims challenging the denial of service may be brought only outside the confines of the Agreement, through ERISA claims assigned by CIGNA patients,” and therefore “clearly do not concern the performance and interpretation of the Agreement,” the appeals court said. Plaintiffs are not challenging the amount of payment, but rather the right to payment under the terms of the relevant plans.

In addition, even if the claims would have fallen within the arbitration clause if plaintiffs had brought them directly, “it does not follow that these claims when brought derivatively on behalf of others would necessarily fall within the arbitration clause.” The agreement does not explicitly require the arbitration of assigned claims and, as a basic principle, the assignee “stands in the shoes” of the assignor. Thus, if the participant assignors could have asserted the claims, than plaintiff assignees should be able to as well.

From a policy standpoint, moreover, a contrary ruling may discourage such assignments, which “would make it more difficult for patients to receive necessary services where their insurers have denied coverage,” the Third Circuit reasoned.


**Disability Issues**

*U.S. Court in California Says Hospital May Not Automatically Exclude Service Dog Without Individualized Assessment*
On August 2, the U.S. District Court for the Northern District of California precluded a hospital from automatically excluding service animals from its psychiatric unit without having conducted an individualized assessment of a patient’s service animal in accordance with the Americans with Disabilities Act (ADA) to determine whether the service animal’s presence would fundamentally alter the nature of the facility or its services and if the service animal posed a direct threat to the health and safety of others.

Plaintiff is a qualified disabled person who uses a service dog for independence and mobility. In December 2011, plaintiff started experiencing physical pain when her psychiatrist changed her medication. Defendant hospital admitted her to the psychiatric ward even though her medical issues at the time were physical, not psychological. The hospital refused to let plaintiff’s service dog stay with her during her 13-day hospitalization, citing its policy that prohibited service animals in the psychiatric ward.

Following discharge, plaintiff received outpatient psychiatric treatment but her condition required her to consider inpatient treatment. Plaintiff alleged another hospital admission would result in being deprived of her service dog. She therefore sought a preliminary injunction requiring the hospital to admit her service dog unless the hospital could present substantial evidence that the dog posed a direct threat to others’ health and safety that could not be mitigated by reasonable modifications according to the ADA. The court granted plaintiff’s preliminary injunction.

The court held the service dog’s presence would not fundamentally alter the nature of the hospital or the services it offered, and that the hospital’s blanket prohibition against service animals and its failure to conduct an individualized assessment of plaintiff’s situation constituted discrimination under the ADA. The court pointed out the hospital also failed to rebut plaintiff’s assertions that its occupational therapist brought her dog to the psychiatric unit numerous times, that other stand-alone psychiatric hospitals allowed service dogs, and expert testimony showed reasonable accommodations could be made in psychiatric wards.

The court also held the hospital failed to show that plaintiff’s service dog posed a direct and significant threat to others’ health and safety. The hospital’s arguments were speculative (e.g., dog’s harness being possibly used as a weapon, dog’s presence possibly upsetting patients), the court said, and plaintiff provided factual allegations that disputed the hospital’s generalizations, such as the service dog’s extensive training that accustomed it to loud noises and agitating behavior, the harness’ hard-to-remove buckles, a separate locked section in the ward for intensive care patients, and the hospital’s failure to consider reasonable accommodations so that plaintiff could care for the dog’s hygiene needs.

The court rejected the hospital’s argument that plaintiff’s harm was too remote to justify a preliminary injunction as plaintiff would not be harmed unless she was admitted. The court disagreed, finding plaintiff’s current relapse and difficulty managing her condition on an outpatient basis made hospitalization likely. The hospital’s discriminatory deprivation of her service dog “without substantial evidence of a direct threat to health or safety” would cause plaintiff imminent and irreparable harm, the court said.

Finally, the court concluded that the public has a strong interest in promoting equality for all persons and the hardships plaintiff and others similarly situated would suffer (decreased independence, equality, and dignity) outweighed the administrative inconvenience that the hospital would experience in complying with the ADA.


U.S. Court in North Carolina Finds No Intentional Discrimination in Hospital's Failure to Provide Deaf Patient with ASL Interpreter
The U.S. District Court for the Western District of North Carolina dismissed August 19 a deaf plaintiff’s disability discrimination claims against a hospital that failed to provide a qualified American Sign Language (ASL) interpreter.

According to the court, the hospital attempted to make a reasonable accommodation, and plaintiff failed to show he notified the hospital that its efforts were inadequate. Accordingly, the court found no intentional discrimination.

Plaintiff Michael Godbey, who is deaf, brought a disability discrimination action against defendant Iredell Memorial Hospital alleging it failed “to provide interpreter services to ensure effective communication with him during each of his medical visits.” According to plaintiff, the hospital violated Title III of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

Rather than providing a qualified interpreter of ASL, defendant, during the course of plaintiff's several visits, attempted to communicate with plaintiff through written notes or employees who were able to “finger spell” words. Plaintiff was not fluent in English and alleged he could not communicate effectively with the hospital.

While finding a genuine issue of fact as to defendant's failure to communicate effectively with plaintiff, the court granted defendant summary judgment because it did not intentionally discriminate.

Underlying plaintiff’s request for relief "is his perceived entitlement to an ASL interpreter merely upon providing hospital staff with notice of his deafness," the court noted. But “where reasonable accommodations were made and in the absence of information indicating that such accommodations would fall short in ensuring effective communication, there is no intentional discrimination,” the court held.

Although defendant “may have overestimated Plaintiff's command of English, it cannot be held liable for monetary damages under the Rehabilitation Act,” the court said.

The court also found plaintiff’s request for injunctive relief moot because defendant already amended its policy of providing translation services "in ways adequate to prevent a recurrence of the alleged violation."


U.S. Court in New Hampshire Refuses to Dismiss Deaf Patient’s Claim for Enhanced Compensatory Damages Against Hospital

The U.S. District Court for the District of New Hampshire denied April 7 a hospital’s motion to dismiss a claim for enhanced compensatory damages against it under the Americans with Disabilities Act and the Rehabilitation Act for failing to provide a profoundly deaf patient with a sign language interpreter.

Plaintiff Colleen Collins, who is deaf, underwent a surgical procedure at Dartmouth-Hitchcock Medical Center to replace her Cochlear implant. The procedure, which was performed by defendant Dr. James Saunders, was unsuccessful and Collins was unable to hear at all upon waking.

Collins alleged that despite knowing she would be unable to hear, Saunders did not provide a sign language interpreter and instead attempted to relay the results of the procedure through her sisters, but they insisted Saunders communicate with Collins directly. After attempts to do were unsuccessful, Saunders left and returned eight hours later, again without an interpreter,
and attempted to provide a written explanation. Collins claimed that due to her inability to understand Saunders, she believed she might die.

Collins alleged she was not provided an interpreter at subsequent appointments and was forced to sign a waiver indicating she did not wish to have one after being told she would not be treated otherwise.

Collins sued Saunders and DHMC (collectively, defendants). Defendants moved to dismiss Collins’ claim for enhanced damages, arguing the complaint did not allege “wanton, malicious or oppressive conduct.”

The court disagreed. Making all reasonable inferences in the light most favorable to the plaintiff, the court found the conduct alleged could support a claim defendants “recklessly created a great risk of harm.”

Additionally, the court held the allegations that defendants forced Collins to surrender her right to an interpreter by threatening to withhold medical care could be considered malicious or oppressive.


**Employment and Labor**

_U.S. Court in Ohio Rejects Resident’s Discrimination Action for Failure to Allege Disparate Treatment_

The U.S. District Court for the Southern District of Ohio granted June 3 defendant hospital and two of its employees summary judgment in a former resident’s action alleging his termination was discriminatory and violated federal and state law.

Plaintiff Sunil Nayyar was a physician in Mt. Carmel Health System’s (MCHS) internal medicine residency program. In June or July of 2009, he expressed concern to his supervisor and residency program director, Dr. John Weiss, about the intensive care unit (ICU) not being appropriately staffed during certain shifts, making patient safety an issue. At Weiss’ suggestion, Nayyar shared his concerns with Dr. Li Tang, MCHS’ Director of Medical Education, and provided him with a copy of the ICU schedule that included Nayyar’s handwritten notes. Despite Nayyar’s concern, Tang did not change the ICU schedule.

Following these conversations, Nayyar unsuccessfully attempted to insert an arterial line (A-line) into a comatose patient. Nayyar asked two nurses if they would like to try. One told Nayyar it was beyond a nurse’s scope of practice but the other agreed to try and successfully inserted the A-line. The nurse who refused to perform the procedure reported the incident that launched an investigation. During the investigation, Nayyar discussed the A-line incident with multiple MCHS employees even though he was specifically instructed not to do so.

On July 22, Weiss terminated Nayyar’s employment by letter, listed the reasons, and informed him he had the right to request review. Nayyar exercised that right but the termination was upheld. Nayyar then sued in federal and state court. The state action was removed and consolidated with the federal action.

The court first rejected Nayyar’s claim of race and national origin discretion in violation of federal and state law. Specifically, the court found Nayyar failed to identify a similarly situated employee of a non-protected class who was treated more favorably.
Nayyar contended another third-year resident, who was of U.S. origin and Caucasian, received the benefit of progressive discipline instead of immediate termination for a similar offense. But the court disagreed, noting that resident, who also was eventually terminated, lied about being chronically tardy or absent; his offense did not involve conduct that could have directly impacted patient safety.

The court also rejected Nayyar’s numerous state law claims, including that his termination violated Ohio whistleblower protections for reporting potential patient abuse or neglect—namely, the concerns he raised about staffing in the ICU.

The court found Nayyar failed to demonstrate violation of a state law (in this case, Ohio Rev.Code § 2903.34, which makes patient abuse or neglect a criminal offense) that would have invoked the whistleblower protections of Ohio Rev. Code § 4113.52(A)(1)(a). According to the court, Nayyar’s only evidence was a conversation he had with Dr. Weiss expressing concern about insufficient ICU staffing during certain shifts. The court said plaintiff’s affidavit about this conversation was not sufficient to raise a disputed issue of material fact that defendants attempted, or intended to, abuse, neglect, or otherwise harm patients. In any event, the court added, plaintiff failed to provide written notice to defendants that a law had been violated.

Next, the court held Nayyar could not maintain a claim that his termination violated Ohio public policy. According to the court, Nayyar failed to cite any source for a public policy exception to employment at-will where the employee has a dispute with a supervisor over a patient care decision.

The court also found Nayyar did not have a cognizable claim for abuse of process. Under state common law, an abuse of process claim may only be alleged in connection with a legal proceeding, the court said, noting an “administrative investigation for employment purposes . . . is not a legal proceeding.”

Rejecting his breach of contract claim, the court found Nayyar’s termination complied with MCHS’ Residency Physician Handbook, pointing to his utilization of MCHS’ appeal and review process and his termination letter that listed specific reasons for his termination and identified program expectations that Nayyar failed to meet.


U.S. Court in New Jersey Rejects Nurse’s Claims Against Hospital That Disciplined Her Based on Facebook Post

A federal district court in New Jersey held August 20 that the Federal Stored Communications Act (SCA) does protect non-public Facebook wall posts, but in this case the statute’s “authorized user exception” applied. The U.S. District Court for the District of New Jersey therefore rejected a nurse’s claim that the hospital she formerly worked for violated the SCA by taking disciplinary action against her based on one of her posts.

The court also rejected the nurse’s other claims against the hospital, including violations of the Family Medical Leave Act (FMLA) and state whistleblower protection laws and common law invasion of privacy.

Plaintiff is a registered nurse and paramedic who started working for defendant Monmouth-Ocean Hospital Service Corp (MONOC) in 2004. In July 2008, she became president of a local union. In this capacity, she filed complaints with the Environmental Protection Agency and the New Jersey counterpart about a disinfectant used by emergency workers and testified in the wage and hour lawsuit of another MONOC employee.
According to the opinion, during plaintiff’s seven-year tenure at MONOC, she developed an extensive disciplinary record for lateness, violating hospital policy, and failing to submit required documentation. By July 2011, she had accumulated 12 disciplinary “points,” which under MONOC policy was grounds for termination. Plaintiff also used FMLA leave on numerous occasions without filling out required certifications.

During this time, MONOC also temporarily suspended plaintiff with pay following a post she made on her Facebook wall criticizing paramedics following a shooting at a Washington, DC museum. Although none of MONOC management had access to her Facebook page, plaintiff had “friended” several of her coworkers, one of whom, on his own initiative, took a screen shot of the post and gave it to hospital management.

MONOC eventually terminated her after she exhausted her FMLA leave and refused to provide documentation for her request for additional time off despite the hospital’s repeated attempts to obtain it.

Plaintiff sued the hospital. The court granted the hospital’s motion for summary judgment on all plaintiff’s claims.

The SAC protects (1) electronic communications, (2) that are transmitted via an electronic communication service, (3) that are in electronic storage, and (4) that are not public, the court explained.

Noting few courts have addressed the issue, the New Jersey district court found the SAC applied to non-public Facebook wall posts where the user took steps to limit access. At the same time, the court found the SCA’s “authorized user exception” applied in this case because the coworker, an authorized user as one of plaintiff’s “friends,” who forwarded her post to MONOC managers did so voluntarily without any coercion or pressure.

The court also granted summary judgment to the hospital on plaintiff’s invasion of privacy claim as there was no evidence MONOC “intentionally intruded” on her Facebook page. Instead, according to the court, “the evidence shows Defendants were the passive recipients of information they did not seek out or ask for.”

The court also rejected plaintiff’s FMLA claim, saying the evidence showed the hospital had been “extremely accommodating” of her requests and had a right to ask for the appropriate certifications and recertifications.

Finally, the court granted summary judgment in the hospital’s favor on plaintiff’s state law claims under the New Jersey Law Against Discrimination and the Conscientious Employee Protection Act.


**Sixth Circuit Dismisses Surgeon’s Racial Discrimination Claims Against Hospital**

The Sixth Circuit affirmed November 15 the dismissal of a surgeon’s racial discrimination claims against a hospital after her privileges were revoked. In so holding, the appeals court found the surgeon was not able to support her claims with sufficient evidence.

Dr. LeCesha Brintley, an African-American, board-certified surgeon, cut two of her patients’ major blood vessels while performing a routine appendectomy at St. Mary Mercy Hospital, resulting in the patient suffering cardiac arrest followed by a day-long coma, according to the
opinion. St. Mary’s ultimately revoked Brintley’s surgical privileges after other interventions were unsuccessful.


Brintley argued the hospital violated Title VII when it revoked her privileges, but the appeals court noted Title VII protects employees—not independent contractors—from racial discrimination by an employer. On the threshold question of her employment status, the appeals court found all the “factors here point uniformly towards an independent-contractor relationship.” Accordingly, Brintley’s Title VII claim failed, the appeals court held.

Brintley next argued the hospital violated 42 U.S.C. § 1981 when it revoked her privileges. To proceed with this claim, however, Brintley must show the existence of a contract between her and St. Mary’s, the appeals court highlighted. Although Brintley argued the hospital bylaws created such a contract, “[n]othing in them speaks to or creates a contractual relationship with Brintley,” the appeal court found.

As to her state law racial discrimination claim, the appeals court said that because Brintley lacked any direct evidence that St. Mary’s discriminated against her on the basis of her race, she had to present evidence that the hospital treated her differently than “similarly-situated employees” who were not African-American.

Brintley argued St. Mary’s imposed less restrictive interventions on two Caucasian doctors than it imposed upon her. “But neither of the other two doctors had the history of serious complications that Brintley did. Thus, neither of them are similarly situated to Brintley, and her Elliot-Larsen claim therefore fails,” the appeals court held.


Alaska Supreme Court Affirms Dismissal of Medical Clinic Employee’s Suit After Termination

The Alaska Supreme Court affirmed November 29 the dismissal of an unfair termination action brought by a medical assistant against her medical clinic employer after she was fired for falsifying drug records.

Plaintiff Michele Beach worked as a medical assistant at Iliuliuk Family and Health Services. A report a person bought Vicodin from someone claiming to have obtained it at the clinic prompted an investigation that turned up a pattern of discrepancies. On every drug record entry for which the discrepancy could not be explained by a cross-check of the medical charts or superbills, the person who had initialed it was Beach, the investigation revealed. Beach was immediately fired.

Beach sued the clinic, and its executive director alleged that her discharge had breached the implied covenant of good faith and fair dealing. Defendants moved for summary judgment and the lower court granted the motion.

Beach appealed, arguing her termination was objectively unfair, given the clinic failed to interview her or relevant doctors and patients or to consider progressive discipline. She also argued her prior complaints about clinic security were protected activity and the lower court erred in rejecting her retaliatory discharge claim.

The Alaska Supreme Court first noted even though Beach was an at-will employee, an employer must act in a manner that a reasonable person would regard as fair.
Beach conceded it was reasonable for the clinic to conclude she was the one responsible for the drug records’ falsification, and there was no evidence, "at that time," that would have pointed to someone else as the culprit, the high court pointed out. Given the clinic’s reasonable conclusion about what had occurred and who was responsible, the immediate dismissal of Beach "without prior warning" was in accordance with what was required in the employee handbook, the high court found.

The lower court rejected Beach's retaliation theory on three alternative grounds, the high court explained. It held first that her complaints about security procedures were not protected activity, and second, even if the complaints were protected, that the evidence showed they were well received by her employer, "strongly refuting any causal connection between her proffered protected activity and her termination." The lower court further held even if there were evidence supporting these elements of a prima facie case, the clinic proffered a legitimate, non-retaliatory explanation for her discharge—the falsification of drug records—and, with the burden shifting back to her, Beach failed to offer evidence this explanation was pretextual.

Noting Beach argued on appeal only that her complaints were protected activity and did not address the alternative bases for the lower court's rejection of the claim, the high court refused to further consider the issue.


**U.S. Court in Minnesota Finds Terminated Nurse Not Entitled to Protection Under Whistleblower Law**

The U.S. District Court for the District of Minnesota dismissed January 10 a plaintiff's claims under the state’s whistleblower protection law, finding she failed to show she was engaged in protected conduct at the time of her job termination as a registered nurse at a dialysis company.

Plaintiff Lisa Pedersen worked as a registered nurse at Bio-Medical Applications of Minnesota d/b/a Fresenius Medical Care (BMA), a dialysis company. After an incident in which blood samples were allegedly mishandled, Pedersen reported the incident to her supervisor, BMA's Employee Access and Response telephone line, a BMA Regional Vice President, and BMA's Employee Relations Manager. The company officers inquired about the incident to Pedersen's supervisor, who informed them that the matter had been investigated and the specimens had not been affected.

After a medical leave, Pedersen was informed by her supervisor that she was suspended pending an investigation by BMA, due to several performance issues. Following its investigation, BMA determined Pedersen would be permitted to return to work, but she would receive a "corrective action" plan upon her return.

Pedersen's counsel then faxed a letter to BMA, asserting Pedersen had been constructively discharged in retaliation for her complaints regarding the blood samples.

BMA's counsel responded that Pedersen had not been discharged and requested she return to work, but Pedersen's counsel informed BMA she would not return to work unless, among other things, (1) she was permitted to work three days per week, in a “float” position, (2) BMA instituted company-wide whistleblower training, and (3) the company informed all persons involved that BMA had committed a “medical error” regarding the blood samples. The company refused these requests.

Additional efforts to reach an accord between the parties failed, and BMA eventually informed Pedersen that her employment had been terminated due to “abandonment” of her job.
Plaintiff sued BMA under the Minnesota Whistleblower Act (MWA), which prohibits an employer from taking adverse action against an employee who, in good faith, “reports a violation or suspected violation of any federal or state law . . . to an employer” or “reports a situation in which the quality of health care services provided by a health care facility . . . violates a standard established by federal or state law or a professionally recognized national clinical or ethical standard and potentially places the public at risk of harm.” Minn. Stat. § 181.932, subd. 1(1), (4).

BMA moved for summary judgment, which the court granted, finding plaintiff failed to show she engaged in statutorily protected conduct.

Pedersen did not show her complaints about the blood samples constituted “reports” under the MWA, the court said. According to the court, when Pedersen first raised the issue, BMA already was fully aware of it and had taken steps to address it. “Minnesota courts have long recognized that ‘the mere mention of a suspected violation that the employer already knows about does not constitute a ‘report’ under the [MWA],’” the court pointed out.

Moreover, even if Pedersen's complaints constituted “reports,” her claim would still fail because those “reports” did not implicate a violation of any law or ethical standard. The statute cited by plaintiff does not state that leaving blood samples out overnight is unlawful or unethical and simply alleging that a defendant violated internal policies is not enough under the MWA to state a claim, the court held.

The court further noted that, although Pedersen also cited several federal regulations regarding a patient's right to privacy and confidentiality, none of those regulations discusses the handling of blood specimens specifically and she “has failed to explain how the alleged misconduct she reported—leaving blood samples out overnight — would transgress these regulations.”


U.S. Court in Illinois Denies Summary Judgment to Physician Who Alleged Hospital’s Breach Excused Contract Performance

The U.S. District Court for the Southern District of Illinois said April 7 that it could not resolve on summary judgment whether a hospital’s breach of an employment agreement with a physician excused her non-performance of the contract.

Physician April Toelle previously was employed by Hamilton Memorial Hospital (MHM). The employment agreement provided Toelle would work for MHM between August 2010 and August 2013. The agreement included several provisions for compensation above Toelle’s base pay, including $500 per month for each nurse or physician’s assistant she primarily supervised, $500 per month to act as medical director of the clinic, and incentive compensation based on the weighted value of certain procedures. The agreement also contained a non-compete clause for the duration of the employment term and an integration clause.

Dissatisfied with her job at HMH, in June 2011 Toelle contacted Deaconess Hospital, where she previously worked and expressed interest in returning. After additional meetings, Toelle indicated she intended to resign from HMH and in February 2012 signed a contract to begin work at Deaconess in October 2012.

HMH sued, claiming Toelle violated the employment agreement and Deaconess tortuously interfered with the contract. Toelle counterclaimed for failing to compensate her for supervision work or providing incentive bonuses. Toelle moved for summary judgment granting her
counterclaim and dismissing HMH’s suit on the basis its prior breach justified her failure to perform, while Deaconess filed for summary judgment dismissing the tortious interference claim.

As regards Toelle’s countersuit, the court held the contract was breached in that the hospital failed to provide additional compensation for certain supervisory work.

The court also found, however, a genuine issue of fact as to whether Toelle waived the claim by continuing to perform the agreement after the breach, because the parties disputed whether and when Toelle had objected to the breach.

Furthermore, the court held Toelle had not presented any evidence to establish she was actually owed incentive pay.

Finally, the court found a genuine issue of fact as to whether the failure to pay Toelle for her supervisory work or other breach, if any, was sufficiently material to justify her nonperformance.

Turning to Deaconess’ motion, the court found no intentional inducement to breach the contract. While it was undisputed Deaconess clearly had the intent to hire Toelle, the court found no evidence Deaconess intended to induce a breach.

The court noted the contact at each step was initiated by Toelle, and Deaconess merely expressed a willingness to hire her if she was available. Deaconess was entitled to rely on Toelle’s representation as to her availability and under no obligation to investigate whether her conduct might violate the contract.


In a subsequent decision issued April 11, the court held the hospital could not seek damages against Toelle for medical malpractice “tail insurance,” lost goodwill/lost revenue, and continuing medical expenses, including salary and payroll taxes.

The hospital could seek damages, however, for the costs of recruiting and signing a replacement physician.


**Eleventh Circuit Affirms Dismissal of Physician’s Racial Discrimination Claims**

The Eleventh Circuit found May 2 in a long-running case that a Palestinian physician alleging racial discrimination failed to establish the defendant hospital’s legitimate, nondiscriminatory reason for revoking his medical staff privileges was pretextual. Accordingly, the appeals court affirmed the lower court’s grant of summary judgment to the hospital.

Plaintiff Abraham Awaad had medical staff privileges at defendant Largo Medical Center, Inc. (LMC) until LMC revoked and failed to renew his privileges. Plaintiff sued alleging numerous claims, including racial discrimination.

The district court granted summary judgment to LMC on plaintiff’s racial discrimination claims, concluding Awaad failed to identify any suitable comparators and failed to show LMC’s asserted legitimate, nondiscriminatory reason for firing him was false.

On appeal, the Eleventh Circuit noted that when a plaintiff relies on circumstantial evidence to prove discrimination, the court applies the burden shifting analysis in *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973). Under the *McDonnell Douglas* framework, a plaintiff has the initial burden to establish a prima facie case of discrimination. If a plaintiff makes the requisite showing
of a prima facie case, and the employer articulates a legitimate, nondiscriminatory reason for its actions, then the plaintiff must offer evidence that the alleged reason of the employer is a pretext for illegal discrimination, the appeals court explained.

Here, LMC offered a legitimate, nondiscriminatory reason for revoking Awaad’s medical staff privileges—that he failed to complete the hospital’s medical executive committee’s requirements—and “Awaad has not shown that there is a genuine dispute of fact suggesting that this reason was pretextual because, among other things, Awaad has not shown the falsity of the proffered reason,” the appeals court found.

The appeals court also rejected Awwad’s argument “that there is ‘a convincing mosaic’ of circumstantial evidence raising a reasonable inference that LMC discriminated against him,” finding he failed to raise a genuine issue of fact.

_Awaad v. Largo Med. Ctr., Inc._, No. 13-14275 (11th Cir. May 2, 2014).

**EMTALA**

**First Circuit Revives EMTALA Failure to Screen Claim**

On May 29, the First Circuit held a district court erred when it concluded a physician’s medical judgment may substitute for a hospital’s internal protocols for the purposes of meeting the Emergency Medical Treatment and Labor Act’s (EMTALA’s) appropriate screening requirements. In so holding, the appeals court reversed the court’s grant of summary judgment to a hospital and remanded for further proceedings on the EMTALA screening claim.

On January 4, 2007, plaintiff Hazel Cruz-Vazquez arrived at Mennonite General Hospital’s emergency room (Mennonite) complaining of vaginal discharge and blood spotting but no pelvic pain. She was in her third trimester of her first pregnancy. The on-duty emergency physician, Dr. Brenda Torres-Perez (Torres), performed only a pelvic exam, found Cruz-Vazquez was not dilated, and consulted with Cruz-Vazquez’s obstetrician who advised Torres to administer some medications and discharge the patient in stable condition, all of which Torres did. He discharged Cruz-Vazquez less than two hours after her arrival.

On January 6, Cruz-Vazquez saw her obstetrician who performed another pelvic exam, diagnosed her as suffering from an incompetent cervix, and recommended transfer to another hospital to which Cruz-Vazquez agreed. She transferred “in stable condition” that same morning and underwent a cesarean section. Her baby died on January 7 for unspecified reasons.

Cruz-Vazquez filed a complaint in the U.S. District Court for the District of Puerto Rico alleging Mennonite violated EMTALA by failing to screen her appropriately and failing to stabilize or properly transfer her before she was discharged.

The case followed what the appeals court described as a “tortured” procedural history that included an earlier remand from the First Circuit to the district court. The district court ultimately dismissed Cruz-Vazquez’s complaint, finding it stated facts that were limited to a medical malpractice claim.

The First Circuit vacated the district court’s judgment and remanded the case for trial as genuine issues of material fact existed as to whether Cruz-Vazquez was adequately screened under EMTALA.

Noting EMTALA does not define an appropriate medical screening, the First Circuit cited its decision in _Correa v. Hospital San Francisco_, 69 F.3d 1184 (1st Cir. 1995), which defined an
appropriate medical screening as one “reasonably calculated to identify critical medical conditions that may be afflicting symptomatic patients and provides that level of screening uniformly to all those who present substantially similar complaints. The essence of this requirement being there be some screening procedure, and that it be administered even-handedly.”

In this case, Mennonite stipulated it had a relevant screening protocol for female patients who presented with vaginal bleeding in their third trimester and that it failed to activate that protocol for Cruz-Vazquez. In light of this stipulation, the First Circuit focused on the district court’s failure to see how the case law distinguished between a hospital’s failure to follow a regular screening protocol, as in this case, and a screening protocol that was not followed because no identifiable symptoms triggered the need for such screening or that a screening protocol was followed but resulted in an improper diagnosis.

The First Circuit distinguished Reynolds v. MaineGeneral Health, 218 F.3d 78 (1st Cir. 2000), by pointing out the defendant-hospital’s only standard screening policy was a general one requiring “the taking of all presenting patients’ complete histories.” The Reynolds court held inquiries into a patient’s medical history absent a more detailed hospital policy was insufficient to find the patient received materially different screening from other similarly situated patients. In this case, however, Mennonite’s policy “straightforwardly set forth a series of testing requirements in its ‘Gravid with 3rd Trimester Bleeding’ protocol for all patients presenting a specific set of symptoms.”

The First Circuit also distinguished Vickers v. Nash Gen. Hosp. 78 F.3d 139 (4th Cir. 1996). In Vickers, hidden conditions in the emergency patient resulted in misdiagnosis followed a few days later by death. The Vickers court held the patient received screening that would have been provided to other similarly situated patients. “Treatment decisions . . . were fundamentally distinguishable from disparate treatment of individuals perceived to have the same condition,” the Fourth Circuit said. In this case, however, Mennonite staff was not blind to any hidden conditions in Cruz-Vazquez, so her evidence pointed not to Mennonite’s failure to properly diagnose based on a faulty screening but rather, a failure to treat her equally to others who were perceived to have the same condition.

The First Circuit refused, however, to grant Cruz-Vazquez summary judgment at this stage of the litigation, noting the evidence was unclear as to whether Torres may have been justified in treating her differently from other patients with like symptoms. “While a treating obstetrician’s medical judgment may inform whether or not a patient was sufficiently ‘like’ other patients that come under a given hospital protocol, it should not be improperly relied on to entirely bypass the hospital’s obligation to equally screen under the statute,” the appeals court cautioned.


U.S. Court in Massachusetts Refuses to Dismiss EMTALA Retaliation Claim

The U.S. District Court for the District of Massachusetts refused June 17 to dismiss an Emergency Medical Treatment and Labor Act (EMTALA) retaliation claim, finding the plaintiff registered nurse raised material issues of fact regarding whether she was terminated for reporting an EMTALA violation.

Plaintiff Margaret O’Connor was employed by defendant Jordan Hospital for over 38 years as a registered nurse and in various other healthcare positions relating to quality control.

After an incident where a Jordan Hospital patient was improperly transferred in violation of EMTALA, plaintiff in her position as variance manager drafted a self-report letter that was submitted to the Centers for Medicare & Medicaid Services (CMS). Subsequent to the incident,
plaintiff was criticized repeatedly by senior management regarding her performance and was eventually terminated, according to the opinion.

Plaintiff sued the hospital, alleging a host of claims, all of which were dismissed except for her claim of retaliation under EMTALA and under the Healthcare Provider Whistleblower Statute (HPWS). Jordan Hospital then moved for summary judgment on those claims.

For purposes of summary judgment, the court found plaintiff was a whistleblower under EMTALA entitled to protection from any retaliation from the hospital because she reported the EMTALA violation to her supervisors and prepared a report for CMS, a regulatory authority.

The court next found plaintiff set forth prima facie evidence of retaliation. “The time between the report of the EMTALA violation on March 15, 2010, and plaintiff's termination on May 19, 2010, was approximately two months,” the court noted. “A jury could reasonably find this temporal proximity alone sufficient to demonstrate a causal connection between the report of the EMTALA violation and plaintiff's termination.”

The hospital presented evidence that plaintiff received poor performance reviews both before and after the EMTALA violation was reported. But the court noted the majority of the documents Jordan Hospital submitted as the basis for plaintiff's poor performance in the variance manager role postdated the report of the EMTALA violation.

Thus, “[a]t the summary judgment stage, viewing the evidence as a whole and avoiding credibility assessments, the evidence in this case supports an inference of pretext,” the court found.

Turning next to plaintiff's claims under HPWS, the court noted that the state statute, like EMTALA, protects whistleblowers from retaliatory action taken against them by healthcare facilities. The court agreed, however, to dismiss these claims, finding plaintiff did not meet all the requirements of the HPWS.

Specifically, the court noted a lack of evidence that Jordan Hospital's senior management was aware plaintiff disclosed, threatened to disclose, or objected to alleged violations of state law and “there is no evidence in the record indicating that any such disclosure or objection contributed to her termination.”


Tenth Circuit Rejects Physician’s EMTALA Claim Alleging Hospital Terminated Him for Reporting Overcrowding

On August 20, the Tenth Circuit held that plaintiff physician could not assert an Emergency Medical Treatment and Labor Act (EMTALA) claim against a hospital that allegedly terminated him for reporting overcrowding in the emergency room because plaintiff did not suffer direct harm as a result of an actual EMTALA violation. The court also held plaintiff waived his ability to assert contract and tort claims against the hospital based on his termination.

Plaintiff Dr. Ron Genova is an emergency room physician employed by a physicians’ group that contracted with defendant Banner Health to provide the hospital’s emergency department services. According to the opinion, plaintiff and the hospital's administrators often clashed as plaintiff disagreed with the hospital’s decision to keep its emergency room open even when he thought its capacities were overtaxed.

Plaintiff sued the hospital after it decided to discontinue his services, alleging it violated EMTALA and state contract and tort law by discharging him for reporting overcrowded emergency room...
conditions. The district court granted the hospital summary judgment, and the Tenth Circuit affirmed.

The appeals court held EMTALA’s whistleblower protections did not apply because plaintiff was not directly or personally harmed or retaliated against for reporting an existing EMTALA violation, i.e. a failure to screen a patient, stabilize a patient, or transfer a patient in an unstable condition. In this case, plaintiff essentially was alleging the opposite of an EMTALA violation—"patient hoarding" rather than "patient dumping." While patient hoarding could lead to a situation where the hospital lacked the capacity to meet its screening and stabilization requirements, whatever impending violations could flow from overcrowding was not the type of harm EMTALA was meant to address, the appeals court said.

As to plaintiff’s state law claims in contract and tort, the appeals court held plaintiff expressly waived any right to sue the hospital under a contract he agreed to that provided if the hospital decided, for any reason, to discontinue his services, plaintiff would be “deemed to have resigned from the Medical Staff” and no longer “entitled to provide at the Hospital any of the professional physician services [he] previously provided.” Plaintiff’s contract with the hospital also released the hospital from any liability, claim, cause of action, or demand connected with the termination of his medical staff membership and clinical privileges.

The appeals court rejected plaintiff’s argument that the release in his contract with the hospital violated Colorado’s public policy as plaintiff failed to identify a state statute, administrative regulation, or ethical code that clearly mandated reporting of patient overcrowding.

An amicus brief filed by the American Academy of Emergency Medicine argued the hospital acted in bad faith when it invoked a provision in the contract between the hospital and plaintiff’s employer to seek plaintiff’s replacement at the hospital. The appeals court disagreed, stating the duty of good faith and fair dealing “cannot be used to contradict terms or conditions for which a party has bargained.” In this case, plaintiff’s contract with the hospital clearly stated that discontinuation of plaintiff’s services for any reason would result in his resignation and release of legal claims.


**U.S. Court in California Dismisses EMTALA Claims**

The U.S. District Court for the Northern District of California dismissed August 20 claims that a hospital violated the Emergency Medical Treatment and Labor Act (EMTALA) after a patient who was treated in the emergency department died the next day in the hospital parking lot.

According to the court, plaintiff’s complaint failed to show violations of either EMTALA’s screening or stabilization requirements.

Michael Jene Torres was brought by ambulance to the Santa Rosa Memorial Hospital’s emergency room. Torres was diagnosed with alcohol withdrawal, given one milligram of a sedative, and was instructed to go to a clinic the next day. Torres refused to leave the hospital premises and was found the next morning dead in the parking lot of the hospital.

Plaintiffs Michael Jene Torres, Jr., Robert Sexton, and Zenaida Stilley sued the hospital and other defendants claiming violations of EMTALA and state law and general negligence. Defendants moved to dismiss.

The court said plaintiff failed to adequately allege the hospital violated EMTALA’s screening requirement.
Plaintiffs acknowledged the hospital did screen the decedent when he presented at the emergency department, but argued because the decedent's bacterial pneumonia was not detected, any screening exam must have been inadequate.

Plaintiffs “appear unable to state a plausible claim that the examination was so cursory that it was not designed to identify the bacterial pneumonia,” and accordingly, that claim must be dismissed, the court held.

The court also dismissed the claim that the hospital failed to stabilize Torres' alcohol withdrawal, finding “plaintiffs rely on wholly conclusory allegations without providing any support for their argument that the administered dose of Lorazepam was insufficient to stabilize the decedent's alcohol withdrawal.”

Turning next to plaintiff's claim that the hospital failed to stabilize Torres' bacterial pneumonia, the court pointed out that “plaintiffs overlook the fact that the 'duty to stabilize the patient does not arise until the hospital first detects an emergency medical condition.'”

The court also dismissed plaintiffs' claim that the hospital had a duty to perform a second screening of the decedent when he remained on hospital premises. “[I]t appears that plaintiffs' actual complaint is that the first screening examination was improperly performed (which supports plaintiffs' allegation of negligence), not that the Hospital was obligated to continue screening the decedent as long as he remained on hospital premises,” the court said.

The court next rejected plaintiffs’ claims under Cal. Welf. & Inst. Code Section 15657, which imposes liability for physical abuse and neglect, finding they failed to show the decedent was a dependent adult as defined under the statute.

The court lastly addressed other motions regarding damages and standing and gave plaintiffs a time frame to file a second amended complaint in accordance with its decision.


U.S. Court in Wisconsin Says Plaintiff Must Show Jurisdiction Under EMTALA Statute

The U.S. District Court for the Eastern District of Wisconsin ordered October 4 a plaintiff in a suit alleging retaliation under the Emergency Medical Treatment and Labor Act (EMTALA) to respond to the defendant hospital’s argument that plaintiff was not an employee covered by the statute.

According to the court, it could not rule on defendant’s motion to dismiss for lack of subject matter jurisdiction until that factual issue was resolved.

Plaintiff Kamal Muzaffar, M.D. alleged Aurora Health Care Southern Lakes, Inc. retaliated against him because he complained about patient transfers he believed violated EMTALA. Aurora moved to dismiss based on lack of subject matter jurisdiction.

A claim arises under federal law for purposes of determining subject matter jurisdiction if the complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law. Here plaintiff argued jurisdiction arose under the federal EMTALA statute.

Looking at whether the complaint alleged a violation under the whistleblower provision of EMTALA, the court found it “unclear whether Dr. Muzaffar is a hospital employee covered under this provision.”
The complaint alleged Muzaffar “contracts with Aurora to provide services under hospital privileges,” and further stated that on a specified date, Muzaffar served as the on-call physician, the court noted. These allegations may be enough to establish an employee relationship, but “additional information is required for the court to ascertain jurisdiction in this case,” the opinion said.

Because the plaintiff bears the burden to establish jurisdiction, Muzaffar “will be provided an opportunity to respond to the factual challenge to jurisdiction raised by Aurora,” the court said.


### Sixth Circuit Holds ER Patient Failed to Allege an EMTALA Violation for Improper Screening

On October 24, the Sixth Circuit held in an unpublished opinion that a plaintiff who sought treatment in defendant hospital’s emergency room failed to establish a causal nexus between his injury and the alleged Emergency Medical Treatment and Labor Act (EMTALA) violation and failed to show the hospital acted with an improper motive.

The appeals court also found a preliminary determination letter from the Centers for Medicare & Medicaid Services (CMS) was not an adjudication that the hospital did not provide an appropriate medical screening.

Plaintiff lacerated his hand and went to defendant St. Joseph Health System’s (SJMS’s) emergency room, where the receptionist told him to complete an intake form and wait as no beds were available at the time. After 10 to 12 minutes, plaintiff left so his son could drive him to another hospital’s emergency room. The bleeding was severe so plaintiff returned to SJMS where the same receptionist told him to wait as no beds were available. A nurse noticed his injury and immediately brought plaintiff into the emergency room for treatment. Staff temporarily stopped plaintiff’s bleeding but airlifted him to a medical center for further treatment by a hand surgeon. Plaintiff could not work for one month due to his injury.

In August 2011, plaintiff sued SJMS alleging defendant violated EMTALA by failing to provide him an appropriate medical screening and stabilize his injury. SJMS removed the suit to federal district court, which granted SJMS’ motion for summary judgment. Plaintiff appealed to the Sixth Circuit.

As to the issue of causation and expert testimony, the appeals court cited its decision in *Cleland v. Bronson Health Care Group, Inc.* 917 F.2d 266 (6th Cir. 1990), stating the phrase “appropriate medical screening” means a screening that SJMS would have offered to any paying patient. In this case, the appeals court found plaintiff failed to present any evidence that would have allowed a jury to determine how much harm was caused by his initial laceration and how much was caused by SJMS’ alleged treatment delay. The appeals court noted “while medical expert testimony is not always needed to prove causation in EMTALA suits, it is necessary in cases such as [plaintiff’s] where, to a significant extent, [plaintiff’s] harm resulted from the initial injury.”

Relying on *Cleland* again, the Sixth Circuit also affirmed the district court’s alternative finding that plaintiff failed to adduce evidence SJMS acted with an improper motive. Plaintiff failed to show how his screening differed in some way from that given to other patients and that the difference was improperly motivated, the appeals court said.

Lastly, the Sixth Circuit disagreed with plaintiff’s argument that a preliminary determination letter from CMS constituted an adjudication that SJMS did not provide him with an appropriate medical screening. The appeals court reiterated that plaintiff must provide evidence of causation of his injury and SJMS’ improper motive, none of which was proven by CMS’ preliminary
determination letter. Moreover, plaintiff failed to “cite a single decision in which a court adjudicating an EMTALA action gave preclusive effect to a CMS preliminary determination letter or, in fact, any CMS decision,” the appeals court said.


U.S. Court in Wisconsin Finds Physician with Privileges Is an Employee for Purposes of EMTALA Whistleblower Provision

The U.S. District Court for the Eastern District of Wisconsin held November 27 in an issue of first impression that a physician with privileges at a hospital was an employee for purposes of the Emergency Medical Treatment and Labor Act (EMTALA) whistleblower provision.

“To find that physicians with staff privileges are not employees for purposes of EMTALA’s whistleblower provision would leave unprotected a group of people in an ‘advantageous position’ to observe and report potential violations” which would be “‘demonstrably at odds’ with the purpose of the statute as well as the intentions of the drafters, which were to provide protection to those reporting violations,” the court held.

Plaintiff Kamal Muzaffar, M.D. sued Aurora Health Care Southern Lakes, Inc. claiming Aurora retaliated against him for reporting patient transfers he believed violated EMTALA.

Muzaffar was a member of the medical staff at Aurora and thus contended EMTALA conferred jurisdiction. Aurora argued Muzzaffar’s on-call services are a condition of privileging rather than a condition of employment.

The court noted EMTALA’s whistleblower provision protects two categories of individuals: (1) qualified medical persons or physicians who refuse to authorize a transfer of a patient who has not been stabilized and (2) hospital employees who report violations of EMTALA.

Accordingly, for EMTALA to cover Muzzaffar, he must be considered an employee for purposes of the whistleblower provision. Aurora urged the court to adopt Seventh Circuit precedent under which a physician with staff privileges is not an employee but rather an independent contractor for purposes of bringing an employment discrimination suit under Title VII.

Declining to adopt this theory, the court said “Aurora has not cited--and I have not found--any Seventh Circuit cases applying this rule to EMTALA generally or, of importance here, to the definition of employee under EMTALA’s whistleblower protection.”

The court instead relied on Zawislak v. Memorial Hermann Hospital System, No.H-11-1335 (S.D. Tex. Oct. 26, 2011), which found the purposes of EMTALA would be frustrated if a physician who had staff privileges was not considered an employee for purposes of whistleblower protection.


U.S. Court in Minnesota Refuses to Dismiss EMTALA Claim, Finds Alleged Refusal of Treatment in Dispute

A federal court in Minnesota denied December 11 a defendant hospital’s motion to dismiss an Emergency Medical Treatment and Labor Act (EMTALA) claim alleging it failed to provide a mental health screening or stabilizing treatment to a patient who sought care there.

The hospital argued the patient refused an examination offered by a psychiatric evaluator at the facility. But the court found the issue of whether the evaluator provided an actual offer to
examine the patient, and whether the patient in fact refused that offer, were disputed questions of fact.

Plaintiff Claire Lee went to Hennepin County Medical Center’s Acute Psychiatric Services facility seeking emergency services and stabilization treatment for a psychiatric crisis that included suicidal thoughts, the opinion said.

Plaintiff said a triage nurse told her to go home, as did the nursing supervisor, who said plaintiff should call her doctor in the morning. After insisting she needed to be seen, a psychiatric evaluator allegedly yelled at plaintiff “I suppose I can see you—do you want to see me or not,” to which plaintiff replied, “not with that attitude.” According to plaintiff, the evaluator then had security escort her out of the facility.

The hospital argued plaintiff refused its offer to provide an examination and therefore it was relieved under the statute from complying with the screening and stabilization requirements.

Under EMTALA, a hospital does not violate the statute if a patient is offered an examination and treatment but the individual refuses.

The U.S. District Court for the District of Minnesota said it could not determine based on the current record whether the hospital in fact offered an examination and whether the patient in fact refused. For that reason, the court refused to dismiss the EMTALA claims.


U.S. Court in California Dismisses EMTALA Claim Against Hospital Alleging Bad Faith Admission

The U.S. District Court for the Northern District of California held February 28 that a hospital was not liable under the Emergency Medical Treatment and Labor Act (EMTALA) as it provided undisputed evidence the patient was admitted as an inpatient and that her emergency medical conditions were identified and treated throughout her hospital stay.

Plaintiff sued defendants Contra Costa Medical Center and the County of Contra Costa (collectively, CCRMC) alleging medical malpractice and violation of EMTALA. Plaintiff’s wife, Sandra Lopez, passed away two days after giving birth to a healthy baby at CCRMC.

CCRMC moved for summary judgment on the EMTALA claim, arguing it was not liable under the statute because Lopez was admitted directly to the obstetrics department as an inpatient when she arrived to deliver her baby on the night of September 29, 2011. Plaintiff contended, however, there were fact issues about when CCRMC admitted Lopez as an inpatient and whether it admitted her in good faith.

The court granted CCRMC’s summary judgment on the EMTALA claim based on “undisputed evidence” showing Lopez was admitted as an inpatient for treatment of the emergency medical conditions that presented themselves at the time of admission (preeclampsia and the HELLP syndrome). The court retained jurisdiction over the remaining state claim.

Addressing the issue of whether and when Mrs. Lopez was admitted to CCRMC, the court said “undisputed” records—as indicated on Lopez’s Labor Progress Report, medical records, Patient Registration Face Sheet, and testimony by an emergency room physician expert—supported the conclusion she was admitted as an inpatient when she arrived in labor on the night of September 29, 2011.
Next, the court found the medical records and expert testimony established Lopez received
treatment for the delivery of her baby and for her accompanying emergency medical conditions
as evidenced by the lab and diagnostic tests that various health care providers ordered upon
admission to identify her conditions, medications she received to address those conditions, and
repeated blood pressure checks.

The court therefore concluded Lopez was admitted as an inpatient, her emergency medical
conditions were identified and treated, and that CCRMC was not liable under EMTALA.


**U.S. Court in Massachusetts Finds Hospital Transfer Complied with EMTALA**

The U.S. District Court for the District of Massachusetts dismissed March 12 a patient’s
Emergency Medical Treatment and Labor Act (EMTALA) claim, finding her transfer complied with
the statute.

Plaintiff Sabrina Bryson, individually and as the Administratrix of the Estate of Vaughn Adam
Wilson, Jr., sued defendant Milford Regional Medical Center, Inc. (MRMC) after being taken there
by ambulance when she was 34+ weeks pregnant and experiencing severe abdominal pain.
Plaintiff previously had gastric bypass surgery.

Plaintiff was evaluated in MRMC’s Labor and Delivery Department and because of worsening
symptoms the decision was made to transfer her to a tertiary care center. Upon her arrival at the
second hospital, plaintiff underwent an emergency caesarian section. Her baby was born with no
detectable heart beat and passed away 11 days later.

Plaintiff alleged MRMC violated EMTALA by failing to stabilize her emergency medical condition
and failing to properly stabilize her before transferring her to another hospital. Plaintiff argued
EMTALA applied to her case despite the fact she presented to the Labor and Delivery
Department, and not to the Emergency Room at MRMC.

After concluding EMTALA could apply to patients who presented to other parts of the hospital and
not just the emergency room, the court found the record “replete with evidence to support that
that Plaintiff was experiencing an emergency medical condition.”

Given that plaintiff had an emergency medical condition, the court noted EMTALA required MRMC
either to provide treatment to stabilize the condition, or arrange a transfer that complied with
the statute.

According to the opinion, Dr. Hayley Marshall testified she decided to transfer plaintiff because
the second hospital had the ability to care for a premature child and to offer gastric bypass
surgeons should plaintiff require that type of surgery.

“Dr. Marshall considered all of the circumstances and determined that Plaintiff needed to be
transferred because the benefits of having the NICU and a gastroenterologist available to Plaintiff
outweighed the dangers of transportation to [the second hospital].” This process
therefore complied with EMTALA’s requirements, the court found.

U.S. Court in Pennsylvania Refuses to Dismiss EMTALA Claims Because Hospital Failed to Submit Evidence of Regular Screening Procedures

The U.S. District Court for the Eastern District of Pennsylvania denied April 3 a hospital’s motion to dismiss screening claims under the Emergency Medical Treatment and Labor Act (EMTALA) because the hospital failed to submit its standard screening procedures into evidence.

“Because all determinations regarding Plaintiff's EMTALA screening claim flow from the factual issue of what the hospital's standard screening procedures are, including whether these procedures were followed in the instant case, there remains a genuine issue of material fact,” the court said.

Plaintiff Gregory Blake argued defendants Main Line Hospitals, Inc. d/b/a Lankenau Medical Center and Lankenau Hospital, and Main Line Health, Inc. d/b/a Main Line Health System, violated EMTALA after Arlene Blake was transported to the Lankenau Hospital Emergency Department by ambulance when she called 911 because of chest pain.

Dr. Seema Rathi eventually saw Blake in the emergency room and ordered medications, but Blake passed away hours later from an undiagnosed ruptured aortic dissection.

Defendants moved for partial summary judgment on plaintiff's EMTALA screening claim, arguing the claims sounded in negligence only.

According to defendants, EMTALA’s screening requirements were met because Blake was "triaged, monitored, assessed, and treated in accordance with the normal and customary practice of the Emergency Department."

However, the court denied defendants' "because one of the foundational factual determinations in assessing an EMTALA screening claim remains unresolved: what the hospital's standard screening procedures are."

Instead of submitting evidence of its standard screening procedures, the hospital relied on testimony from hospital personnel, leading the court to conclude that the record presently before it “simply does not allow it to resolve Plaintiff's claim because of this deficiency.”


U.S. Court in Texas Says EMTALA Claim Needed Expert Witness Backing to Proceed

A federal court in Texas granted summary judgment to a defendant hospital in an action alleging a violation of the Emergency Medical Treatment and Labor Act (EMATLA) because the plaintiff in the case failed to designate an expert witness.

Although declining to adopt a "bright line rule” requiring expert testimony in every EMTALA case, the U.S. District Court for the Eastern District of Texas said the questions at issue in the instant action, including if and how defendants’ conduct in attempting to transfer plaintiff contributed to his injuries or illness, and whether defendants provided sufficient “stabilizing treatment,” clearly were “not a ‘matter of common knowledge’ . . . within the experience of the layman.”

Plaintiff sued various health care providers for medical malpractice, EMTALA violations, conspiracy to violate EMTALA, and fraud. Defendants moved for summary judgment, arguing plaintiff failed to designate expert witnesses and that such testimony would be necessary to support her claims.

In an unpublished decision, the court agreed that the failure to designate an expert was fatal to plaintiff's claims.

As to the EMTALA claims, plaintiff alleged the defendant hospital attempted to transfer or discharge him in a medically unstable condition.

According to the court, the Fifth Circuit suggested expert testimony is required to prove an EMTALA violation by defining “to stabilize” as “treatment that medical experts agree would prevent the threatening and severe consequence of the patient’s emergency medical condition.” See Battle v. Memorial Hosp., 228 F.3d 544 (5th Cir. 2000).

“Other courts,” the opinion noted, have held that “elements necessary to prove an EMTALA claim must be established by expert testimony, as they involve the analysis of complex medical decisions and treatment which are not within the general knowledge and understanding of lay persons.”

In this case, the court found the questions at issue clearly required expert testimony to establish plaintiff's EMTALA claim.

The court also dismissed the fraud and conspiracy claims as they were predicated on the alleged EMTALA violations.


**ERISA**

**U.S. Court in California Sends Hospital’s Claims Against Plan Back to State Court**

On September 12, the U.S. District Court for the Eastern District of California held the Employee Retirement Income Security Act (ERISA) did not completely preempt a hospital’s state law claims against a health insurance plan because they arose from two written contracts that created an independent legal duty for defendants.

Plaintiff Lodi Memorial Hospital Association, Inc. sued Aetna Health Plans of California and related entities (collectively, defendants) in state court for breach of two written contracts and declaratory relief. Defendants removed the action to federal district court contending ERISA completely preempted plaintiff’s state law claims. Plaintiff moved to remand, arguing the claims were not completely preempted and therefore the district court lacked subject matter jurisdiction.

Plaintiff and defendants were parties to two written contracts that took effect in 1995. Plaintiff alleged defendants began unilaterally taking discounts to what was owed under the contract, resulting in an alleged underpayment to plaintiff of millions of dollars.

The court applied the two prong test developed by the Supreme Court in Aetna Health Inc. v. Davila, 542 U.S. 200 (2004), to determine whether ERISA completely preempted a state law cause of action.
As to the first prong, the court determined plaintiff could not have brought its claim under ERISA because it arose from the two written contracts. The fact that plaintiff received assignments of benefits from its patients did not alone convert its claims into claims to recover benefits under ERISA, the court said. Plaintiff alleged defendants’ inappropriately discounted the contractual rates, not that the hospital was owed an additional amount under a patient’s ERISA plan, the court noted.

As to the second prong, the court found defendants’ alleged actions implicated an independent legal duty—i.e., under the two written contracts between the plan and the hospital.

Finding neither Davila prong satisfied, the court held plaintiff’s state law causes of action were not completely preempted and granted the motion to remand.


U.S. Court in New Jersey Refuses to Dismiss Provider’s ERISA Claim, Finds Anti-Assignment Clause Waived

On September 25, the District Court for New Jersey refused to dismiss a medical provider’s Employee Retirement Income Security Act (ERISA) claim, finding it established proper standing by assignment under ERISA; defendant waived its right to enforce its anti-assignment clause through “passive conduct”; the provider asserted its claim under ERISA and not under state law; and the provider adequately pled an ERISA breach of contract claim.

Plaintiff North Jersey Brain and Spine Center is an out-of-network medical provider specializing in brain and spinal cord conditions. Plaintiff performed “emergent surgical and other medical procedures” on a patient in February and March 2011. The patient is employed by defendant Saint Peter’s University Hospital, which also sponsors the patient’s health care plan.

Plaintiff submitted its bills to defendant or defendant’s administrator, a Blue Cross Blue Shield (BCBS) plan, for payment and processing. When plaintiff believed its bills were not being appropriately reimbursed and all appeals had been exhausted, plaintiff, as assignee to the patient’s benefits, sued under ERISA to recover benefits due and attorneys’ fees.

The court held plaintiff had proper standing by assignment under ERISA. While plaintiff’s allegations did not reproduce the actual assignment language, the court concluded plaintiff’s allegations were “buttressed” by two actual assignment forms that were executed by the patient, assigning plaintiff the right to file an appeal and a right to all payments for medical services. Moreover, “two federal court judges in this District have already found that this same assignment form, used by [plaintiff] with all of its patients, is ‘sufficient to establish [plaintiff’s] derivative standing under ERISA.’” The court therefore found plaintiff’s pleaded allegation coupled with the two forms established that the only benefit at issue, the right to reimbursement, was in fact assigned.

Defendant argued the BCBS plan contained an anti-assignment clause. The court noted that the Third Circuit has not addressed the enforceability of anti-assignment clauses in health care plans. Relying on other court decisions that have addressed this issue, the court concluded an anti-assignment provision in a health care plan is enforceable.

Given this holding, the court next considered whether defendant waived its right to enforce the provision against plaintiff and concluded that it had. The court found defendant’s involvement with the reimbursement claims constituted a waiver. The court noted BCBS interacted voluntarily and repeatedly with plaintiff without once invoking the anti-assignment clause. “Such passive
conduct, i.e., taking no action to invalidate the assignment vis-à-vis the assignee” was, according to the court, sufficient to waive defendant’s right to invoke the provision.

The court was not persuaded by defendant’s argument that Count I of plaintiff’s complaint was preempted by ERISA because it arose from a state regulation. The court held plaintiff asserted an ERISA claim, not under Section 11:24-5.3 of the New Jersey Administrative Code.

The court further held plaintiff properly pled a claim for recovery of benefits due under BCBS’ plan as plaintiff alleged defendant owed medical reimbursements “pursuant to an assignment of benefits” signed by the patient.

Lastly, the court denied defendant’s request for attorneys’ fees pursuant to Section 1132(g)(1) or ERISA, which allows an award of attorneys’ fees to a prevailing party at the court’s discretion. In this case, the court held plaintiff’s complaint survived defendant’s motion to dismiss and therefore found the facts did not suggest the presence of bad faith.


U.S. Court in New Jersey Finds Patients' Assignments of Rights Under ERISA Benefit Plan Did Not Confer Standing

The U.S. District Court for the District of New Jersey held March 6 that a group of surgeons did not have standing to sue an insurer under the Employee Retirement Income Security Act (ERISA) because the assignments signed by patients were not sufficient to confer standing in this instance.

Surgeons working at plaintiff North Jersey Brain and Spine Center (NJBSC) performed surgical procedures on three patients with Aetna health care insurance plans. Each patient signed an "Insurance Authorization and Assignment" form.

NJBSC sued defendant Aetna Life Insurance Company, alleging it authorized the three patients' procedures but then refused to pay the related claims in violation of ERISA.

Aetna moved to dismiss, arguing NJBSC did not demonstrate standing to assert claims for the alleged ERISA violations.

The court first noted standing to sue under ERISA Section 502(a) generally is limited to participants or beneficiaries of ERISA plans. NJBSC argued the assignments from its patients, who are participants/beneficiaries of ERISA-covered Aetna benefits plans, allowed it to “stand in the shoes” of those patients.

“[N]umerous courts in this district” have held a health care provider has standing to sue under ERISA where a beneficiary or participant has assigned their right to benefits to the provider, the court noted.

The court explained that the district is split, however, on what type of assignment is necessary to confer derivative standing. “Some judges, including myself, have found that more than the mere right to receive payment is needed,” the opinion said.

Other judges, however, “including judges considering the exact language at issue in this case, have found that the right to recover payment is enough.”

But the court said it “remains persuaded” that to confer ERISA standing an assignment must include the patient’s legal claim to benefits under the plan. Accordingly, the Assignment Form
here, “which includes only the right to payment and the right to appeal to Aetna on the patient's behalf,” is insufficient, the court held.


**U.S. Court in New Jersey Remands to State Court Hospital’s Action Alleging Improper Payment Denials**

A federal court in New Jersey remanded January 21 to state court a hospital’s action against various health benefit plans seeking millions of dollars in damages for allegedly improperly denying or underpaying claims.

The court said the complaint was limited to state law claims that were not preempted by the Employee Retirement Income Security Act (ERISA). The court also found no federal question jurisdiction under Supreme Court precedent as the complaint did not present substantial and disputed questions of federal law.

Plaintiff MHA, the owner of Meadowlands Hospital Medical Center, sued various health plans (defendants) in state court alleging violations of state law and common law claims of negligent misrepresentation, estoppel, and unjust enrichment, among other things.

Defendants removed the case to federal court alleging complete preemption by ERISA and “embedded federal question jurisdiction” pursuant to *Grable & Sons Metal Prod., Inc. v. Darue Eng’g & Mfg. Co.*, 545 U.S. 308 (2005). Plaintiff moved to remand.

In an unpublished opinion, U.S. District Court for the District of New Jersey agreed that remand to state court was appropriate.

For complete preemption under ERISA’s Section 502(a), the Third Circuit requires a showing that the plaintiff could have brought the claim under the civil enforcement provision and that “no other legal duty” supported the claim.

Here, the court found plaintiff did not have standing to “recover benefits due . . .under the plan.” Plaintiff was not a participant or beneficiary of the plans and a payment “authorization” signed by patients did not confer “standing by assignment,” even assuming the Third Circuit would endorse such a theory.

The court also rejected defendants’ contention that the court had “embedded federal question jurisdiction” under *Grable*.

Defendants argued the complaint raised questions of interpretation regarding federal Medicaid law, but the court disagreed. While the complaint referred to federal statutes and regulations, it expressly pled only state law claims. And to the extent the federal Medicaid statute is relevant, “it is not substantial and disputed,” the court said.

“[T]he parties’ dispute is not over an interpretation of the Medicaid fee-for-service reimbursement rates, but rather whether those rates apply at all, or whether Plaintiff should be entitled to be paid some other ‘equitable’ or ‘customary’ rate,” the court observed.

The court summed up the case as a state law contract claim that belonged in state court.

**Fraud and Abuse**

**OIG Says Arrangement Offering GPO Members Equity Interest in Parent Organization Presents Fraud and Abuse Risk**

The Department of Health and Human Services Office of Inspector General (OIG) found problematic a proposed arrangement to transfer an equity interest in the opinion requestor to members of a group purchasing organization (GPO) in exchange for the members’ agreement to extend their GPO contracts under new terms.

In an Advisory Opinion posted July 23, OIG said the arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute and thus OIG could potentially impose administrative sanctions. “Under the particular facts presented here, we do not believe that the Proposed Arrangement is sufficiently low risk,” the opinion said.

The opinion requestor, a publicly traded company that provides financial and performance improvement technology-based products and services to hospitals and health systems, has a wholly owned subsidiary that operates a GPO.

Under the proposed arrangement, the requestor would offer certain current and prospective GPO members an equity interest in the requestor in exchange for the member: (1) extending its contract with the GPO for five to seven years; (2) committing not to decrease purchasing volume; and (3) relinquishing its right to a portion of the administrative fees that would otherwise have been passed through to the members.

According to the opinion, when a GPO gives anything of value to its members to induce the members to order federally reimbursable products under the GPO’s contracts, the Anti-Kickback Statute is implicated. Although the GPO safe harbor and the discount safe harbor potentially apply to the arrangement, the “equity interest is a form of remuneration that would not meet any safe harbor to the anti-kickback statute,” OIG said.

Under Centers for Medicare & Medicaid Services guidance, when a GPO passes through a portion of its administrative fees to its members, those members are required to treat such distributions as discounts or rebates, which can reduce costs to federal healthcare programs, the opinion explained.

But under the proposed arrangement, the requestor would ask members to forego a portion of those distributions in exchange for shares of stock in the publicly traded parent of the GPO. As a result, unlike a discount, the remuneration under the arrangement would have no potential to benefit payors, including federal healthcare programs, OIG said.

In addition, OIG said the particular terms of the arrangement increased the risk of fraud and abuse.

“In sum, we believe that the Proposed Arrangement would allow the Requestor to give remuneration to GPO members to reward past referrals and to induce them to continue purchasing items, including those reimbursable by Federal health care programs, at equal or higher volume as in the past through the GPO, for an extended period of time,” the opinion stated.

OIG Says Anesthesia Services Arrangement Risks Sanctions

Anesthesia services provider’s proposal to contract with a psychiatry practice group to provide anesthesia services in connection with electroconvulsive therapy (ECT) procedures at a hospital could potentially generate prohibited remuneration under the Anti-Kickback Statute (AKS) and trigger sanctions, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted November 12.

The opinion requestor, an anesthesia services provider, contracted until 2011 with a hospital to exclusively provide anesthesia services. After a Psychiatry Group relocated its practice to the hospital and began performing ECT procedures, the hospital insisted in its negotiations for the requestor’s 2011 contract that Dr. X, a co-owner of the Psychiatry Group who is board certified in both psychiatry and anesthesiology, would also be allowed to provide anesthesia services to ECT patients.

The 2012 contract between requestor and the hospital allowed Dr. X to provide anesthesia services to ECT patients and required requestor “to provide coverage for [Dr. X] with prior notice as agreed to between [Requestor] and [Dr. X].”

The 2012 contract also included the following provision:

In the event [the Psychiatry Group] or the Hospital determines that an additional anesthesiologist is needed to provide ECT, [Requestor] shall negotiate in good faith with [the Psychiatry Group] to contract with [Requestor] to provide those services. If, after good faith negotiations, [Requestor] and [the Psychiatry Group] are not successful in negotiating the terms of an agreement for [Requestor] to provide anesthesia services to [the Psychiatry Group], then, so long as the last offer from [the Psychiatry Group] was at a fair market value rate, as reasonably determined by the Hospital, [the Psychiatry Group] or [Dr. X] may contract with an additional anesthesiologist to provide anesthesia services for ECT, and the provision of anesthesia services by that additional anesthesiologist shall not constitute a violation of [Requestor’s right to provide anesthesia services on an exclusive basis].

After the 2012 contract went into effect, the Psychiatry Group informed requestor that it determined an additional part-time physician was needed to provide ECT anesthesia services and asked the requestor to enter into a contract pursuant to which requestor would fulfill the Psychiatry Group’s need for an additional part-time physician to provide ECT anesthesia services.

Under the Proposed Arrangement, the requestor would reassign its right to bill for the services rendered by its anesthesiologists to the Psychiatry Group on coverage days. The Psychiatry Group would then bill and collect for those services and, in turn, would pay requestor a fixed, per diem rate for the anesthesiologists’ services.

OIG said this arrangement could potentially run afoul of the AKS because requestor “would provide the Psychiatry Group the opportunity to generate a fee equal to the difference between the amounts the Psychiatry Group would bill and collect from Medicare, Medicaid, other third party payors, and patients for Requestor’s anesthesia services, and the per diem amounts the Psychiatry Group would pay to Requestor.”

These per diem amounts would not qualify for protection under the safe harbor for personal services and management contracts for a number of reasons, OIG said, including that the aggregate compensation to be paid over the term of the agreement would be neither set in advance nor consistent with fair market value.
OIG concluded the arrangement presents more than a low risk of fraud and abuse because “it appears to be designed to permit the Psychiatry Group to do indirectly what it cannot do directly; that is, to receive compensation, in the form of a portion of Requestor’s anesthesia services revenues, in return for the Psychiatry Group’s referrals of ECT patients to Requestor for anesthesia services.”

This scenario “presents the significant risk that the remuneration Requestor would provide to the Psychiatry Group—i.e., the opportunity to generate a fee equal to the difference between the amounts the Psychiatry Group would bill and collect for Requestor’s anesthesia services, and the per diem amounts the Psychiatry Group would pay to Requestor—would be in return for the Psychiatry Group’s anesthesia referrals to Requestor,” OIG observed. Further, OIG said it could “discern no safeguards in the Proposed Arrangement that would minimize this risk.”


OIG Revokes Favorable Opinion on Online Exchange Service, Rejects Lab’s “Per-Order” Fee Arrangement with EHR Vendor

The Department of Health and Human Services Office of Inspector General (OIG) reversed course on a previously favorable determination that an online service to facilitate the exchange of information between health care practitioners, providers, and suppliers was structured to mitigate fraud and abuse concerns.

In a final notice, posted April 8, OIG terminated Advisory Opinion No. 11-18, dated November 30, 2011, saying it now believes the arrangement poses “more than a minimal risk of fraud and abuse under the anti-kickback statute [(AKS)].”

Under the arrangement, as described in the earlier opinion, the requestor, a company providing web-based business services to physician practices, provides access to an electronic database to identify health professionals for potential referrals. Health professionals interested in receiving referrals through the service can enter into “Trading Partner Agreements” with the requestor.

Physicians who purchase the service are given a discount of up to $1.00 on their monthly electronic health record (EHR) subscription fees; this discount is reduced, however, each time they use the service to make a referral to a “Non-Trading Partner.”

“We no longer find that the factors to which we cite in OIG Advisory Opinion No. 11-18 are sufficient to mitigate against the risk that the discount could be an improper payment to induce referrals of Federal health care program business, particularly in the context of high-volume services, such as laboratory tests,” OIG said in the notice of termination. Final Notice of Termination of OIG Advisory Opinion No. 11-18 (Dep’t of Health and Human Servs. Office of Inspector Gen. Apr. 1, 2014).

Per-Order Fee Arrangement

At the same time it issued the termination notice, OIG posted an advisory opinion finding a laboratory’s proposed arrangement with the EHR vendor could trigger sanctions under the AKS.

Under the arrangement, the laboratory would pay a per-order fee for each test order the vendor transmits to the laboratory. In return, the laboratory would be designated as an “in-network” laboratory in the vendor’s interface and therefore referring physicians would avoid the $1.00 transmission fee if they selected the lab over a non-network provider.
“The Arrangement implicates the anti-kickback statute because Referring Physicians are relieved of a financial obligation when they refer laboratory test orders to Requestor,” OIG noted.

While acknowledging the efficiencies and benefits of transmitting patients’ health information electronically and having the results automatically incorporated into the EHR, OIG found the arrangement’s fee structure “could potentially influence the Referring Physicians’ referral decisions in a material way.”

Echoing its comments from the notice of termination, OIG noted this concern was particularly significant for high-volume services like laboratory tests, where the transmission fees for using a non-network lab could add up quickly.

“[T]he risk that such a fee could influence a Referring Physician’s decision-making increases as the number of referrals increases, and physicians typically order laboratory tests with considerable frequency,” OIG observed.

OIG also could not identify any other reason for the lab to pay the per-order fees “other than to secure referrals.”

According to OIG, the arrangement “appears to permit Requestor to do indirectly what it cannot do directly; that is, to pay compensation to the Referring Physicians, by relieving them of a financial obligation, in return for the Referring Physicians’ laboratory test referrals.”


Vendor’s Statement

Although not identified in the opinion, athenahealth in an April 8 blog post by its Executive Vice President and Chief Operating Officer Ed Parks confirmed it was the requestor of Advisory Opinion No. 11-18.

In the post, Parks noted charging a transmission fee for using non-network service providers is common in other industries, including banking and long distance.

“The OIG’s walk-back closes one promising path forward to a functioning, sustainable economic model for health information exchange,” according to the post.

OIG Says Proposed “Carve Out” Arrangement Involving Clinical Labs Could Be Problematic

A proposed arrangement in which the operator of a clinical laboratory would contract with physicians groups to help them set up their own labs that would provide testing only for non-federal healthcare program beneficiaries does not pass muster under the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said June 13.

In an advisory opinion, OIG noted “long-standing concerns about arrangements” involving the “carve out” of federal healthcare program business “from otherwise questionable financial arrangements.”

“Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business,” the opinion said.
Under the proposal, the parent lab would establish a management company that would contract with physician groups to aid their establishment of their own clinical labs. The company would provide the groups with facility space and management and support services and offer to lease them personnel, equipment, and licenses to use the parent lab’s proprietary methods of operation, according to the opinion.

The physicians groups would pledge that their labs would provide testing only to non-federal healthcare program beneficiaries. The groups would send any testing for federal healthcare program beneficiaries to another lab, including potentially the parent lab.

OIG said the proposal would allow the parent lab to offer the groups “remuneration in the form of the potentially lucrative opportunity to expand into the clinical laboratory business with little or no business risk.”

OIG also noted the proposed arrangement could increase the likelihood that physicians would order services from the parent lab for federal healthcare program beneficiaries. “Thus, we cannot conclude that there would be no nexus between the potential profits the Physician Groups may generate from the private pay clinical laboratory business, on the one hand, and orders of the Parent Laboratory’s services for Federally insured patients, on the other,” OIG said.

Finally, OIG said the proposal’s financial incentives could affect physician decision making for all patients, including federal healthcare program beneficiaries, and could result in the overutilization of laboratory services.


Manufacturer’s “Tiered Rebate” Program Qualifies for Discount Safe Harbor, OIG Finds

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion released July 1 that a “tiered rebate” program based on purchases of both federally reimbursable products and non-federally reimbursable products would not trigger administrative sanctions.

According to the opinion, OIG believes the rebate program qualifies for protection under the discount safe harbor.

The requestor is a corporation that makes products used to treat ophthalmologic disorders and to improve vision, including pharmaceutical products, surgical equipment, vision aids, and related supplies, the opinion said.

The company is proposing a rebate program that would provide a tiered, percentage rebate based on purchases of surgical supplies and devices. The requestor certified the rebate amount would not vary based on the number of federally reimbursable products.

Under the proposal, the requestor would notify purchasers of their obligation to report rebates on surgical products reimbursed by federal healthcare programs in three ways—in the initial contract between the parties; on invoices sent to buyers; and in a year-end report summarizing the customer’s total qualifying purchases and total rebate.

To qualify for the discount safe harbor, the requestor would have to comply with the requirements for sellers, OIG noted.
First, OIG deemed the proposed rebates to be “discounts” as defined in the safe harbor—i.e., “a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction.” 42 C.F.R. § 1001.952(h)(5).

OIG distinguished the proposed arrangement from bundled discounts, which are viewed as problematic, because “a discount on one product [would] not be contingent on the purchase of another product” and “the discount would be readily attributable to each item purchased.”

Second, OIG found the rebates offered under the proposal met the safe harbor’s definition of “rebate” as “any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.” 42 C.F.R. § 1001.952(h)(4).

Specifically, OIG noted the contract with customers would spell out the terms of the rebate program, so buyers would know the types of products involved and the amount they would need to purchase to qualify for each rebate tier.

Finally, OIG concluded the proposal would satisfy the safe harbor’s notification requirements—i.e., by providing the buyer with sufficient information to meet the buyer’s reporting requirements.


OIG Declines to Issue Favorable Advisory Opinion to Ambulance Supplier Proposing Equipment Donations

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted November 27 that an ambulance supplier risked sanctions under the Anti-Kickback Statute if it donated equipment to an unidentified city as proposed in its bid for an exclusive two-year contract.

The city issued a request for proposals (RFP) for the provision of all emergency medical services (EMS) and certain equipment and related services. The RFP asked bidders to provide the following, or note an exception:

- Free emergency ambulance services to city-insured individuals;
- Two complete suction units, two automated external defibrillators, and two pulse oxygenators (collectively, equipment) pursuant to a nominal value lease;
- Free EMS training and classes for city personnel;
- Discounts for uninsured senior citizens; and
- Replenishment of disposable medical supplies used by the city during delivery of care prior to the patient’s transfer to the ambulance.

In its bid, the ambulance supplier that requested the advisory opinion agreed to provide the replenished supplies, but made a number of exceptions to the other provisions. Specifically, the supplier declined to provide free services, lease the equipment below cost or at no charge, provide free training, and provide uninsured discounts.

The requestor did indicate it would bill the city directly for the fair market value of emergency ambulance services to city-insured individuals; allow its compliance officer to decide whether to donate the equipment to the city; and continue its practice of offering charity care to uninsured patients based on financial need. The requestor also noted one of its affiliates already offers annual free EMS classes that are open to the public.
OIG noted the RFP’s requirements that bidders provide services, equipment, and training for free or at a nominal charge “are particularly suspect,” but added the requestor’s exceptions satisfactorily minimized most of these concerns.

OIG’s “primary concern,” however, was the requestor’s proposal to defer to its compliance officer’s determination on a “case-by-case basis” whether to donate equipment to the city.

“Unfortunately, in some circumstances, payments characterized as ‘donations’ or ‘grants’ are kickbacks intended to part to induce or reward referrals, directly or indirectly,” OIG said.

Without established, objective criteria and other safeguards, OIG viewed this aspect of the proposal as posing a “significant risk that donation of the Equipment by the Requestor would be tied to the contract award under the RFP.”

Viewed as a whole, OIG could not bless the proposed arrangement, even though only this aspect raised fraud and abuse concerns.


**U.S. Court in Florida Finds Bonuses to Physicians Violated Stark, But Denies Summary Judgment on Damages, FCA Claims**

The U.S. District Court for the Middle District of Florida granted November 14 the federal government summary judgment on its claim in a whistleblower action that Halifax Hospital Medical Center’s (Halifax's) financial relationships with six medical oncologists violated the Stark Law.

The court found the compensation arrangements did not meet the Stark Law “bona fide employment relationships” exception because the incentive pool established for the oncologists varied based on their referrals to the hospital and was not limited to the services they personally performed.

The court denied, however, summary judgment to the government on damages, finding outstanding issues on the “extent of the violation.”

The court also refused to grant summary judgment on the government’s False Claims Act (FCA) claims because of genuine issues of material fact regarding whether Halifax acted “knowingly.”

**Employment Agreements**

Halifax entered into employment agreements with six medical oncologists that provided both a base salary and the potential for bonuses starting in 2005. The agreements established an “Incentive Compensation” pool equal to 15% of the operating margin for the hospital’s medical oncology program.

The pool included fees for services that were not personally performed by the medical oncologists, such as fees for services related to the administration of chemotherapy, although the amount distributed to each individual was based on the oncologist’s personally performed services. Halifax paid bonuses to the medical oncologists for fiscal years 2005–2008.

Relator Elin Baklid-Kunz initiated the qui tam action in 2009, alleging Halifax’s financial relationships with the oncologists violated the Stark Law and the hospital therefore improperly billed Medicare for items resulting from these physicians’ referrals. The government intervened in 2011.
Bonuses Tied to Referrals

In ruling on the government’s motion for summary judgment with respect to the Stark issue, the court found Halifax’s compensation arrangements with the oncologists did not fall into the bona fide employment exception because the bonuses took into account the volume or value of referrals for designated health services. 42 U.S.C. § 1395nn(e)(2)(B)(ii).

Halifax pointed out that the Stark Law employment exception specifically permits productivity bonuses based on services that a physician personally performs, and then tried to argue the bonus pool at issue was distributed in exactly this manner—i.e., based on services personally performed by the oncologists.

But the court rejected this argument, disagreeing that the bonuses were based exclusively on services personally performed. Instead, bonuses were “divided up” based on services the oncologists personally performed. The court said this distinction was significant because the size of the pool (and ultimately the size of each oncologist’s bonus) could be increased by making more referrals.

Damages Unclear

While the government established a Stark violation, the court declined to rule on damages at the summary judgment stage, citing outstanding genuine issues of material fact concerning the amount the government was entitled to recover.

The government initially asserted damages totaling nearly $34.3 million for Medicare claims that were improperly submitted and paid as a result of the Stark violation, but later reduced its expected recovery to $27.1 million in response to the hospital’s objections.

But the court still found the government failed to sufficiently verify this figure and to address all the hospital’s objections, precluding summary judgment.

The court also refused to resolve the government’s False Claims Act, payment by mistake of fact, and unjust enrichment claims at this juncture.


U.S. Court in Florida Grants Defendants Summary Judgment in Halifax Case on Relator's AKS Claims, Allows Some Stark Claims to Proceed

In the latest chapter in the ongoing Halifax case, the U.S. District Court for the Middle District of Florida agreed to grant defendants summary judgment on certain claims asserted by the relator in which the government did not intervene, but allowed other claims to proceed.

Specifically, the court granted defendants summary judgment on relator’s claims that Halifax Hospital Medical Center (Halifax Hospital) and its instrumentality Halifax Staffing (collectively, defendants) violated the Anti-Kickback Statute (AKS) by paying neurosurgeons, oncologists, and psychiatrists for referrals. The court also agreed to dismiss relator’s Stark Law claim as to a medical director, but refused to dismiss the Stark Law claims as to two psychiatrists.

The court also declined to grant summary judgment on relator’s claim that defendants inappropriately billed Medicare for “short-stay” admissions.

Relator Elin Baklid-Kunz initiated the qui tam action in 2009 against Halifax Hospital and Halifax Staffing, which employs the individuals who work for the hospital. In 2011, the government
intervened in some of relator’s claims—specifically, those alleging defendants’ financial relationships with certain medical oncologists and neurosurgeons violated the Stark Law and, in turn, claims submitted to Medicare for referrals they made violated the False Claims Act (FCA).

In a November 2013 decision, the court granted the federal government summary judgment on its claim that Halifax’s financial relationships with six medical oncologists violated the Stark Law.

The court found the compensation arrangements did not meet the Stark Law “bona fide employment relationships” exception because the incentive pool established for the oncologists varied based on their referrals to the hospital and was not limited to the services they personally performed.


The court’s latest decision addresses defendants’ motion for summary judgment on the relator’s claims in which the government did not intervene.

Relator alleged defendants billed Medicare for improper “short-stay” admissions in violation of the FCA. Denying defendants’ motion for summary judgment on this claim, the court found relator’s expert reports established a genuine issue of material fact as to the medical necessity of at least some of the short-stay admissions at issue.

As to the AKS claims, defendants argued the bona fide employment safe harbor applied. Relator contended the safe harbor was inapplicable because the physicians were employed by Halifax Staffing and therefore were independent contractors of the hospital rather than employees.

The court pointed out that Halifax Staffing is “merely an instrumentality and alto ego of Halifax Hospital,” and none of the evidence established they were actually controlled by Halifax Staffing or were otherwise independent contractors. Therefore, the court held the bona fide employment safe harbor applied and summary judgment was granted to defendants on the AKS claims.

As to the Stark Law claims, the court agreed to grant summary judgment to defendants as to a medical director because relator failed to identify any prohibited referrals of designated health services (DHS) that he made.

The court refused, however, to grant summary judgment on the Stark Law claims as to two psychiatrists, after determining the bona fide employment exception did not apply because remuneration to them would vary with the amount of referrals.

Specifically, under the hospital’s agreement with the two psychiatrists, they would receive incentive payments equal to 100% of the hospital’s gross collections less the amount of their salary and the hospital’s costs for billing and collection.

U.S. Court in Florida Rejects Challenge to Relator’s Standing in Halifax Case

The U.S. District Court for the Middle District of Florida rejected February 6 a challenge to a relator’s standing to seek civil penalties under the False Claims Act (FCA) in the ongoing Halifax litigation.

The Supreme Court in Vermont Agency of Natural Resources v. United States ex rel. Stevens, 529 U.S. 765 (2000), found a relator has standing, as a partial assignee of the government’s claim, to seek damages under the FCA. The court here saw no reason for a different conclusion as to a relator’s ability to pursue civil penalties.

The court also noted the long-standing tradition of qui tam actions, including those in which the relator recovers a fine. The court further noted the Fourth and Federal Circuits have concluded relators have standing to pursue civil penalties, with no federal appeals court precedent to the contrary.

The court also summarily rejected the argument that the FCA violates the Appointments Clause of Article II of the U.S. Constitution to the extent it permits non-appointed private parties to seek civil penalties to vindicate public rights.

“This question is more easily disposed of than the question of standing,” the court said, pointing to four federal appeals court decisions rejecting this argument.

In particular, the court highlighted a Tenth Circuit decision that found qui tam relators were not “officers” within the meaning of Article II and therefore the whistleblower provisions of the FCA did not run afoul of the Appointments Clause. United States ex rel. Stone v. Rockwell Int’l Corp. 282 F.3d 787 (10th Cir. 2002).

Relator Elin Baklid-Kunz initiated the qui tam action in 2009 against Halifax Hospital Medical Center (Halifax Hospital) and its instrumentality Halifax Staffing concerning financial relationships with certain neurosurgeons, oncologists, and psychiatrists. In 2011, the government intervened in some of relator’s claims.

The court since has issued several rulings rejecting some claims but allowing others.

In a November 2013 decision, the court granted the federal government summary judgment on its claim that Halifax’s financial relationships with six medical oncologists violated the Stark Law, but denied judgment on damages, finding outstanding issues on the “extent of the violation.” The court also refused to grant summary judgment on the government’s FCA claims because of genuine issues of material fact regarding whether Halifax acted “knowingly.” United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-01002-GAP-TBS (M.D. Fla. Nov. 13, 2013).

In January, the court granted defendants summary judgment on relator’s claims that Halifax Halifax Hospital and Halifax Staffing violated the Anti-Kickback Statute by paying neurosurgeons, oncologists, and psychiatrists for referrals. The court also agreed to dismiss relator’s Stark Law claim as to a medical director, but refused to dismiss the Stark Law claims as to two psychiatrists. The court also declined to grant summary judgment on relator’s claim that defendants inappropriately billed Medicare for “short-stay” admissions. United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002-Orl-31TBS (M.D. Fla. Jan. 8, 2013).
First Circuit Rules First-Filed Complaint Dismissed for Lack of Particularity Can Bar Later-Filed Action

The first-to-file bar, 31 U.S.C. § 3730(b)(5), can apply to a False Claims Act (FCA) qui tam action alleging an illegal kickback scheme even though the originally filed complaint was dismissed for failing to meet the particularity requirements of Fed. R. Civ. P. 9(b), the First Circuit held May 31.


The First Circuit agreed the first-filed complaint barred the instant action because the purpose of a qui tam action—to provide the government with sufficient notice of potential fraud—was satisfied, even if the complaint was dismissed on Rule 9(b) grounds.

Relator Heidi Heineman-Guta brought the action against her former employer, defendants Guidant Corp. and Boston Scientific Corp.

She alleged defendants engaged in a scheme involving illegal kickbacks to physicians to promote the sales of their cardiac rhythm management devices in violation of the FCA. The United States declined to intervene in the action. Defendants moved to dismiss the complaint, citing the first-to-file bar.

The district court found a previously filed complaint, United States ex rel. Bennett v. Boston Scientific, disclosed the “essential elements” of the alleged fraud in Heineman-Guta’s complaint, namely, the provision of trips, entertainment, meals, grants, honoraria, and other remuneration as kickbacks to physicians to increase defendants’ market share in cardiac rhythm management devices.

On an issue of first impression, the First Circuit held Section 3730(b)(5) does not require the first-filed complaint to meet the heightened pleading standards of Rule 9(b) to bar the later-filed complaint.

The appeals court affirmed the application of the “essential facts” test to determine whether the first-filed complaint precluded a later-filed complaint under Section 3730(b)(5), rejecting relator’s argument that the Rule 9(b) pleading standard should be used instead.

Section 3730(b)(5) itself makes no mention of Rule 9(b)’s particularity requirements, but rather indicates an action is barred if it is a “related action” that is “based on the facts underlying the pending action.” Applying the rules of statutory construction, the appeals court also noted the significance of Congress referencing the Federal Rules of Civil Procedure in other FCA provisions but not in Section 3730(b)(5).

Relator argued her complaint offered more specific details of the alleged illegal kickback scheme, but the appeals court said if the first lawsuit sufficiently placed the government on notice of the alleged fraud, the provision of additional details would not change the fact that the later-filed action would duplicate the first and be barred under Section 3730(b)(5).
“A later-filed complaint that mirrors the essential facts as the pending earlier-filed complaint does nothing to help reduce fraud of which the government is already aware,” the appeals court observed.

Applying the “essential facts” test, the appeals court held the Bennett complaint unquestionably served to bar the instant action.


First Circuit Holds Lower Court Properly Limited Discovery in Qui Tam Action

On June 12, the First Circuit affirmed the grant of summary judgment in favor of Ortho Biotech Products, L.P. (defendant) after the district court limited the scope of discovery in a long-running False Claims Act (FCA) qui tam action that was brought by Mark Duxbury who, following his death in 2009, was substituted by his surviving wife, Chinyelu Duxbury.

In the second appeal to reach the First Circuit in this case, the appeals court found the district court, on remand, “sensibly” limited the scope of discovery for Duxbury’s remaining claims based on the First Circuit’s earlier ruling, the FCA statute of limitations, and to those allegations for which Duxbury had “direct and independent knowledge.”

Duxbury, who formerly worked for defendant, filed a qui tam action alleging, among other things, that defendant offered “kickbacks” to healthcare providers “across the United States” to encourage them to prescribe the anti-anemia drug Procrit from 1992-2003. The district court dismissed the action with prejudice. On appeal, the First Circuit reversed and remanded as to the kickback claims spanning the period Duxbury worked for defendant (1992-1998), finding these allegations were pled with sufficient particularity under Fed. R. Civ. P. 9(b), and affirmed in all other respects. United States ex rel. Duxbury v. Ortho Biotech Products, L.P.(Duxbury I), 579 F.3d 13 (1st Cir. 2009).

On remand, the district court found Duxbury was only an “original source” for claims during his employment with defendant, and therefore the court lacked subject matter jurisdiction over any kickback claims arising after Duxbury’s termination on July 20, 1998. In addition, Duxbury only possessed “direct and independent knowledge” of defendant’s activities in the western United States and his discovery was limited to that geographic area. The district court denied Duxbury’s motion for leave to appeal the order.

The parties then stipulated to limiting discovery to Duxbury’s kickback claims from November 6, 1997 to July 20, 1998, and to five of the eight accounts described in the amended complaint. Three of the accounts were removed because they fell outside of the FCA’s statute of limitations.

At the end of the discovery period, the parties stipulated that Duxbury failed to identify any admissible evidence to support the remaining allegations. The district court then granted the defendant’s motion for summary judgment on the basis of Duxbury’s stipulation.

The appeals court held the district court did not abuse its discretion by limiting the scope of discovery for the kickback claims and therefore upheld summary judgment for defendant. Duxbury argued, among other things, that the district court order limiting discovery directly contradicted the First Circuit’s decision in Duxbury I in remanding the 1992 to 1998 kickback claims.

The appeals court found, however, the limitations imposed on discovery were entirely consistent with Duxbury I and within the district court’s broad discretion in managing discovery. According to the appeals court, the district court properly limited discovery to those claims that satisfied Rule 9(b) particularity requirements.
“In light of [Duxbury’s] stipulation, the district court acted within its discretion in declining to issue Duxbury] license to undertake a ‘fishing expedition’ into the amended complaint’s purely speculative allegations of fraud through discovery,” the appeals court said.


Eleventh Circuit Finds Restitution Amount Should Have Excluded Value of Medically Necessary DME

The Eleventh Circuit held June 28 that a lower court should have excluded the value of medically necessary goods and services in its restitution order for a durable medical equipment (DME) owner who was convicted for fraudulently billing Medicare, Medicaid, supplemental insurers, and patients for certain pulse oximetry testing and portable oxygen.

Restitution is not supposed to be punitive, but rather is intended to ensure victims are made whole for their losses, the appeals court said in vacating the lower court’s restitution order and remanding for recalculation of the amount to take into account the value of the medically necessary goods and services that were provided.

The appeals court also vacated the district court’s imposition of a $3 million criminal fine on defendant Ben Bane, who owned and operated two companies, Bane Medical Services (BMS) and Oxygen & Respiratory, Inc. (ORT). According to the appeals court, the fine exceeded the statutory maximum without a jury finding regarding the amount of the loss.

From January 2001 to December 2004, defendant directed BMT and ORT to conduct pulse oximetry testing and then falsely represent to Medicare they were using independent laboratories as required for reimbursement of portable oxygen.

A jury convicted defendant of one count of conspiracy to commit healthcare fraud, in violation of 18 U.S.C. §§ 287, 371, 1001, and 1347; five counts of healthcare fraud, in violation of 18 U.S.C. §§ 2 and 1347; and four counts of making false claims against the government, in violation of 18 U.S.C. §§ 2 and 287. Following the convictions, the district court sentenced defendant to 151 months’ imprisonment and ordered him to pay over $7 million in restitution and a $3 million fine.

Defendant appealed his sentence, arguing the district court improperly calculated his sentencing guidelines range, improperly calculated the restitution amount, and imposed a fine that exceeded the statutory maximum.

The Eleventh Circuit upheld the sentencing guidelines range, finding the district court properly applied a 20-level enhancement for a loss between $7,000,001 and $20,000,000, a six-level enhancement for an offense involving more than 250 victims, and a two-level sophisticated-means enhancement.

The appeals court found the sophisticated-means enhancement was warranted because “Bane’s offenses involved repetitive, coordinated conduct designed to allow him to execute his fraud and evade detection.” The appeals court also held the district court properly included the value of oxygen provided that was in fact medically necessary in determining the loss and number of victims for purposes of the other enhancements. The Sentencing Guidelines specifically state that a defendant is not entitled to a credit for the value of items or services actually provided.

The appeals court agreed with defendant, however, that the lower court erred in ordering him to pay restitution that included the value of medically necessary oxygen that was actually provided. The appeals court saw no reason for distinguishing this type of case from the kickback context,
where it previously determined the proper measure of restitution is not based on the full value of the goods or services patients received.

“[F]ailing to offset the amounts paid for those goods from the restitution amount would be inconsistent with the purpose of the restitution because it would give a windfall to victims who received goods they actually needed in the form of both the goods and what they paid for them,” the appeals court commented.

In this case, the lower court found 80%-90% of the goods and services defendant’s companies provided to patients were medically necessary. On remand, the appeals court said defendant must offer evidence on the value of the medically necessary goods and services to receive an offset.

Finally, the Eleventh Circuit held the lower court violated defendant’s substantial rights by imposing a $3 million criminal fine that exceeded the maximum allowable statutory amount of $2.5 million without a jury finding on the amount of the loss. See Apprendi v. New Jersey, 530 U.S. 466 (2000) (holding Sixth Amendment requires “any fact that increases the penalty for a crime beyond the prescribed statutory maximum must be submitted to a jury, and proved beyond a reasonable doubt”), and Southern Union Co. v. United States, 132 S. Ct. 2344, 2357 (2012) (a criminal fine is impermissible where it exceeds the amount authorized by either the facts the jury necessarily found to convict the defendant, his prior convictions, or his admissions).

Because the jury convicted defendant of ten felonies, the maximum fine authorized by the facts the jury found was $2.5 million under 18 U.S.C. § 3571(b). Therefore, the imposition of a $3 million fine, without a jury finding, violated the defendant’s Sixth Amendment jury-trial guarantee, the appeals court said.


U.S. Court in Illinois Refuses to Dismiss Whistleblower Action Alleging Pharmacy, Nursing Home Arrangements Violated AKS, FCA

On July 23, the U.S. District Court for the Northern District of Illinois held plaintiff-relator presented sufficient evidence to create factual disputes about whether defendants knowingly and willfully received remuneration from a pharmacy services company in exchange for business from nursing homes that the defendants owned.

In May 2002, Philip Esformes, Bruce Paler, and Tim Dacy formed pharmacy service companies Total Ancillary Services LLP (Total Ancillary) and Total Pharmacy of Illinois (TPI). Fifty percent of TPI was owned by Total Ancillary and the other half by another company called Lifeline. A few months later, defendants formed Total Pharmacy of Florida, which was solely owned by Total Ancillary (collectively, Total Pharmacy or TP). When TP was formed, Morris Esformes, Philip’s father, had ownership interest in 27 nursing homes in Illinois and Florida, and Philip had ownership interest in 13 of them (the Esformes Homes).

Before TP was formed, Morris sought and obtained a legal opinion that concluded TP’s proposed structure could potentially violate the Anti-Kickback Statute (AKS) and strongly advised that TP fulfill the requirements of the Small Entity Investment Interests safe harbor. Despite the legal opinion, 27 of the 29 nursing homes to which TP provided pharmacy services were Esformes Homes. Morris also had his nursing homes switch their contracts to TP contracts even though Morris admitted there were no complaints about the pharmacies that had been providing services to the Esformes Homes, the opinion said.
In 2004, Omnicare acquired TP. Omnicare’s offer factored in business with 17 nursing homes that were owned by Sharo Shirshekan in Missouri (Missouri Homes) even though TP did not have a license to provide pharmacy services in that state. TP’s agreement with Missouri Homes was assigned to Omnicare, however, before TP was even able to provide services to those homes. Further, TP’s contracts with the Esformes Homes were renegotiated from one-year non-assignable contracts that were cancelable with 30-days notice to five-year assignable contracts that were cancelable only for cause.

Maureen Nehls, TP’s former Vice President of Pharmacy Operations, alleged TP was formed to secure business from the Esformes Homes. On October 9, 2012, Nehls filed her Sixth Amended Complaint alleging defendants Omnicare, Morris, and his son, Philip, violated the False Claims Act (FCA), the AKS, and parallel state statutes by accepting remuneration to induce referrals for pharmacy services reimbursed by Medicare and Medicaid, thereby causing TP and Omnicare to submit false claims to the Illinois and Florida Medicaid programs. The claims against Omnicare ended in settlement, the court said.

Philip asserted a counterclaim alleging Nehls breached her fiduciary duty by failing to report the alleged FCA and AKS violations to TP and its owners. In January 2013, Nehls filed a motion to dismiss Philip’s counterclaim. Morris and Philip filed their separate motions for summary judgment.

Defendants contended Nehls was not the original source of the allegations, as required under the FCA’s public disclosure bar (31 U.S.C. § 3730(e)(4)(A)), and should therefore not be permitted to proceed to trial. Specifically, Philip argued that in August 2004, Adam Resnick informed the Federal Bureau of Investigation (FBI) of TP’s alleged wrongdoings. The court concluded Philip failed to show Resnick’s allegations to the FBI were publicly disclosed prior to the filing of Nehls’ lawsuit and that Resnick’s allegations were part of the public domain.

The court also pointed out defendants misconstrued Section 3730(e)(4)(A) as requiring Nehls’ lawsuit be filed by “the” original source (i.e., Resnick) rather than “an” original source. The court stated while original sources should be independently aware of some essential pieces of information, he or she “need not have direct knowledge of all or the vital ingredients in a fraudulent transaction.” In this case, Nehls was a former TP employee and had knowledge of the following: Philip owned 40% of TP; Morris and Philip owned nearly all of TP’s customers (i.e., the nursing homes); Morris and Philip lengthened their nursing homes’ contracts; and the Missouri-based business had been secured after negotiations with Omnicare began. According to the court, all of these facts were sufficient to show Nehls was an original source of the information.

Having established Nehls as an original source, the court turned to the issue of whether she provided sufficient admissible evidence to create a triable issue of fact about whether Philip knowingly and willfully received remuneration in exchange for referrals, or conspired to receive remuneration in exchange for referrals, in connection with TP’s formation and Omnicare’s acquisition of TP. Pointing to Philip’s 40% stake in TP as a result of paying $4,000 to form the company; testimony and acknowledgements made by Dacy and Paler regarding Philip’s level of involvement in TP’s formation; and the replacement of the Esformes Homes’ pharmacy contracts with TP contracts, the court found it would not be unreasonable for a jury to infer Philip largely paid for his substantial stake by delivering to TP the nursing homes he owned as customers.

Secondly, the court found Nehls presented sufficient evidence to create a factual dispute about whether Philip received remuneration in exchange for securing long term contracts with the nursing homes in which he had ownership interest, including 17 Missouri-based nursing homes, in connection with Omnicare’s acquisition of TP. In January 2005, TP rejected Omnicare’s initial offer of $16–$18 million to buy TP’s assets and receivables. Two months later, TP accepted Omnicare’s second offer of $25 million, which factored in TP delivering business in Missouri even though TP did not provide services to any nursing homes in Missouri or have a license to operate...
a pharmacy in the state, according to the court. TP finalized its expansion plans in Missouri a month later, and Morris testified he spoke to Sharo Shirshekan, the owner of 17 nursing homes in Missouri, about “going along with Total Pharmacy as a courtesy to his son Philip.” Shirshekan committed all of his homes to TP in a single agreement. TP then assigned its pharmacy service contracts with Shirshekan’s Missouri-based homes to Omnicare before ever providing services to any of those nursing homes, the court observed.

Third, the court found Nehls provided sufficient evidence at this stage of the litigation to create a triable issue of fact concerning whether Philip received remuneration in exchange for securing longer term and more favorable contracts to each of the nursing homes TP provided services to in Illinois and Florida. TP’s contracts with nursing homes in Illinois and Florida were for one year, not assignable, and cancelable for any reason with 30-days notice. Nehls alleged, however, that Omnicare favored lengthier service contracts so that when Omnicare acquired TP, the new contracts were signed for five years, automatically renewed for another five-year period, assignable, and only cancelable for cause. The court held a reasonable jury could find Philip received his share in TP—worth approximately $7.6 million—not in exchange for a capital contribution of $4,000 but for referring his nursing home business.

The court also noted Nehls provided sufficient evidence for purposes of avoiding summary judgment that Philip received remuneration knowingly and willfully based on his participation in a meeting with attorneys regarding TP’s formation where the attorneys cautioned the proposed arrangement “could be subject to scrutiny, and potentially, civil and criminal penalties” and strongly recommended their proposed arrangement comply with the Small Entity Investment Interests safe harbor.

Turning its attention to Morris, the court found Nehls also provided sufficient evidence to create issues of material fact about whether Morris knowingly and willfully received remuneration in connection with TP’s formation and its sale to Omnicare. According to the court, Morris effectively admitted—and a jury might reasonably conclude—one of the many reasons he caused the nursing homes he owned with Philip to enter into contracts with TP was “to benefit his son.” As a result of those efforts, Philip received $400,000 in TP distributions and over $7 million in proceeds from Omnicare’s acquisition of TP.

Under the AKS, remuneration may be direct, indirect, overt, covert, in cash or in kind, the court said. Citing Klaczak v. Consol. Med. Transp., 485 F. Supp. 2d (N.D. Ill. 2006), the court noted remuneration can be defined broadly, meaning “anything of value.” The court held the economic benefit inured to Philip, Morris’ immediate family member and business partner, was sufficient evidence for a jury to reasonably conclude Morris indirectly benefitted as well.

The court also pointed to Advisory Opinions issued by the Office of Inspector General for the Department of Health and Human Services that suggest payments to family members can constitute remuneration. Further, as was the case with Philip, the court held other facts, including the legal advice Morris sought regarding TP’s AKS compliance, his decision to switch all of his nursing homes’ contracts to TP contracts, his hosting of and attendance at meetings regarding Omnicare’s acquisition of TP, his assistance in delivering Shirshekan’s Missouri-based nursing homes to TP, and renegotiating key provisions in his nursing homes’ contracts with TP leading up to Omnicare’s acquisition, allowed for reasonable inference that Morris knowingly and willfully accepted remuneration in exchange for referrals.

The court next addressed Nehls’ motion to dismiss Philip’s counterclaim that alleged she breached her fiduciary duty as TP’s Vice President of Pharmacy Operations by failing to report to TP and its owners that TP was set up on an illegal kickback scheme in violation of the AKS. As a result, Philip alleged, he incurred substantial money damages by way of litigation expenses and compensation paid to Nehls during and after her breach.
The court held Philip’s counterclaim failed to show a causal link between Nehls’ alleged failure to report violations and Philip’s litigation expenses as Nehls could have informed TP of its violations and still have filed her qui tam action against TP. In addition, the court pointed out any damages related to Nehls’ salary belonged to TP, not to Philip who expressly stated he was suing in his own capacity and not on TP’s behalf. The court also held Philip’s counterclaim was foreclosed under the FCA because an FCA defendant cannot seek contribution or indemnification from a relator.

For these reasons, the court denied defendants’ motion for summary judgment. The court granted Nehls’ motion to dismiss Philip’s counterclaim, and denied without prejudice Philip’s motion for summary judgment as a set off in the amount of the Omnicare settlement.


**U.S. Court in Ohio Says Jury Must Decide Whether Discounts Were Illegal Remuneration**

A federal court in Ohio denied July 23 a whistleblower summary judgment in his False Claims Act (FCA) lawsuit alleging long term care pharmacy Omnicare Inc. offered discounts and below-cost per diem pricing in exchange for patient referrals.

The U.S. District Court for the Northern District of Ohio said the issue of whether the discounts Omnicare offered to Montefiore Home amounted to illegal remuneration under the Anti-Kickback Statute (AKS) was a question for the jury and not one that could be decided on summary judgment.

Relator Donald Gale worked as a consulting pharmacist and in various management positions for Omnicrocare, Inc. from 1994 to 2010, when he voluntarily resigned.

Skilled nursing facilities (SNFs) receive a flat per diem rate for their Part A patients, which includes drug costs, and enter into per diem contracts with pharmacies, such as Omnicare, under which SNFs pay the pharmacy a fixed daily rate to cover prescription drugs for each Part A patient.

Relator alleged Omnicrocare solicited contracts from SNFs such as Montefiore and offered them lower per diem pricing, even below its own costs, for Medicare Part A patients, to induce an SNF to refer to Omnicrocare business from its other patients.

Relator alleged these arrangements violated the AKS and resulted in the submission of false claims to federal health care programs in violation of the FCA. The federal government declined to intervene in the action. Relator moved for summary judgment on his claims regarding Montefiore and on three of Omnicrocare’s affirmative defenses.

The court denied relator summary judgment on his FCA claims and on two of the affirmative defenses related to statutory and regulatory safe harbors, finding Omnicrocare offered sufficient evidence to raise triable issues of fact. The court did grant relator summary judgment on Omnicrocare’s affirmative defense that Gale’s share of any award should be reduced because he has unclean hands, holding Omnicrocare lacked standing to assert that defense.

Under the AKS, remuneration generally means “payment” or “compensation” but does not include a “discount” as defined in the statute, the court observed. A “discount” does not include, however, “[s]upplying one good or service . . . at a reduced charge to induce the purchase of another good or service,” the court explained. In this scenario, a discount offered to induce the purchase of another good or service would be remuneration under the AKS.
The court noted two open questions that, given the evidence, could not be resolved on summary judgment: whether Omnicare in fact offered price reductions to Montefiore (with the parties disputing whether the baseline should be “fair market value” or Omnicare’s own usual and customary rate) and, if so, whether Omnicare “gave Part A reductions to induce the referral of other Medicare-reimbursable patients—i.e., that Omnicare intended to use remuneration to induce referrals.”


**U.S. Court in Ohio Allows FCA Claims Against Long Term Care Pharmacy to Proceed**

The U.S. District Court for the Northern District of Ohio refused to strike certain evidence or allow a new defense in a qui tam relator’s False Claims Act (FCA) suit against Omnicare, Inc. Instead, the court found defendant had sufficient notice the relator would pursue Medicare Part D and Medicaid claims as damages for the alleged kickbacks.

The court also found Omnicare’s previous fraud settlement with the government did not bar the current relator from bringing his claims.

From 1994 to 2010, relator David Gale worked as a consulting pharmacist and in various management positions for Omnicare, Inc., which supplies prescription drugs to skilled nursing facilities (SNFs). Gale alleged Omnicare offered kickbacks, including discounts and below-cost per-diem Medicare Part A pricing to the SNFs to obtain SNF referrals of other Medicare customers, especially Part D customers. Because Medicare pays the SNFs at a fixed per-diem rate, Omnicare’s lower per-diem medication rate increases the SNFs profits, Gale alleged.

In an earlier decision, the court dismissed some of relator’s claims but allowed other FCA claims to go forward. See *United States ex rel. Gale v. Omnicare, Inc.*, No. 1:10CV127 (N.D. Ohio Sept. 26, 2012). Most recently, in a July 23 decision, the court denied Gale summary judgment, saying a jury needed to decide whether the discounts Omnicare offered to one SNF amounted to illegal remuneration under the Anti-Kickback Statute. See *United States ex rel. Gale v. Omnicare, Inc.*, No. 1:10CV127 (N.D. Ohio July 23, 2013).

In the latest development in the case, Omnicare moved to exclude all evidence of Medicare Part D and Medicaid reimbursements. Looking back at the record, however, the court found Omnicare had notice that Gale would pursue such claims. Although Gale did not specifically state he was pursuing damages based on Medicare Part D and Medicaid reimbursements, he could seek these damages if he showed they were based on the wrongful conduct set out in the complaint, the court said. The court went on to find that the Medicare Part D and Medicaid damages were sufficiently based on the wrongful conduct described in Gale’s complaint.

Omnicare next argued its prior settlement with the United States on FCA claims asserted by a different relator should bar Gale from recovering damages for Medicare Part D and Medicaid reimbursements between September 1, 2005, and September 1, 2008.

The court rejected this argument, however, noting that Omnicare did not assert in its answer to relator’s complaint the defenses of election of remedies or res judicata.

“Omnicare may only assert one of these defenses if the Court grants leave under *Federal Rule of Civil Procedure 15(a)(2)*, which tells the Court to freely grant leave ‘when justice so requires,’” the opinion explained.

But the court found leave to assert the defenses was not required by the interest of justice, noting “Omnicare could have asserted this defense to Gale’s damages claim all along.”
“Omnicare made the decision not to assert this previous settlement as a defense to Gale’s claim for statutory damages at those facilities that might overlap; it must now live with that decision,” the court held.


**Fifth Circuit Rejects FCA Action for Failure to Allege Merchantability Warranty Was a Condition of Payment**

On August 20, the Fifth Circuit affirmed the dismissal of a relator’s claim that alleged a medical device manufacturer sold the U.S. Department of Veterans Affairs (VA) defective infusion pumps resulting in violations of the False Claims Act (FCA). The Fifth Circuit held relator failed to state and plead with particularity her implied false certification claim and worthless goods theory.

Relator Leslie Steury marketed infusion device pumps to the VA on behalf of defendant, Cardinal Health, Inc. In 2000, relator said she discovered a defect with the pumps and talked to an area manager about it in early 2001. A few months later, Cardinal suspended shipment of its pumps for three months to review the defect but relator continued to market the pump during that time. When Cardinal completed its three-month review, it fired relator.

Relator sued Cardinal in 2007 for alleged violations of the FCA and several state statutes. The government declined to intervene. The district court dismissed relator’s case for failure to satisfy the heightened pleading standards of Fed. R. Civ. P. 9(b). Relator appealed to the Fifth Circuit, which remanded to allow her the opportunity to amend her complaint. The district court dismissed her amended complaints for failure to state a claim and failure to plead fraud with sufficient particularity.

Relator alleged her FCA claim was based solely on an implied false certification theory where Cardinal expressly warranted the pumps were merchantable, Cardinal’s contract with the VA specifically required the pumps be merchantable, Cardinal’s contract with the VA required it to implicitly certify the pumps were merchantable, and that merchantability was a material contractual requirement.

The Fifth Circuit held during its review of relator’s first appeal that “a false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.” The appeals court went on to explain that this fact about the contract’s conditions will “depend on the specific statutes, regulations, and contracts at issue in a particular case.”

In this case, the Fifth Circuit held relator’s allegations were conclusory and deficient under Rule 9(b) as she failed to clearly state the substance of the fraud committed. In terms of an implied warranty of merchantability, relator failed to point to statutes, regulations, or court opinions that “imported” such implied warranties into the government’s contracts. Whether express or implied, Steury did not allege, “in more than an utterly conclusory manner,” that the contractual merchantability provision was a condition of government payment.
As to relator’s allegation that Cardinal violated the FCA under the worthless goods theory, the Fifth Circuit refused to examine the theory’s viability because relator failed to plead with the requisite particularity that any of the pumps sold to the VA in the past several years were found to be deficient or worthless, that patients were harmed, or that the VA was ever sued for an injury caused by a malfunctioning pump. “There is no who, what, when, where, or how on this claim to comply with Rule 9(b),” the court said.


**Fifth Circuit Vacates Restitution That Included Payments Outside Temporal Scope of Fraud Conviction**

On August 29, the Fifth Circuit upheld the health care fraud convictions of a durable medical equipment (DME) owner, but vacated the lower court’s $750,000 restitution order because it included Medicare and Medicaid payments to the defendant outside the temporal scope of the conduct alleged in the indictment.

Defendant Juan De Leon Jr was indicted for defrauding Medicare and Medicaid from June or July 2008 through April 2010 by billing for items of DME before they were delivered; billing for new power wheelchairs while used wheelchairs or cheaper scooters actually were provided; and billing for diabetes supplies that were never delivered. A jury convicted defendant of all five counts charged in the indictment.

On appeal, the Fifth Circuit found the district court erred in excluding admissible character evidence pursuant to Fed. R. Evid. 608(a), which only applies to a witness’s credibility. The appeals court found the error harmless, however, as the government presented “overwhelming evidence” of defendant’s knowing submission of fraudulent claims.

Defendant also contended the district court erroneously awarded restitution for time outside the dates of the specific conspiracy for which he was charged and convicted. The appeals court agreed, noting restitution is limited to the loss actually caused by the offense of conviction where the time span is defined by the specific temporal scope of the indictment—in this case, June or July 2008 through April 2010.

The court found the presentence investigation report figure on which the district court relied overstated the maximum possible actual loss because it included every dollar that Medicare and Medicaid paid to defendant on any and all claims from 2005-2011. Payments made to defendant in 2005, 2006, 2007, and 2011 should not have been counted among the actual losses incurred by Medicare and Medicaid because defendant was not indicted for and convicted of conspiring during those years.

As this amounted to plain error, the appeals court vacated the restitution order and remanded for a recalculation.


**Third Circuit Says Public Disclosure Bars Whistleblower’s Action Against Medicare Contractor**

The Third Circuit upheld August 26 the dismissal of a whistleblower action under the False Claims Act (FCA) against two Medicare contractors alleging they fraudulently billed the United States for
unperformed reviews of benefit claims denials required by law, governing regulations, and their federal contracts.

The appeals court found the allegations in the relator’s complaint were based on public disclosures in prior litigation challenging the exclusion from Medicare coverage of durable medical equipment (DME), specifically, the BioniCare Stimulator System (BIO-1000), used to treat osteoarthritis in the knee as not “reasonable and necessary.”

The relator in the instant case, Thomas M. Zizic, MD, was President and Chief Executive Officer of the company that manufactured the BIO-1000 device. According to the opinion, he personally participated on behalf of BioniCare at the third level of appeal for claims denials of the device before an Administrative Law Judge.

The two targets of his qui tam action were Q2 Administrators, LLC (Q2A) and RiverTrust Solutions, Inc. (RTS), who served as Medicare qualified independent contractors (QICs) at the second level of appeal. At the “reconsideration” stage, QICs are supposed to use physicians in determining whether an item of DME was medically reasonable and necessary.

Q2A contracted with the Department of Health and Human Services (HHS) from July 2005 to roughly December 2006 to serve as a QIC to review DME claim denials nationally. According to the opinion, Q2A frequently denied BIO-1000 claims as medically unreasonable and unnecessary without the physician review required by law. RTS replaced Q2A in January 2007 and similarly failed to perform the required physician review, the opinion said.

After BioniCare declared bankruptcy in 2008, the bankruptcy trustee Monique D. Almy sued HHS, arguing, among other things that the two QICs failed to subject the BIO-1000 claims to physician or nurse review. Zizic participated in this litigation. The Fourth Circuit ultimately rejected the lawsuit. See Almy v. Sebelius, No. 10-2241 (4th Cir. Apr. 26, 2012).

In filing his qui tam complaint, Zizic included an affidavit of a former Q2A employee who contended the contractor was short-staffed and implemented an internal policy to deny all BIO-1000 claims, which were not reviewed by a panel of physicians as required. The government declined to intervene in the action. The district court granted the QICs’ motion to dismiss, finding jurisdiction lacking under the FCA’s public disclosure bar.

Affirming, the Third Circuit agreed with the district court that the Almy litigation publicly disclosed the fraudulent transaction on which Zizic’s claims were based.

The appeals court employed a formula for determining when information publicly disclosed qualifies as an allegation or transaction of fraud: X + Y = Z, where the allegation of fraud [Z] equals “a misrepresented [X] and a true [Y] state of facts.”

Here, the appeals court found both X—that the QICs were supposed to perform physician reviews under their contracts and the law—and Y—that they failed to do so but still received payment under their contracts—were in fact disclosed in the Almy litigation. Although Q2A and RTS were not specifically named in the Almy litigation, “they were directly identifiable from that public disclosure” as they were the only QICs during the relevant timeframe.

The appeals court also concluded Zizic’s claims were substantially similar to the Almy litigation even if his complaint added some minor details to the publicly disclosed description of the fraudulent transaction.

Next, the appeals court held Zizic was not an original source because he lacked direct knowledge to the extent his claims depended on the affidavit of the former Q2A employee.
In addition, his knowledge was not independent because he applied his expertise to publicly disclosed information or because of his direct involvement in the DME Medicare appeals process. To the extent his allegations were based on information protected by the Health Insurance Portability and Accountability Act, the appeals court said Zizic failed to show how such information was the basis of his allegations of fraud.

Finally, the appeals court held the district court properly dismissed the complaint with prejudice.


U.S. Court in Illinois Dismisses “Fraud-Alert” Employee’s FCA Retaliation Claim Against Hospital

On August 26, the U.S. District Court for the Southern District of Illinois granted defendant hospital’s motion to dismiss a False Claims Act (FCA) retaliation claim as plaintiff pathologist failed to demonstrate she put defendant hospital on notice of the distinct possibility of a qui tam action and failed to establish her termination was motivated at least in part by her engaging in activity that was protected under the Act.

Plaintiff Pamela Gronemeyer is a pathologist who worked at defendant Crossroads Community Hospital from 1998-2009. Plaintiff believed defendant was submitting false claims for Medicare and Medicaid reimbursements and informed her superiors of her findings. Defendant terminated her employment shortly thereafter and plaintiff brought an FCA retaliation claim under 31 U.S.C. § 3730(h).

The court found plaintiff adequately pled the first element of an FCA retaliation claim—that her investigation was in furtherance of an FCA action, as shown by her efforts to describe to defendant in detail seven different cases where she suspected fluids were being improperly administered to justify subsequent, unnecessary transfusions that were billed to Medicare and Medicaid. Plaintiff undertook independent review of these cases at her own expense and informed her superiors of the alleged fraud through conversations, emails, and letters, the court noted. As a result, the court found plaintiff sufficiently alleged she in good faith believed, and a reasonable employee in the same or similar circumstance might believe, that defendant was committing fraud against the government.

Plaintiff’s complaint failed, however, to adequately allege the remaining elements of an FCA retaliation claim—that her protected conduct put the hospital on notice of the distinct possibility of a qui tam action and that her discharge was partly motivated by the protected conduct.

As to the notice element, the court noted defendant was “at the very least, aware of plaintiff’s investigation.” However, given plaintiff’s regular employment duties, which included reporting and investigatory duties that involved reviewing records, approving transfusions, and conducting after-the-fact quality assurance assessments of a transfusion’s medical necessity, the court deemed her a “fraud-alert” employee, meaning she was subject to a heightened pleading standard for putting the hospital on notice of the possibility of a qui tam action. For example, in communicating with the hospital about her investigation, plaintiff failed to use terms such as “illegal,” “improper,” “fraudulent,” or other analogous words that would have otherwise informed her superiors they were violating the FCA. Plaintiff therefore failed to allege facts to establish she was doing anything other than her job as required and expected of her.

Lastly, the court held plaintiff failed to show defendant terminated her employment because she engaged in the protected conduct. According to the court, by failing to allege defendant was sufficiently informed of a potential FCA action, it was impossible for any action taken by defendant to be in retaliation as contemplated by § 3730(h).
U.S. Court in Tennessee Finds Public Disclosure Bar Forecloses FCA Claims Against Hospital

Whistleblower claims against a hospital authority under the False Claims Act (FCA) were barred because the alleged billing improprieties at issue were publicly disclosed in a previous audit and investigation, the claims were based on the information disclosed, and the relator was not an original source, a federal court in Tennessee ruled.

The court granted the defendant hospital authority’s motion for summary judgment on relator’s allegations relating to short-stay, same-day surgery, and renal dialysis claims.

Relator Robert Whipple, who worked as a revenue cycle consultant for an auditor under contract with the Department of Health and Human Services, brought the qui tam action under the FCA against defendant Chattanooga-Hamilton County Hospital Authority, alleging it submitted fraudulent reimbursement claims to federal health care programs.

Defendant argued the FCA's public disclosure provision barred certain of relator’s claims, citing a three-year audit and investigation that resulted in the hospital authority paying the government almost $500,000 to resolve the allegations.

The court initially debated whether it should apply the public disclosure bar as it existed when the alleged misconduct took place, or at the time the action was filed, which was after changes made by the Affordable Care Act. The court ultimately found the issue moot because the public disclosure bar foreclosed the action either way.

The U.S. District Court for the Middle District of Tennessee determined the fraudulent activity at issue was publicly disclosed during the 2006-2009 audit and investigation.

While acknowledging a split on the issue of whether a disclosure to government officials is a “public disclosure,” the court noted here the information was publicly disclosed to more than just the government, through additional investigations and audits conducted by consultants, attorneys, and contractors.

Citing Sixth Circuit precedent, the court also found the disclosure was sufficient to put the government on notice of fraud because the prior audit and investigation revealed the true set of facts—what should have been billed—and the false set of facts—what was actually billed—for specific claims.

Next, the court held relator’s allegations related to short-stay and renal dialysis admissions were based on the public disclosure.

“The information gathered by [ ] investigators, auditors, employees, attorneys and government agencies was sufficient to put the Government on notice that Defendant was submitting improper and allegedly fraudulent bills. That they ultimately found no fraud does not automatically mean that the same information was not disclosed to them,” the court said.

Finally, the court found relator was not an original source because he failed to show direct and independent knowledge of the information on which the allegations were based. Here, the alleged misconduct occurred before relator worked at defendant’s facility.

Relator argued under the post-ACA public disclosure provision, he possessed knowledge that was independent of and materially added to the publicly disclosure by asserting facts to demonstrate
the required scienter to prove fraud. But the court disagreed, noting the “prior investigations offered ample opportunities for others to determine whether scienter existed.”


Eighth Circuit Says Qui Tam Action Pled Only Regulatory Non-Compliance, Not FCA Violation

On September 4, the Eighth Circuit held defendant did not violate the False Claims Act (FCA) when it chose not to prepare and submit a second report to Medicare regarding examination of permanent tissue slides as the applicable Medicare regulation and the Current Procedural Terminology (CPT) Codebook did not explicitly require written reports for the CPT codes at issue.

Relators brought a qui tam action under the FCA against defendant Mayo Foundation and related entities (Mayo), alleging Mayo billed Medicare for surgical pathology services it did not provide. The government intervened and the parties settled the claim.

Relators filed a second amended complaint, asserting additional claims that Mayo fraudulently billed for services it did not provide whenever it prepared and read a permanent tissue slide but did not prepare a separate written report for that service. Specifically, relators argued Medicare regulations required a written report for every permanent slide for which a health care provider billed Medicare. Relators contended Mayo failed to do this and therefore habitually submitted false claims for Medicare payment of surgical pathology services not provided.

The Eighth Circuit affirmed the district court’s decision to dismiss relators’ claim under Fed. R. Civ. P. 12(b)(6) as the billing codes submitted by Mayo did not explicitly require written reports and the regulation regarding Medicare conditions of payment did not require written reports for surgical pathology services.

In this case, the relevant CPT codes involved codes 88300 through 88309 for general surgical pathology services. The court found those CPT codes required “reporting” but did not explicitly require a written report for each slide created and examined for a particular surgery. By contrast, the court pointed out, the regulation for another category of pathology services, “clinical consultation services,” required the service “result in a written narrative report,” which strongly suggested CPT codes 88300–88309 did not require a separate written report for each surgical pathology slide.

The appeals court found relators failed to provide specific evidence that Medicare considered the existence of a separate written report to be a material condition of paying each separate claim for surgical pathology services. Moreover, the appeals court was not persuaded by relators’ argument that pathology reports always be written as a matter of standard industry practice according to the recommendation published by the American College of American Pathologists. The appeals court pointed out that the authors of that article considered what must be done in every surgical case, not for each individual specimen considered in a surgical case.

Lastly, the appeals court held relators’ desire to have the Medicare regulation and CPT Codebook interpreted to require a separate written report for each permanent slide that is billed as a separate surgical pathology service failed to state an FCA claim of knowing fraud. In other words, relators pleaded a claim of regulatory noncompliance, not a plausible claim that Mayo submitted false or fraudulent claims for Medicare payment.

Seventh Circuit Reverses Dismissal of Qui Tam Action for Failure to Name Expert Witnesses

The Seventh Circuit reversed August 28 a grant of summary judgment in favor of a defendant psychiatrist in a qui tam action for the relator’s failure to name expert witnesses to testify on the Medicaid payment system and on whether certain drugs were not prescribed for “medically accepted indications” and therefore ineligible for reimbursement.

As to the Medicaid payment system, the appeals court found it was not beyond the comprehension of a lay jury that a physician knew a patient was covered by Medicaid and that prescribing a particular drug to that individual would cause a submission of a claim to the program.

The appeals court agreed that determining whether a particular drug was “medically indicated” and therefore eligible for Medicaid reimbursement could require expert testimony, but found granting summary judgment was premature and overbroad.

Relator Dr. Toby T. Watson initiated a qui tam action under the False Claims Act (FCA) against defendant Dr. Jennifer King-Vassel, a psychiatrist who treated a minor designated as “N.B.” in the opinion. Relator alleged defendant wrote N.B., a Medicaid patient, 49 prescriptions for “off-label” uses, which caused false claims to be submitted to the federal government in violation of the FCA. The federal government declined to intervene.

Relator obtained N.B.’s treatment records through N.B.’s mother, who responded to an advertisement relator placed in a local newspaper soliciting Medicaid patients who had been prescribed psychotropic medications to “participate in a possible Medicaid fraud suit” and share in any recoveries.

Defendant moved for summary judgment, arguing relator lacked “direct and independent knowledge” of the alleged fraud and the allegations were based on publicly available information. Defendant also contended the action should be dismissed because relator failed to name an expert to testify on “how claims for reimbursement for medications are presented to Medicaid programs, and how payments are made by those Medicaid programs.”

The district court ruled against defendant on her primary arguments for summary judgment, but granted the motion on the ground relator failed to name expert witnesses to testify on the essential elements of the case.

Reversing on this issue, the Seventh Circuit disagreed with the lower court that an expert witness would be needed to demonstrate defendant’s state of mind—i.e., that she had “knowledge” that her prescription of a drug for allegedly off-label uses would result in a submission of a fraudulent claim.

Instead, the appeals court found a “reasonable jury could plausibly interpret the evidence Watson assembled to show that King-Vassel recklessly disregarded the fact that N.B. received Medicaid assistance, and that claims for payment for his prescriptions would be submitted to Medicaid.”

The appeals court acknowledged relator’s failure to name a medical expert to testify on whether the prescriptions were “medically accepted indications” based on a review of the drug compendia was more problematic, but was not convinced granting summary judgment on this issue was appropriate at this stage of the litigation.
For one thing, defendant did not raise this failure as a basis for her summary judgment motion. Moreover, nothing in the record gave relator notice that the court would grant summary judgment absent an expert to explain the compendia. The appeals court also was skeptical that an expert would in fact be needed for every aspect of relator’s claims. For example, a claim that defendant prescribed a drug that was not indicated for patient’s age group would not require expert analysis.

In concluding, the appeals court felt “compelled to note that nothing in this opinion should be read to countenance the pre-suit actions of either Watson or his trial counsel,” on whom the district court levied monetary sanctions. “[W]e hope that the district court’s sanctions will dissuade professionals from stooping to such unsavory tactics in the future.”


**U.S. Court in DC Rejects Relator’s Action Against Government for Failing to Intervene in Whistleblower Suits**

The U.S. District Court for the District of Columbia dismissed September 16 a relator’s action against the federal government alleging its failure to intervene in two qui tam actions he filed under the False Claims Act (FCA) violated the Administrative Procedure Act (APA).

The decision whether to intervene in a qui tam action, regardless of how overwhelming the evidence of alleged fraud, is left entirely to agency discretion and therefore presumptively unreviewable, the court held.

The FCA not only makes intervention optional, but allows the government to go further and dismiss a qui tam action if it chooses to do so.

Plaintiff Michael Davis filed two qui tam actions against the District of Columbia asserting various fraud allegations involving its Medicaid program. The government declined to intervene in both actions, one of which was dismissed under the public disclosure bar and the other of which is pending.

In the instant case, plaintiff sued the Department of Health and Human Services and the Department of Justice, as well as various attorneys of the agencies and others, (collectively, defendants) under the APA, alleging defendants knew the District of Columbia had committed fraud and yet did not intervene.

The court granted defendants’ motion to dismiss, agreeing that whether and how to proceed in a qui tam action is committed to agency discretion, no matter how indisputable the evidence.

Plaintiff also could not assert that defendants failed to “diligently investigate” as required by the FCA since the pleadings clearly showed the government did investigate.

Plaintiff also alleged defendants committed “fraud on the court” by withholding material information that substantiated his fraud claims. While “fraud on the court” may warrant a departure from the presumptive deference owed to the government’s intervention decision, it is a difficult standard to meet, the court said.
“[T]he mere fact that the government did not tell the court everything it knew about Davis’s claims in the qui tam actions does not mean that there was fraud on the court.” But critical here, the court said, was the fact that the United States was not a party to either of plaintiff’s actions. The court found it “highly unlikely that non-disclosure by an attorney for a non-party could ever rise to the level of fraud on the court.”

The court rejected plaintiff’s remaining claims and dismissed the action.


**U.S. Court in D.C. Says Local Government Violated FCA, But Relator Only Entitled to Share of Civil Penalty**

The U.S. District Court for the District of Columbia said March 31 the District of Columbia’s failure to maintain legally required documentation to support its Medicaid reimbursement requests violated the False Claims Act (FCA) under an implied certification theory.

Because the federal government, which did not intervene in the whistleblower action brought against the District, suffered no actual damages, however, relator was only entitled to a share (30%) of the civil penalties, which amounted to $11,000, the court held.

“The District is lucky it did not have to pay more,” the court commented, “given the cavalier attitude it adopted in submitting millions of dollars in reimbursement claims without the legally required supporting documentation” and the fact that other claims were time barred.

Relator Michael L. Davis initiated the qui tam action in April 2006 alleging the District of Columbia and its schools violated the FCA by submitting Medicaid reimbursement claims for medical and transportation services provided to special-education children without maintaining adequate supporting documentation.

Davis’ firm prepared the Medicaid reimbursement claims made by the District of Columbia Public Schools (DCPS) to the District’s Medicaid agency, the Medical Assistance Administration (MAA), for fiscal years (FYs) 1995, 1996, and 1997. In FY 1998, DCPS used a different firm to prepare its claims, but Davis contended the District failed to submit the required supporting documentation because his firm still had it.

Davis said he alerted District officials about the lack of supporting documentation, but DCPS made no adjustment to its claim. MAA paid DCPS $10.3 million as a tentative settlement for FY 1998, but $7.6 million of this amount was later returned to the federal government after an auditor determined certain claims should be disallowed because they were not adequately documented.

In an earlier decision, the D.C. Circuit _affirmed_ the district court’s dismissal of Davis’ claims for treble damages and conspiracy on the ground he failed to allege actual damage to the United States, but remanded to the lower court to determine whether he was entitled to a portion of any civil penalties if he proved the District made one or more false claims. _United States ex rel. Davis v. District of Columbia_, No. 11-7039 (D.C. Cir. May 15, 2012).

“Davis’s claims expose very troubling behavior by the District, and are sufficient to establish liability under the False Claims Act,” the court said. The court did grant the District summary
judgment on relator’s claims stemming from a fiscal year (FY) 1998 final cost report for medical services as time-barred by the FCA’s six-year statute of limitations.

But the District failed to prove a similar affirmative defense as to the FY 1998 final cost report for transportation services, the submission of which the court went on to find violated the FCA.

According the court, Davis adequately alleged and proved all elements of FCA liability—i.e., that the District “presented” a false claim for payment to the federal government when it submitted the cost report; that the claim was false because the submission did not include legally required documentation; that the documentation was “material” to the government’s decision to pay the claim; and the District “at the very least, exhibited ‘reckless disregard’ for whether it was in compliance with Medicaid regulations.”

As noted in previous decisions, the federal government suffered no actual damages because the services actually were provided and the District paid back $7.6 million of the tentative reimbursement. As a result, Davis could not claim any damages.

The court concluded he was entitled to a share of the civil penalty. Davis argued the penalty should be based on every interim claim paid to DCPS during the relevant time period, which amounted to $2.2 billion to $4.4 billion.

The court flatly rejected this approach, noting there was only one false claim—the final transportation cost report—not every time an interim claim was paid during the year.

To hold otherwise, the court added, would lead to an absurd result where the District would be liable for billions of dollars in civil penalties even though the federal government suffered no actual harm.

The court determined the appropriate penalty for the cost report submission was $11,000, of which it awarded relator a 30% share.


**U.S. Court in Kansas Allows Nurse’s FCA Retaliatory Discharge Claim to Proceed**

A federal district court in Kansas refused September 20 to dismiss a nurse’s retaliatory discharge claim under the False Claims Act, 31 U.S.C. § 3730(h), alleging she was fired four days after telling the managers of the assisted living facility where she worked they were performing glucose monitoring tests in violation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Plaintiff Trina Lipka was hired in January 2013 as the Director of Nursing at an assisted living facility operated by defendants Norm and Kathy Wilcox and their companies Advantage Health Group, Inc. and Superior Senior Living, Inc. In this position, plaintiff oversaw all certified medication aides and certified nursing assistants employed by the facility and defendants.

In March, she began to question whether facility staff, under CLIA, could obtain blood samples by using finger sticks to test residents’ glucose levels. She believed the facility needed a CLIA waiver to obtain blood samples for glucose testing, which plaintiff confirmed by emailing the Kansas Health and Environment Laboratories (KHEL), the state agency responsible for administering CLIA.

On April 1, plaintiff met with the operator of the facility and Kathy Wilcox about the need to obtain a CLIA waiver. According to plaintiff, she told them their current practice of obtaining
blood samples without a CLIA waiver was illegal and fraudulent and informed them she had previously filed an FCA qui tam action concerning the same issue. On April 5, plaintiff was terminated.

Plaintiff sued defendants alleging an FCA whistleblower retaliation claim and a violation of Kansas public policy. Defendants moved to dismiss.

The U.S. District Court for the District of Kansas denied in part defendants’ motion. The court held plaintiff could proceed with her FCA whistleblower retaliation claim, although it agreed to dismiss her claims under Section 3730(h) against the individual defendants and under state law.

Defendants argued plaintiff did not engage in conduct in furtherance of an FCA action (i.e., “protected activity”) because the activities she described in her complaint were part of her regular job duties. But the court disagreed, noting that, at least at this stage of the litigation, plaintiff indicated her duties were limited to overseeing medication aides and nursing assistants at the facility, not investigating fraud or monitoring compliance with Medicaid requirements.

Defendants also argued the $150 CLIA waiver was too trivial to trigger a viable qui tam action. But the court noted the whistleblower retaliation provision does not require an actionable FCA claim at the time of the alleged retaliation.

Having found plaintiff engaged in “protected activity,” the court next held plaintiff sufficiently pled facts that would demonstrate defendants had notice she was taking action in furtherance of a qui tam action.

Plaintiff alleged she specifically told defendants during the April 1 meeting that she had contacted KHEL, that the facility needed the CLIA waiver to obtain the blood samples by finger sticks, and that the facility’s current practices were “illegal” and “fraudulent.” She also allegedly informed them of her prior FCA lawsuit concerning the same CLIA issue.

“Taken together, these allegations are sufficient to create a reasonable inference that defendant had notice that there was a distinct possibility that she would sue defendants under the FCA,” the court said.

The court also refused to require a heightened pleading standard on the notice element applicable to employees whose job descriptions include investigating fraud or monitoring Medicaid compliance as there was no evidence at this point that these were in fact part of plaintiff’s duties as the Director of Nursing.

Finally, the court found the timing of the termination decision—four days after the April 1 meeting—supported a causal connection between the protected activity and the adverse employment action.

The court did dismiss plaintiff’s common law claim that her termination violated state public policy, finding the FCA provided an adequate alternative remedy even though punitive damages are not available under the statute.

The court also held plaintiff could not maintain an FCA retaliation action against the individual defendants, finding the 2009 amendment to Section 3730(h) was not intended to provide individual liability.


**U.S. Court in Illinois Refuses to Dismiss Certain Counterclaims Against Qui Tam Relators**
On September 19, the U.S. District Court for the Northern District of Illinois granted in part and denied in part relators’ motion to dismiss defendants’ counterclaims, which were filed in response to relators’ qui tam action. The court dismissed with prejudice to the extent defendants’ counterclaims sought recovery should relators prevail in their qui tam suit.

Relators Cathy Wildhirt and Nancy McArdle were employed by defendants AARS Forever (AARS) and THH Acquisition (THH) where they signed an Employee Confidentiality, Non-Compete, and Health Insurance Portability and Accountability Act (HIPAA) Agreement (Agreement) as well as a Confidential Acknowledgment of No Known Suspect Practices statement.

Prior to filing their action, relators did not report any alleged suspect practices to AARS or THH. Relator McArdle also took home and retained the companies’ confidential and HIPAA-covered documents; disclosed to third parties contents of company-related verbal communications; and following her employment termination, made disparaging remarks to the Veterans Administration (VA) about THH and its business practices as well as to the state of Illinois and private payers about the defendants’ compliance with various agreements it had with the VA. Relator Wildhirt also made similarly allegedly false statements to the VA, the state, and private payers even though neither relator had any knowledge about defendants’ general billing practices or specific contract requirements.

Relators eventually filed a qui tam action alleging AARS and THH violated the False Claims Act (FCA) and the Illinois Whistleblower Reward and Protection Act. AARS and THH each filed six materially identical counterclaims under Illinois law. Counts I and II alleged relators breached their Agreement through unauthorized disclosure of confidential information; defendants sought indemnification for damages suffered as a result of those disclosures under Count III; Count IV alleged relators breached the Agreement by failing to report suspect practices before filing a qui tam lawsuit; Count V claimed relators committed tortious interference with prospective economic advantage by making false statement to third parties about defendants’ practices; and Count VI sought reimbursement for legal costs and expenses should defendants prevail in the qui tam suit.

Relators moved to dismiss AARS’ and THH’s counterclaims. The court granted in part and denied in part relators’ motion.

With respect to Counts I, II, III, IV, and VI, the court held those counterclaims by defendant must be dismissed if defendants are found liable for FCA violations. Otherwise, the court held defendants’ counterclaims were independent of the FCA claim because the counterclaims’ success did not require as an essential element that defendants be liable or not liable under the FCA for Counts I and II.

For Count III, the court held defendants could proceed to the extent they sought damages not directly connected with the qui tam litigation. The court also allowed Counts III and VI to proceed with respect to defendants’ attorney fees and legal expenses in the event defendants prevailed on the merits, especially if defendants continued to maintain that relators’ claims were frivolous given their lack of relevant knowledge of the VA contracts and defendants’ performance under those contracts. Lastly, the court held Count IV could proceed if defendants prevailed on the qui tam claims and showed a causal relationship between relators’ failure to report and their filing of a qui tam action.

On defendants’ counterclaim regarding tortious interference with prospective economic advantage, the court found defendants’ allegations regarding the nature of relators’ misrepresentations, to whom they were made, and the basis for alleging they were false were sufficient to plead the third element of the tortious interference claim under Illinois law.
Lastly, the court disagreed with relators’ contention that Counts I-III and V were barred by absolute privilege under Illinois law for statements related to, made preliminary to, or made in the course of judicial proceedings. According to the court, “it [was] impossible to say at this point whether realtors’ qui tam suit was contemplated in good faith and under serious consideration.” Therefore, the court held dismissal under Fed. R. Civ. P. 12(b)(6) on absolute privilege grounds would be inappropriate.


U.S. Court in Pennsylvania Remands Whistleblower Suit to State Court Finding Amount in Controversy Requirement Not Met

The U.S. District Court for the Eastern District of Pennsylvania remanded September 27 a wrongful discharge and whistleblower retaliation suit to state court, finding the removing defendant did not bear its burden of proving the required amount in controversy.

Plaintiff Brian Heffner was employed by defendant LifeStar Response of New Jersey, Inc. as an emergency medical technician (EMT) from March 2011 until January 2012. Plaintiff’s primary duties involved transporting nursing-home patients who were in a wheelchair or a stretcher to and from medical appointments or emergency treatments.

Plaintiff voiced his concern to LifeStar executives that some of the forms being generated by LifeStar employees for transportation services indicated patients were bedridden when, in fact, they were not. Plaintiff also alleged he was asked to alter reporting forms.

After getting an unsatisfactory response to his complaints, plaintiff resigned his position as crew chief. According to plaintiff, he was subsequently fired for purportedly misusing a company gasoline card. Plaintiff then sued LifeStar for wrongful discharge and alleged his termination violated Pennsylvania’s Whistleblower Law.

The case was removed to federal court, and plaintiff moved to remand. The court found defendant had the burden to prove federal jurisdiction and failed to do so.

To meet the amount in controversy requirement of $75,000, defendant asserted plaintiff’s complaint sought damages in excess of $100,000. But the court found that “types of relief sought and the measures of damages sought in each Count overlap substantially” and cannot be counted separately.

The court also rejected defendant’s argument that the amount in controversy requirement was satisfied because plaintiff’s complaint sought punitive damages in addition to compensatory damages, fees, and costs.

According to defendant, an award of reasonable attorney’s fees might be as much as 30% of plaintiff’s judgment. Although it could be “reasonably inferred that plaintiff’s claimed damages are greater than $50,000, exclusive of the reasonable attorney fees permitted under the Whistleblower Law . . . because defendant has not presented any record evidence (and did not offer any witnesses or exhibits at the April 10, 2013 proceeding), [the court] cannot do more than guess at the amount of the judgment by which defendant would have me calculate using the thirty-percent-of-judgment measure suggested,” the opinion said.

Accordingly, the court granted the motion to remand.

U.S. Court in D.C. Orders Disclosure of Some Documents in FOIA Dispute over CIA Reports

The U.S. District Court for the District of Columbia resolved some, but not all, disputed document requests under the Freedom of Information Act (FOIA) for annual reports submitted to the government by two pharmaceutical companies pursuant to their respective Corporate Integrity Agreements (CIA).

The Department of Health and Human Services (HHS) and the company intervenors Pfizer Inc. and Purdue Pharma LP claimed the materials at issue were not subject to FOIA disclosure under Exemption 4 on the ground they contained confidential, commercial information and under Exemption 6 on the ground they included private, personal information.

Plaintiff Public Citizen requested the documents, which relate to annual reports submitted by Pfizer pursuant to a 2004 CIA with the HHS Office of Inspector General (OIG) and by Purdue pursuant to a 2007 CIA. The CIAs were part of settlements to resolve allegations the companies’ engaged in illegal marketing practices to promote their drugs for off-label uses.

Public Citizen filed the FOIA requests to address “a serious question about the adequacy of OIG oversight of companies during the CIA process,” the opinion noted. Specifically, plaintiff contended to the extent the annual reports at issue, which are required under the CIAs, “reveal instances of illegal activity by the companies, the public has a strong interest in knowing that OIG had access to this information and in knowing whether OIG acted forcefully in responding to it.”

In response to the request, HHS located 1,177 pages related to the Purdue portion of the FOIA request, withheld 1,093 of those pages in their entirety under the FOIA exemptions, and partially released 84 pages with portions redacted. For the Pfizer portion of the FOIA request, HHS identified 9,432 responsive pages, withheld 5,216 pages in their entirety, and partially released 4,216 pages.

Plaintiff filed a lawsuit against HHS in 2011 challenging the adequacy of the agency’s search for responsive records and the withholding under Exemptions 4 and 6 of the following eight categories of records included in the annual reports: reportable events; disclosure log summaries; screening and removal of ineligible persons; summaries of government investigations or legal proceedings; communications with the Food and Drug Administration (FDA) about off-label promotion; portions of Pfizer’s off-label findings and detailing sessions; portions of independent review organization (IRO) reports pertaining to IRO findings and recommendations and the companies’ compliance programs, corrective actions, and the IRO’s description of the companies’ systems, policies, procedures, and practices; and Purdue’s supplement to its first annual report.

HHS filed a so-called “Vaughn Index of Withheld Documents” for each company. Both parties moved for summary judgment.

First, the court agreed with plaintiffs that the adequacy of HHS’ search for records was questionable. The court noted certain required portions of the annual reports for at least two years were “missing” from the documents released and from the Vaughn index for Pfizer. The court also noted some factual questions as to whether the documents for the three other years were responsive to plaintiff’s request.
Next, the court found HHS properly withheld some of the requested materials under Exemption 4, ordered the disclosure of others, and found insufficient information to issue a ruling on certain categories of information.

Under Exemption 4, if the documents at issue are not trade secrets, the agency has the burden of showing the withheld records are “(1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential.”

Relevant to this dispute, the court said, was whether the documents at issue were “commercial” and, if so, whether they were “privileged or confidential.”

For each category of documents, the court ruled as follows.

**Reportable Event Summaries**—The court found insufficient information to determine whether the summaries contained commercial information and were properly withheld. It therefore denied summary judgment to all parties.

**Disclosure Log Summaries**—The court likewise found insufficient information to determine whether the summaries were commercial in nature and again denied summary judgment to all parties.

**Ineligible Persons Information**—The court considered two sub-categories of information. First, the court held documents concerning changes to the company’s process regarding ineligible persons amounted to commercial information that was confidential and therefore granted summary judgment in favor of defendant and defendant intervenors. Second, the court found information relating to the name, title, and responsibilities of any person determined to be an ineligible person was not commercial and therefore granted summary judgment to plaintiff as to this subcategory of information.

**Investigations or Legal Proceedings**—Again the court considered two sub-categories of information. First, documents pertaining to allegations of the company’s criminal or fraudulent conduct were commercial but the record did not establish whether they also were confidential so the court denied summary judgment to all parties. Second, as to the identity of the agency conducting the investigation and the status of the investigation, the court found this information was not commercial and granted summary judgment to plaintiff.

**Company Communications with FDA About Off-Label Promotions**—The court held this information was commercial, but could not determine whether it also was confidential and therefore denied summary judgment to all parties.

**Pfizer’s Off-Label Findings and Detailing Sessions**—The court found this type of information was commercial and granted summary judgment to defendants as to Pfizer’s specific off-label findings after concluding it was confidential as well. The court denied, however, summary judgment to all parties as to documents concerning “detailing sessions” because whether this information was confidential was unclear.

**IRO Reports**—The court held this information was commercial and also confidential and therefore properly withheld. Thus, the court granted summary judgment to defendants as to these documents.

**Purdue Supplement**—The court held information related to the company’s promotional monitoring program fell within the scope of commercial information and also was confidential. The court granted summary judgment to defendants as to this information accordingly. However, the court was unable to judge whether references to “other confidential and proprietary polices”
were commercial and therefore it denied summary judgment to both parties as to this information.

The court directed the parties, by November 8, to provide a status report listing the remaining records in dispute with further identifying information and a proposed briefing schedule for any further proceedings.


U.S. Court in California Refuses to Dismiss Relator’s FCA Action Against MA Plan

A federal district court in California refused October 15 to dismiss a relator’s third amended complaint against Kaiser Foundation Health Plan, alleging it violated the False Claims Act (FCA) in its capacity as a Medicare Advantage (MA) Organization.

Relator Chris McGowan brought the qui tam action alleging Kaiser “has taken advantage of the federal Medicare Advantage program to illegally pad its profits,” according to the complaint. Relator, who formerly worked for Kaiser as a managing director of fixed income and liability management, contended Kaiser disregarded Centers for Medicare & Medicaid Services bid instructions for 2008 and 2009 and provided “inaccurate and false data” in its MA bids.

“Kaiser used these falsely certified bids to obtain money from the government,” the complaint said. Specifically, relator alleged Kaiser violated the FCA by “presenting false claims,” “making or using false records or statements material to payment or approval of false claims,” and “retaining proceeds to which it is not entitled.”

Kaiser moved to dismiss the third amended complaint primarily arguing it contradicted the allegations in the prior complaints.

In an unpublished opinion, the U.S. District Court for the Northern District of California refused, however, to dismiss the complaint on this basis.

“Although Kaiser identifies specific statements in the [third amended complaint] that it contends contradict allegations from the original complaint, . . . the Court cannot say that the allegations are directly and unambiguously contradictory.”

Even if relator pleaded inconsistent allegations, “the crux of this dispute is the correct interpretation of the bid instructions and the manner in which they are to be applied,” the court said. “Given the nature of the dispute, the Court concludes that Relator may plead facts in the alternative.”

The court suggested Kaiser had other means to redress any claim it may have that relator acted in bad faith—including seeking sanctions—but dismissal of the action was not an appropriate remedy.

The court also refused to dismiss the third amended complaint for failure to comply with Fed. R. Civ. P. 9(b).

Relator identified the specific bids that were allegedly false; noted Kaiser’s actuary, chief executive officer, or chief financial officer had to certify the bids were true and accurate; and provided more than a “general indictment” of Kaiser’s business, the court observed.
Whether relator could prove the bids were false “is a matter of proof, not of pleading,” the court commented.


**U.S. Court in Florida Dismisses FCA Claims Alleging Misclassification of IDTF, But Allows Claims of Improper Physician Supervision**

On October 3, the U.S. District Court for the Middle District of Florida dismissed claims alleging the misclassification of a magnetic resonance imaging (MRI) center as a physician practice group instead of an independent diagnostic testing facility (IDTF) was grounds for a False Claims Act (FCA) qui tam action, noting proper classification is not a condition of reimbursement.

The court refused to dismiss, however, relator’s claims alleging improper physician supervision at the center, finding the complaint fulfilled the FCA’s heightened pleading requirement and sufficiently alleged false claims for government reimbursement had actually been submitted by defendant.

Defendant is a private company that operates an MRI center enrolled in Medicare and Medicaid and accredited to perform MRIs, mammography, and positron emission tomography (PET) diagnostic procedures. In 2006, defendant opened another MRI center, Dunnellon Open MRI (Dunnellon), that was accredited to perform MRIs but enrolled it in Medicare and Medicaid as an additional physician practice group rather than an IDTF.

Relator, defendant’s former employee, filed a qui tam action under the FCA alleging: defendant failed to properly register Dunnellon as an IDTF, thereby making all claims submitted to Medicare from Dunnellon fraudulent; defendant submitted claims to Medicare and Medicaid from Dunnellon for PET and MRI procedures that were performed without proper supervision by a physician as required by 42 U.S.C. § 1395y(a)(1)(A); and defendant submitted claims to Medicare and Medicaid from both MRI centers for PET and MRI procedures that were performed by unlicensed and uncertified technicians.

Defendant argued relator cited no authority to support the allegations regarding the purported requirement that Dunnellon be registered as an IDTF. The court agreed, noting no comparable IDTF registration regulation in either Medicare or Medicaid. Citing a Sixth Circuit case, the court also found Dunnellon’s enrollment as a physician practice group instead of an IDTF did not violate Medicare regulations as 42 U.S.C. § 1395cc does not require providers to enroll specifically as one type of provider versus another. The classification requirement, according to the court, is not a condition of Medicare reimbursement “such that an FCA claim would lie.”

Finding defendant’s misclassification of Dunnellon did not violate any Medicare regulations, the court could not conclude defendant’s 2006 enrollment form and certification statement (CMS Form 855B) was “materially false, and/or that this misclassification impacted the reimbursement payments received from Medicare.”

As to relator’s allegations regarding the purported lack of supervision over MRI and PET scans conducted at Dunnellon, the court found the complaint set forth a valid claim for relief and dismissed defendant’s motion to dismiss as to these issues.

The court found relator’s allegations (e.g., that Medicare requires specific levels of supervision over MRI and PET scans for the procedures to be eligible for reimbursement and that a radiologist or physician was not present at Dunnellon to supervise the procedures or interpret
their results), coupled with relator’s detailed allegations as to dates of employment for each of
the unlicensed and uncertified technicians, the exact procedures they performed, the Medicare
CPT codes used, relator’s own position as an insider working for defendant during the relevant
time period, and relator’s position to personally observe the events were “more than sufficient to
satisfy the ‘indicia of reliability’ required to properly assert an FCA claim for relief.”

Lastly, the court found relator sufficiently alleged defendant actually submitted false or
fraudulent claims to Medicare or Medicaid for reimbursement. In this case, the court found
relator provided some indicia of reliability to support his allegation of an actual false claim for
payment being made to the government, as evidenced by the two procedures relator pointed out
involving an MRI scan submitted for reimbursement on July 15, 2009 and a PET scan submitted
for reimbursement on May 21, 2009 in addition to relator’s detailed accounting of over 300
claims defendant actually submitted for reimbursement and for which defendant received
payment.

According to the court, relator’s information was more than enough to satisfy the heightened
pleading standard of Fed. R. Civ. P. 9(b) and to put defendant on notice of the charges against
it.

United States ex rel. Ortolano v. Amin Radiology, No. 5:10-cv-583-Oc-10TBS (M.D. Fla. Oct. 3,
2013).

U.S. Court in Georgia Says Qui Tam Complaint “Plausible on Its Face”

A federal district court in Georgia refused to dismiss a qui tam action under the False Claims Act
(FCA) against a physician alleging the sale of his cancer treatment center to a hospital violated
the Anti-Kickback Statute (AKS) and the Stark Law.

The court found the complaint sufficient to withstand the physician’s motion to dismiss under
Fed. R. Civ. P. (9)(b), noting the relator specifically alleged the parties, the transaction, the date,
and the location of the conduct that allegedly violated the AKS and Stark Law.

The court also refused to dismiss the action under Fed. R. Civ. P. 12(b)(6) as implausible.
Instead, accepting the factual allegations as true at this stage of the litigation, the court found a
“plausible claim” under the law.

Columbus Regional Healthcare System, Inc., through its wholly owned subsidiary, Columbus
Radiation Oncology Treatment Center, purchased the Tidwell Cancer Center from defendant
Thomas J. Tidwell for $10.5 million.

According to relator, Richard Barker, the purchase price was in excess of fair market value,
Columbus Radiation did not need Tidwell’s facilities or equipment, and the equipment did not
meet the standard of care and was essentially worthless.

Relator alleged Columbus Radiation bought the cancer center to induce referrals from defendant
in the two years before he retired and to prevent him from referring business to other
competitors. Relator also contended claims submitted to Medicare and Medicaid while defendant
continued to practice radiation oncology in affiliation with Columbus Radiation were false because
they certified compliance with the AKS and Stark Law. According to relator, Tidwell
also submitted false claims to federal health care programs for services he did not perform.

Defendant moved to dismiss under Rule 9(b) alleging the complaint lacked the required
specificity and under Rule 12(b)(6) for failure to state a claim for relief.
The U.S. District Court for the Middle District of Georgia refused to dismiss the complaint on either ground.

Relator’s complaint alleged the “who,” the “what,” the “when,” and the “where” of the conduct he contended violated the AKS and the Stark Law, the court found. Relator also alleged why no safe harbor or exception to the AKS and the Stark Law applied, the court observed. Relator provided specific examples of the allegedly fraudulent billings, including patient names, dates of service, and types of service.

“While [relator] may not have alleged every tainted bill, he clearly alleges that this conduct occurred over the two-year period following Columbus Regional’s purchase of Tidwell Cancer Center and prior to Tidwell’s retirement,” the court said. Relator also alleged the equipment was so substandard that the services either were not provided or were not medically necessary.

At this stage of the litigation, relator need not come forward with proof of the allegations, the court added. “This case is not analogous to those cases in which the plaintiff simply alleges generally that false claims were submitted,” the court said.

The court also rejected defendant’s motion to dismiss for failure to state a claim for relief, noting relator should be allowed to proceed with his allegations at this stage of the litigation, even if they ultimately may be disapproved.


Second Circuit Says General Counsel Could Not Bring Whistleblower Action Against Former Client

The Second Circuit upheld October 25 the dismissal of a whistleblower action under the federal False Claims Act (FCA) against Quest Diagnostics Inc. brought by several former executives, including one who served as general counsel, of its wholly owned subsidiary Unilab Corp.

The Second Circuit agreed with the lower court that the general counsel violated New York ethics rules in bringing the FCA action against his former client because he relied on confidential information that he was privy to while working there as their attorney. The appeals court found the exception to this rule did not apply because the general counsel disclosed more than was necessary to prevent ongoing criminal conduct.

The U.S. District Court for the Southern District of New York also disqualified the general counsel and the two other executives, who formed the litigation partnership Fair Laboratory Practices Associates (FLPA), as well as FLPA’s outside counsel, from the qui tam lawsuit and any subsequent action based on the same facts. United States ex rel. Fair Laboratory Practices Assocs. v. Quest Diagnostics Inc., No. 1:05-cv-05393-RPP (S.D.N.Y. Apr. 5, 2011). The appeals court also affirmed the disqualifications.

Andrew Barker, Richard Michaelson, and Mark Bibi, three former senior Unilab executives, formed FLPA to prosecute a qui tam action alleging defendants Quest and related entities violated the Anti-Kickback Statute (AKS) by offering medical testing services for manage care patients at a substantial discount or below cost in exchange for Medicare and Medicaid referrals.

Baker served as Chairman and Chief Executive Officer of Unilab from 1993 to 1996; Michaelson served as Chief Financial Officer from 1993 until January 1998, and then as Director until 1999, while Bibi served as General Counsel from 1993 through spring of 2000 and was solely responsible for all of the company’s legal affairs. Quest acquired Unilab in 2003.
FPLA alleged defendants violated the AKS from at least January 1, 1996 through at least 2005 by operating an ongoing “pull through” scheme where they charged independent physician associations and managed care organizations below cost rates for laboratory tests to induce Medicare and Medicaid referrals.

Defendants moved to dismiss, arguing Bibi, as Unilab’s former general counsel, violated New York Rules of Professional Conduct—specifically Rule 1.9(a), which prohibits a lawyer from “switching sides,” and Rule 1.9(c), which prohibits a lawyer from disclosing a client’s confidential information.

While FPLA did not contest that some of the information at issue was confidential, plaintiff asserted that Bibi’s disclosure fit within the exception to the duty of confidentiality under Rule 1.6(b) to prevent the client from committing an ongoing crime.

The district court held the FCA did not preempt applicable state ethical rules, that Bibi’s participation in the qui tam action violated Rules 1.9(a) and (c), and the disclosures went beyond what was “necessary” for the Rule 1.6(b) exception to apply.

Affirming, the Second Circuit agreed the FCA did not trump New York’s ethics rules, which applied here, after balancing the federal government’s interests in encouraging qui tam actions versus its interest in preserving the attorney-client privilege.

The appeals court held the Rule 1.6(b) exception did not apply because the disclosures Bibi made went beyond what was “reasonably necessary to prevent any alleged ongoing fraudulent scheme in 2005.” According to the appeals court, FPLA could have brought the qui tam action without Bibi’s involvement, or he could have made more limited disclosures. Because it held Bibi violated Rule 1.9(c), the appeals court did not consider whether he also violated Rule 1.9(a).

Next, the appeals court held the district court did not abuse its discretion by concluding dismissing Bibi alone from the qui tam action was an insufficient remedy.

Specifically, the appeals court agreed allowing Baker and Michaelson to go forward with the lawsuit “would taint the trial proceedings and prejudice defendants.” Moreover, the district court did not prevent the federal government, the real party in interest, or a different relator from bringing suit.


**U.S. Court in California Affirms Former CEO’s Five-Year Exclusion from Federal Health Care Programs**

On October 22, the U.S. District Court for the Northern District of California affirmed a decision by the Department of Health and Human Services Secretary to impose a minimum five-year exclusion on the former chief executive officer (CEO) of a drug manufacturing company who was convicted of wire fraud following the issuance of a press release that contained false statements about a particular drug’s effectiveness.

Plaintiff W. Scott Harkonen served as a Board member and CEO of InterMune, Inc., a company that developed, marketed, and sold Actimmune, a drug approved by the Food and Drug Administration (FDA) to treat granulomatous disease and malignant osteoporosis. Actimmune was not approved, however, by the FDA to treat idiopathic pulmonary fibrosis (IPF), a fatal lung disease.

In August 2002, clinical trials failed to show Actimmune was effective in treating IPF, and the FDA required further clinical testing to determine if Actimmune could delay death for IPF
patients. Nevertheless, InterMune issued a press release that same month announcing preliminary data from its clinical trials for the drug demonstrated “a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF . . .”

In March 2008, plaintiff was indicted for wire fraud and felony misbranding of a drug. The indictment specifically asserted plaintiff’s press release “contained materially false and misleading information regarding Actimmune and falsely portrayed the result” of the clinical trial.

In September 2009, a jury convicted plaintiff of wire fraud but acquitted him of felony misbranding. In August 2011, the Secretary notified plaintiff he was being excluded from participating in federal health care programs for five years pursuant to Section 1128(a)(3) of the Social Security Act based on the wire-fraud conviction. Plaintiff requested administrative review, arguing his conviction did not trigger a mandatory exclusion because his offense was not “in connection with the delivery of a health care item or service” and was not based on any act or omission in a health care program.

In May 2012, an administrative law judge (ALJ) affirmed the exclusion order, holding it was sufficient “that there be a nexus or common sense connection between the offense and the delivery of a health care item or service.” The ALJ also concluded Section 1128(a)(3) did not require proof that plaintiff intended to cause, or did cause, an effect on the delivery of the health care item or service. Plaintiff appealed to the Departmental Appeals Board (DAB) in November 2012, which affirmed the ALJ’s order based on the same reasoning.

Plaintiff appealed the final agency decision to the district court, which granted summary judgment to the Secretary.

At the beginning of its analysis, the court noted the primary dispute was whether plaintiff was convicted of a crime committed “in connection with the delivery of a health care item or service.”

The Secretary argued there was a common sense nexus because plaintiff’s wire fraud conviction was based on a press release that misrepresented the effectiveness of a health care item (the prescription drug, Actimmune) with the intent of persuading doctors to prescribe and patients to take the drug to treat IPF. Plaintiff contended the Secretary’s standard was arbitrary and capricious, leading to inconsistent results.

The court affirmed the Secretary’s position, holding her interpretation was reasonable and consistent with the Chevron standard (Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. 467 U.S. 837 (1984)). The court held that plaintiff’s wire fraud conviction was connected to false statements about Actimmune’s clinical trials as plaintiff’s statements made through the press release were likely to influence people to purchase the drug. In other words, the connection between plaintiff’s false press release and the likelihood that it would influence the delivery of a health care item was not remote.

Plaintiff argued that the phrase “in connection with the delivery of a health care item” referred only to conduct that occurred in the delivery process itself and that issuing a press release was not part of the delivery process. According to plaintiff, mere issuance of his press release did not have a proximate impact on the delivery of a health care item because there was no direct connection to the drug’s distribution or sale in commerce, thereby making it too remote for the mandatory exclusion to apply.

The court disagreed, noting that courts have interpreted phrases like “in connection with” and “in relation to” as encompassing the type of potential effect created in this instance where plaintiff’s
misleading statements would likely influence doctors to prescribe and patients to purchase the drug.

Plaintiff also argued because Section 1128(a)(3) specifically listed theft, embezzlement, and financial misconduct and they “necessarily occur in connection with a [federal program’s ‘delivery’ of items and services],” it is those types of actions that constitute offenses that if done in connection with Medicare or Medicaid, would constitute stealing from the government.

The court was not persuaded, finding nothing in Section 1128(a)(3) or its legislative history required that plaintiff’s conviction have been for an act equivalent to “stealing from the government” such as defrauding Medicare. The court pointed out that the statute did not require the fraud be one that was perpetrated against the government—“just that it be ‘fraud’ and that it be ‘in connection with the delivery of a health care item or service.’”

Next, the court found substantial evidence in the record supported the Secretary’s exclusion decision that plaintiff’s offense was in connection with the delivery of a health care item or service. Plaintiff argued because he was acquitted on the misbranding charge, which would have involved a connection to the delivery of Actimmune, and was convicted instead on wire fraud, which did not involve a connection, the Secretary had no basis for concluding his “intent” in issuing the press release was to defraud physicians and patients.

According to the court, the misbranding count required a finding that Actimmune bear false or misleading “labeling,” which is far more limited in breadth than “in connection with.” The court therefore affirmed the DAB’s conclusion that a press release can be issued “in connection with the delivery of a health care item” while at the same time not qualify as labeling.

Other evidence supporting the Secretary’s decision included plaintiff being the “controlling force” behind the press release’s content; the jury’s conclusion that multiple statements in the press release were false or fraudulent; letters from the public that evidenced the press release had some influence on IPF patients; and the DAB’s finding that plaintiff committed his crime in the context and under the cover of carrying out his drug manufacturing business “as the sale of a drug and its use by a patient are both necessary parts of the delivery process and both were clearly referenced in the Press Release.”

Plaintiff further contended the Secretary ignored the district court’s finding that there was no evidence he intended to cause any loss, which led the district court to reject an enhancement based on actual and intended loss. The court was not persuaded. The fact that the district court could not determine the amount of loss caused by the press release did not constitute an “affirmative finding that in committing the wire fraud, [plaintiff] did not intend to cause any loss, or did not intend to encourage patients to use and doctors to prescribe Actimmune,” the court said.

After determining that the Secretary applied the correct legal standard and that her decision was supported by substantial evidence, the court looked into whether construing Section 1128(a)(3) as mandating exclusion would result in violating plaintiff’s Fifth Amendment right from double jeopardy and due process, as well as the Eighth Amendment right to be free from excessive fines and cruel and unusual punishment.

The court found the Double Jeopardy Clause did not preclude application of the exclusion because the “statutory scheme is not so punitive in purpose or effect so as to transform what was clearly intended as a civil remedy into a criminal penalty.” The court supported its finding by pointing out that the exclusion does not involve confinement or other form of restraint; exclusion has historically never been regarded as punishment; it does not require a finding of scienter; there is no indication that the purpose of exclusion is retribution; the offenses listed in the statute can also form the basis for civil actions; and the exclusion serves the alternative purpose
of protecting federal program beneficiaries from incompetent practitioners and inappropriate or inadequate care.

The court also found the five-year exclusion was neither excessive and subject to the Excessive Fines Clause nor in violation of the Due Process Clause as the exclusion is a civil sanction imposed by the HHS Office of Inspector General and thus, remedial in nature rather than primarily punitive. The court also pointed out that the Secretary had no discretion with regard to the minimum five-year period as the statutory language’s use of the word “shall exclude” required her to impose the minimum five-year exclusion.


**U.S. Court in Wisconsin Rejects FCA Claims Against Retail Pharmacy Involving Dual-Eligibles Billing**

On November 5, the U.S. District Court for the Western District of Wisconsin held a pharmacist failed to support his federal False Claims Act (FCA) lawsuit against a retail pharmacy chain that allegedly billed Medicaid a higher dollar amount in violation of the federal assignment requirement regarding dual eligibles. The court also concluded there is no clear regulation that requires Medicaid claims in dual-eligible cases to be limited to copayment amounts under a customer's private insurance policy.

Relator Carl Thulin, a pharmacist, filed a qui tam action in April 2010 against Shopko Stores Operating Co., LLC (Shopko), the owner and operator of a retail pharmacy chain where he worked from 2006 until 2009, for allegedly violating the FCA and analogous state laws in its submission of claims to state Medicaid agencies. Neither the federal government nor any of the named states opted to intervene.

The court granted Shopko’s motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6) and failure to plead with specificity under Fed. R. Civ. P. 9(b). The court also declined to exercise its supplemental jurisdiction over relator’s state law claims.

Shopko provides pharmacy prescription medication services to dual-eligible customers in several states. Relator alleged Shopko submitted false claims by readjusting the private insurance claim that Shopko submitted to the private insurer or pharmacy benefit management company, which resulted in a higher dollar amount being submitted to Medicaid for payment. Relator argued Shopko’s billing practice resulted in billing more for dual-eligible patients than was allowed under the assignment of rights and benefits provision of federal law and contract provisions of private insurance companies. Relator also contended certain federal and state regulations limited reimbursement of dual-eligible prescriptions to the copay amount.

The federal assignment requirement states that dual eligibles who apply for benefits to the state’s Medicaid agency must assign any rights they have under their private insurance plan to the state. In this case, the court held relator failed to show how the plain language of 42 U.S.C. § 1396k(a)(1)(A) required medical providers like Shopko to assign their right to medical reimbursement payments from private health care insurers to the state or how Shopko was required under the assignment regulation—which applied to Medicaid recipients—to assign its rights under a contract to which the Medicaid recipient was not even a party. The court further held relator failed to adequately plead that Shopko knew the assignment law applied to it as a provider or allege facts to support how Shopko knew of such an obligation or who in the organization had actual knowledge.

Relator also argued certain federal and state regulations limited reimbursement of dual-eligible prescriptions to the copay amounts. The court concluded that while the National Council for Prescription Drug Programs version 5, release 1 allows for state Medicaid agencies to collect
copay data, it is not required. According to the court, there is no federal obligation for providers like Shopko to disclose copay data and, therefore, relator’s argument that Shopko was limited to seeking a dual-eligible’s copay amount from Medicaid was “fundamentally flawed.”

The court also rejected relator’s reliance on state law regulations to show Shopko as a provider was limited to collecting the copay or deductible as “required by the pertinent Medicaid rule or regulation for certain of the named plaintiff states.” The court found relator failed to allege any individual transactions that took place in a state as required to meet the heightened pleading requirements of Rule 9(b).


Fifth Circuit Finds Public University Could Not Be Sued Under FCA

On November 4, the Fifth Circuit affirmed in an unpublished opinion a district court’s ruling that the University of Texas Health Science Center-Houston (Center) was an arm of the state, not a “person” who could be liable under the False Claims Act (FCA) in a former employee’s qui tam action against the Center. The appeals court also held sovereign immunity barred relator’s claim against the Center under the FCA’s anti-retaliation provision.

The Center terminated relator Terri King's employment as an associate professor in 2005. Relator filed in January 2011 a qui tam suit alleging her supervisor at the Center falsified government-funded research data and results in order to obtain federal funding. Plaintiff also argued the Center defrauded the government by covering up the supervisor’s misconduct relating to federal research grants and retaliated against her for reporting the supervisor’s misconduct by hampering her research opportunities, appointing her to less favorable positions, and eventually firing her when she continued to raise concerns.

Relator also asserted a private action for retaliation and wrongful termination under the FCA’s anti-retaliation provision. The United States declined to intervene.

The Center moved to dismiss relator’s complaint based on three grounds: the Center was a state agency and not subject to liability under the FCA; sovereign immunity barred relator’s FCA claim against the Center; and relator’s complaint did not comply with the particularity requirements of Fed. R. Civ. P. 9(b).

The district court granted the Center’s motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim on which relief could be granted.

The Fifth Circuit affirmed, holding the Center could not be sued under the FCA.

In Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000), the Supreme Court held “that the False Claims Act does not subject a State (or state agency) to liability” because neither a state nor state agency falls within the FCA’s definition of “person.”

To determine whether the Center was an arm of the state, and therefore not subject to the FCA, the appeals court applied the six-factor test it established in Clark v. Tarrant County, Texas, 798 F.2d 736 (5th Cir. 1986): (1) whether state statutes and case law characterized the Center as an arm of the state; (2) the Center's funding source(s); (3) the degree of local autonomy enjoyed by the Center; (4) whether the Center was concerned primarily with local, as opposed to statewide problems; (5) whether the Center had authority to sue and be sued in its own name; and (6) whether the Center had the right to hold and use property.

The appeals court held a survey of Texas statutes and case law weighed in favor of finding the Center to be an arm of the state. For example, the state constitution provides for the
establishment of the University of Texas System and state law considers “a [public] university system or an institution of higher education” to be a “state agency.” The court also pointed to several cases that indicated Texas courts treated the Center as a state agency.

As to the second factor, the appeals court noted the state provided substantial funding to the Center and permitting a civil recovery would interfere with the state’s fiscal autonomy, even if payment was not made directly from the state treasury.

The appeals court also found Clark’s third and sixth factors supported a ruling in the Center’s favor because its degree of local autonomy was governed by a board of regents appointed by the governor with the advice and consent of the senate. As for the right to hold and use property, the court pointed out that the Center’s board of regents had the power of eminent domain under state law.

Regarding the fourth factor, relator argued the Center was primarily concerned with local issues because it did not provide statewide services or have a statewide presence as all of its facilities were in Houston. The appeals court disagreed, however, noting the Texas Higher Education Board was created to “benefit the citizens of the state in terms of the realization of the benefits of an educated populace.”

The sixth Clark factor weighed against finding the Center to be an arm of the state because while it appeared under state law that the Center was not authorized to sue or be sued, relator nevertheless identified several cases in which this was not the case.

The appeals court held, however, because five of the six Clark factors weighed in favor of finding the Center to be an arm of the state, the Center was not a “person” under the FCA and therefore not subject to qui tam liability.

Finally, as the Center was an arm of the state, sovereign immunity barred realtor’s claim for monetary relief under the FCA’s anti-retaliation provision. The appeals court therefore affirmed the district court’s decision on both issues.

U.S. Court in District of Columbia Tosses FCA Action Alleging Hospital Submitted False Claims for Anesthesia Services

A federal district court in the District of Columbia granted November 23 summary judgment to George Washington University (GWU) in a False Claims Act (FCA) qui tam action alleging it submitted claims to Medicare for anesthesia procedures that falsely represented the services were performed by anesthesiologists when in fact the services were provided by certified registered nurse anesthesiologists (CRNAs).

The U.S. District Court for the District of Columbia decision resolved the 18-year action, which was initiated by four CRNAs formerly employed by GWU, Sheila El-Amin, Joyce B. Lasley, Katherine Linden, and Robert A. Roubik. The government opted not to intervene in the case.

The court in its latest opinion recounted the long procedural history of the case, which ultimately whittled down relators’ action to 21 alleged false claims. In August, the court found the 21 remaining alleged false claims also were not supported by admissible evidence that could establish an FCA violation.

Given these rulings, “the Court has little difficulty in concluding that GWU is ultimately entitled to summary judgment,” the opinion said.

“As the factual background tracing the slow narrowing of this case shows, Relators have not provided any evidence that would be admissible at trial to prove their allegations as to the 2,579 medical procedures for which they assert GWU knowingly submitted a false claim,” the court added.


Eighth Circuit Affirms Dismissal of FCA Action Alleging Non-Compliance with Direct Supervision Requirement

The Eighth Circuit affirmed January 9, albeit on different grounds, a district court’s dismissal of a False Claims Act whistleblower action alleging a hospital and related entities defrauded Medicare by failing to provide direct physician supervision of cardiac and pulmonary rehabilitation services as required by applicable regulations.


The appeals court agreed the complaint was properly dismissed, but based its decision on a finding that the relator failed to satisfy the particularity requirements of Fed. R. Civ. P. 9(b).

Relator Michael Dunn was an administrator for an independent cardiology physician group that provided services at North Memorial. In his qui tam action, Dunn alleged North Memorial failed to meet statutory and regulatory physician requirements and, instead, relied on non-physicians for its cardiac and pulmonary rehabilitation programs.

The appeals court found the complaint deficient because it failed to identify even a single false claim submitted to the government for payment.
“Dunn may not simply rely on the generalized conclusion that North Memorial engaged in noncompliant conduct, and in doing so, caused thousands of instances of fraudulent billing,” the appeals court commented.

“Instead, Dunn ‘must provide some representative examples of [North Memorial’s] fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors,’” the appeals court said.


**U.S. Court in Illinois Dismisses Whistleblower Action for Failure to Show Submission of “Ready to Bill” Claims**

A federal district court in Illinois dismissed February 4, with leave to amend, a False Claims Act (FCA) qui tam action alleging a health care company submitted “error-ridden, time-barred claims” to the government for reimbursement.

The U.S. District Court for the Central District of Illinois found the relator failed to plead the OSF Health Care System (OSF) actually submitted any of the claims for durable medical equipment (DME) to Medicare and Medicaid for reimbursement, even if they were marked as “ready to bill.”

The court also dismissed claims alleging the submission of fraudulent claims for home health services performed at facilities ineligible for Medicare and/or Medicaid. According to the court, relator Gail McGinnis failed to allege why the home health services claims “could be deemed false.”

Relator worked as the Director of Reimbursement at OSF Home Care Services from March 211 until July 2011. According to the complaint, OSF operates four separate service channels—hospice, home health services, DME, and pharmacy infusion. Relator alleged each OSF agency has its own provider number and that some are eligible for Medicare and Medicaid reimbursement while others are not.

Relator essentially alleged two schemes—that OSF knowingly submitted DME claims containing a 70% to 75% error rate to the government for payment and that OSF submitted home health services claims as if they were provided at a Medicare or Medicaid eligible facility, when in fact they were performed at other ineligible facilities.

As to the DME claims, the court held relator failed to allege OSF actually submitted any of the claims for reimbursement. According to the court, relator alleged over 9,000 claims were marked as “ready to bill,” but either were untimely or included significant errors or omissions such as statements of medical necessity, physician orders, diagnoses, physician names, modifiers, non-billable items, and insurance validation.

The court refused to equate, however, “ready to bill” with “billed” or “already billed.” In the court’s view, “ready to bill” actually indicated the opposite inference—i.e., that they were not actually billed.

The court also refused to relax the pleading requirements because the relator in this case allegedly “was deeply involved in OSF’s billing” and should have had access to billing and reimbursement procedures.

Moreover, the court said, relator “has not even clearly explained why the DME claims are false or fraudulent in the first place.”
The court likewise dismissed relator’s complaint as to the home health service claims as factually deficient. The complaint “sheds no light on why the location of a facility would even matter for the reimbursement of claims associated with health care rendered in homes,” the court observed.

Instead, the court “is left to speculate on how provider numbers are even relevant to the scheme,” the opinion said.

The court also dismissed relator’s conspiracy and FCA retaliation claims. As to the conspiracy claim, the court said relator failed to allege the existence of a co-conspirator or an agreement. The FCA retaliation claim failed because the complaint failed to show relator was engaged “in the furtherance of an FCA enforcement action.”

The court did allow relator’s claim under Illinois law that prohibits employer retaliation for refusing to participate in an activity that would violate state or federal law. Specifically, relator alleged he was constructively discharged for refusing to submit what he believed to be “error-ridden DME claims.” Critical to the survival of this claim, the court noted, was relator’s alleged belief that submitting the claims would be fraud, even if it actually was not.


**Fifth Circuit Says No Relator Share When Government Initiated Criminal Proceeding Before Qui Tam Action**

On February 14, the Fifth Circuit held under the False Claims Act (FCA), a qui tam action must be pending at the time the government elects to pursue an alternate remedy for the relator to claim a right to share in a multi-million dollar restitution award obtained by the government in a criminal proceeding.

In 2007, relators sent anonymous letters informing various government agencies of allegedly fraudulent claims being submitted by their employer—two physicians—to Medicare, Medicaid, and private insurance companies.

The U.S. government conducted a criminal investigation, and a federal grand jury indicted the physicians (defendants). Defendants pled guilty to conspiracy to commit health care fraud and mail fraud. At their sentencing hearing, the district court ordered defendants to pay over $43 million in restitution to Medicare, Medicaid, and certain private insurers.

Defendants appealed. The Fifth Circuit vacated the restitution order and remanded for a recalculation as the restitution amount exceeded the insurers’ actual losses.

While defendants’ criminal appeal was pending, relators filed a qui tam action in November 2011 under the federal FCA and the Texas FCA. The government and state of Texas declined to intervene. In May 2012, relators filed a motion to compel depositions from Department of Justice employees, asserting discovery about the relators’ share of the government’s restitution award was appropriate because the sole issue was whether the relators were entitled to a share of the criminal forfeiture obtained as an alternate remedy under 31 U.S.C. § 3730(c)(5).

The government filed a motion for partial summary judgment, arguing the relators were not entitled to a share as the government obtained restitution prior to relators filing their November 2011 FCA actions. The district court granted the government’s motion for partial summary judgment, which the court of appeals affirmed.
The appeals court held the district court properly interpreted the FCA to require a pending qui
tam action for another proceeding to constitute an alternate remedy under Section 3730(c)(5).
The appeals court stated that in order for a remedy to be an “alternate” to the qui tam
proceeding, “there must have been two proceedings from which [the government could]
choose.” In this case, there was no qui tam proceeding at the time the government elected to
pursue its criminal suit against the defendants.


**Fourth Circuit Rejects FCA Whistleblower Action Based on FDA Regulatory
Violation**

A violation of Food and Drug Administration (FDA) safety regulations that rendered a drug
“adulterated” could not, by itself, serve as the basis for a False Claims Act (FCA) whistleblower
action, the Fourth Circuit held February 21.

Affirming a district court ruling dismissing the complaint against Omnicare, Inc. and its affiliated
companies (collectively, Omnicare), the Fourth Circuit said to be a “covered outpatient drug”
under Medicare and Medicaid requires only FDA approval of the drug, not compliance with certain
packaging regulations.

Once a drug has FDA approval, a Medicare and Medicaid reimbursement claim is not rendered
“false” under the FCA “on the sole basis that the drug has been adulterated as a result of having
been processed in violation of FDA safety regulations,” the Fourth Circuit held.

**“Adulterated” Drugs**

Relator Barry Rostholder, a licensed pharmacist who worked for Omnicare’s Heartland Repack
Services, LLC, brought the qui tam action alleging Omnicare violated FDA safety regulations
requiring that penicillin and non-penicillin drugs be packaged in complete isolation from one
another.

Heartland is a repacking facility located in Toledo, OH. Heartland repacked non-penicillin drugs
for national distribution, but shared the Toledo facility with a pharmacy that processed penicillin,
according to the opinion.

Relator resigned from Heartland after raising concerns the facility was violating FDA penicillin
isolation requirements. Relator notified the FDA and a subsequent investigation resulted in the
agency issuing a warning letter to Omnicare.

The letter indicated Omnicare’s failure to adhere to the FDA’s Current Good Manufacturing
Practice (CGMPs) regulations caused the drugs to be “adulterated.”

According to the complaint, Omnicare disposed of nearly $19 million worth of inventory, but did
not issue any recalls or reimburse the government for amounts paid for the contaminated drugs.

Relator alleged the CGMP violations rendered the drugs at issue not in their FDA-approved form
and therefore ineligible for Medicare and Medicaid reimbursement.

The district court granted, however, Omnicare’s motion to dismiss, holding relator failed to allege
Omnicare made a false statement to the government or engaged in fraud.

**Regulatory Violation Alone Insufficient**
At the outset, the appeals court held the FCA public disclosure bar was inapplicable, finding the FCA complaint was not “based upon” the warning letter or regulatory filings, and that relator sufficiently alleged “direct and independent knowledge” of the allegations for original source status.

Turning to the merits, the appeals court noted “covered outpatient drugs,” for purposes of Medicare and Medicaid reimbursement, refers to those “approved for safety and effectiveness” under the Food, Drug, and Cosmetic Act.

According to the appeals court, once the drug at issue has FDA approval, a Medicare and Medicaid reimbursement claim is not rendered false simply because the drug was processed in violation of FDA safety regulations.

“Were we to accept relator’s theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct,” the appeals court wrote.

Likewise, Omnicare could not have “knowingly” submitted a false claim where Medicare and Medicaid do not prohibit reimbursement for drugs packaged in violation of the CGMPs, the appeals court reasoned.

Finally, the appeals court upheld the district court’s refusal to allow the relator to file a third amended complaint, noting doing so would be futile.


U.S. Court in Michigan Says Hospice Must Defend Allegations of False Claims

The U.S. District Court for the Middle District of Georgia denied February 21 a hospice provider’s motion to dismiss a qui tam complaint alleging it violated the False Claims Act (FCA) and the Anti-Kickback Statute (AKS).

According to the court, relator Chad Willis sufficiently pled false records and statements were made for the purpose of getting false claims approved, and Willis’ allegations “have the indicia of reliability to excuse any failure to allege with particularity the details of Medicare payments” received by the hospice.

Defendant Angels of Hope Hospice, Inc. (Angels) is a Medicare-certified hospice provider offering services in a number of counties in Georgia. It is operated by Steven Frederick and his wife. The relator was employed by Angels from August 2010 to April 2011.

Willis alleged Angels’ business model was based on continuous admissions of new hospice Medicare beneficiaries, referred to as “undupes.” These were persons who had never previously elected hospice care, which would then represent a “full [Medicare payment] aggregate ‘cap’ cushion to Angels,” because only those persons who had previously elected hospice care were calculated into the aggregate cap on total reimbursable payments to hospice providers for all of its Medicare patients in a given year, Willis alleged.

Generally, all excess Medicare payments would have to be returned, but bringing in “undupes” before Angels’ aggregate cap was determined would allow Angels to avoid repayment, Willis said.

Further, Willis alleged he was told by Frederick that non-Medicare patients, including indigents and those with private insurance, were not admitted, and Medicare patients were admitted,
regardless of eligibility, so long as they had not previously elected hospice care. Additionally, Willis alleged staff “frequently manipulated records to create an appearance that patients were terminally ill when they were not.”

Angels moved to dismiss the suit, arguing Willis could not show Angels actually submitted a false claim to the government. The court determined that Willis’ false presentment claim did not require dismissal because the “allegations in large part [were] based upon the recorded conversations of Angels’ employees.” Although Willis would be required to prove his allegations, at this stage of the case, they were sufficiently detailed to withstand a motion to dismiss, the court found.

Angels also argued Willis “failed to allege with particularity the fraudulent schemes on which he base[d]” his claims, including failing to show the patients he based his claims on were, in fact, ineligible for hospice care. But the court found this argument unconvincing based on accounts from hospital staff that patients did not exhibit symptoms that would make them hospice eligible and information that staff were told to fabricate symptoms for patients to qualify.

The court also found Willis sufficiently alleged patients were coerced into revoking hospice elections and certain individuals were paid remuneration to induce referrals to Angels.

Finally, the court determined, to the contrary of Angels’ argument, that Willis sufficiently alleged the “cap cushion” scheme to avoid or decrease its obligation to repay Medicare formed the basis for a reverse false claim.


U.S. Court in Maryland Tosses Whistleblower Action Second Time Around, Finds Pleadings Still Deficient

A federal district court in Maryland dismissed March 21 a whistleblower’s second amended complaint against a pharmaceutical manufacturer, alleging illegal off-label promotion and the payment of kickback to physicians again failed to allege the actual submission of a false claim to the government for payment.

In a March 2013 decision, the U.S. District Court for the District of Maryland dismissed the action without prejudice under Fed. R. Civ. P. 9(b) as interpreted by the Fourth Circuit in Nathan v. Takeda Pharmaceuticals North America, Inc., No. 11-2077 (4th Cir. Jan. 11, 2013).

The second amended complaint added allegations that nine patients who had federal health care insurance received “off-label” prescriptions, including for refills, from two physicians. But the court found the complaint still fell short of “alleging the presentment of an actual false claim for reimbursement that was submitted to the government.”

Under Nathan, a court may not infer the submission of a false claim to the government based solely on the fact that a patient with federal insurance received an off-label prescription. The patient may not have filled the prescription, may have paid for it out of pocket, or used private insurance, the court observed.

Off-Label Marketing

Jerome Palmieri filed the whistleblower action against Alpharma Pharmaceuticals Inc., Alpharma Pharmaceuticals, LLC, King Pharmaceuticals, Inc., and Pfizer, Inc. (collectively, defendants) on behalf of the federal government and various individual states. Palmieri is a sales representative for Alpharma (and later, King and Pfizer) who marketed defendants’ pain medications, including
Flector Patch, a topical application of a non-steroidal anti-inflammatory approved by the Food and Drug Administration (FDA) to treat acute pain due to minor strains, sprains, and contusions for up to 14 days.

Palmieri alleged defendants unlawfully marketed the Flector Patch for off-label uses, including the treatment of chronic pain over longer periods than 14 days. He also alleged the illegal scheme involved violations of the Anti-Kickback Statute. According to Palmieri, defendants caused off-label prescriptions for Flector Patch to be submitted for reimbursement to federal and state healthcare programs. The federal and state governments declined to intervene in the action.

The court granted defendants’ motion to dismiss the complaint under Rule 9(b), but granted relator leave to amend.

Second Amended Complaint Deficient

The second time around the court found the amended complaint still failed to meet the heightened pleading requirements under Fourth Circuit precedent.

In the initial complaint, the issue of presentment rested on the inference that the total volume of Flector Patch prescriptions submitted to Medicare and Medicaid and the amounts of money reimbursed for those prescriptions suggested at least some of them must have resulted from defendants’ alleged off-label promotion scheme.

In its March 2013, the court found such an inference was not permitted under Nathan.

The court acknowledged some federal circuits have adopted a more lenient pleading standard, allowing a qui tam action to go forward in some instances based on “inferences” of fraud. But the Fourth Circuit soundly rejected that approach in Nathan, the court said.

“The Nathan court plainly indicated that, when allegations concerning Medicare patients ‘do not identify with particularity any claims that would trigger liability under the [FCA,]’ the court is ‘unable’ to infer either that the prescription was filled or that a claim for reimbursement was submitted to a government-funded health care program."

For example, the court said, the Medicare patients who received the allegedly “off-label” prescriptions may have been in the so-called “donut hole” or coverage gap for their Part D coverage. Thus, without evidence a claim was submitted to Medicare for the prescription, the court could not draw the inference that it was.

Relator did not ask for further leave to amend the federal FCA claim, but did request the state FCA claims be dismissed without prejudice. The court agreed, noting they could be viable under a more lenient standard if applicable.


U.S. Supreme Court Declines Review of Decision Requiring FCA Pleadings Allege Actual Submission of False Claims

The U.S. Supreme Court declined to review March 31 a Fourth Circuit decision that held pleadings in a False Claims Act (FCA) whistleblower action must allege the submission of actual false claims to the government for reimbursement to survive a motion to dismiss based on Fed. R. Civ. P. 9(b).
In January 2013, the Fourth Circuit upheld a district court’s decision to dismiss a qui tam action under the FCA in a case involving off-label marketing allegations against a pharmaceutical company. Nathan v. Takeda Pharmaceuticals North America, Inc., No. 11-2077 (4th Cir. Jan. 11, 2013).

Relator in the case was a sales manager for Takeda Pharmaceuticals (Takeda). Relator alleged Takeda’s marketing practices for Kapidex, a drug used to treat various gastric conditions, violated the FCA by causing false claims to be presented to the government for payment under Medicare. Relator alleged Takeda was marketing Kapidex for off-label uses and marketing high doses to treat conditions for which the Food and Drug Administration only approved a lower dose.

The district court dismissed relator’s amended complaint with prejudice because it failed to show false or fraudulent claims had been presented to the government for payment.

Relator argued he need only allege the “existence of a fraudulent scheme that supports the inference that false claims were presented to the government for payment.” Relator also contended “allegations of a fraudulent scheme, in the absence of an assertion that a specific false claim was presented . . . is a sufficient basis on which to plead a [fraud] claim . . . .”

The Fourth Circuit disagreed, stating liability under the FCA “attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme.”

While some federal circuits have adopted a more lenient pleading standing to allow a qui tam action to go forward based on “inferences” of fraud, the Fourth Circuit’s decision in Nathan requires a relator to plead “plausible allegations of presentment” to proceed.


U.S. Court in Massachusetts Allows Some Whistleblower Claims Alleging Off-Label Promotion

A federal district court refused to dismiss allegations in a qui tam action that Pfizer Inc. induced false claims for off-label, non-compendium uses of one of its drugs and by paying physicians kickbacks to prescribe the drug.

The U.S. District Court for the District of Massachusetts did dismiss other aspects of the complaint, which it found either failed to allege the falsity of claims for reimbursement of off-label prescriptions or did not meet the particularity requirement of Fed. R. Civ. P. 9(b).

Relators Alex Booker, a sales representative for Pfizer from June 1991 until he was terminated in January 2010, and Edmund Hebron, who also worked for Pfizer as a sales representative from January 1997 until he was terminated in June 2006, brought the qui tam action on behalf of the federal government, 25 states, and the District of Columbia under federal and state False Claims Acts (FCAs).

Relators alleged Pfizer fraudulent promoted Geodon (zipraisidone) and Pristiq (devsvenlafaxine) for off-label and non-compendium uses. Relators also claimed Pfizer paid physicians kickbacks so they would prescribe Geodon and Pristiq. In addition, relators contended Pfizer made false claims by avoiding its obligations under a 2009 Corporate Integrity Agreement (CIA) that it entered into in August 2009 to resolve false claims liability from a similar off-label promotion scheme involving Geodon. Pfizer moved to dismiss.

No First-to-File, Public Disclosure Bar
As an initial matter, the court ruled neither the first-to-file provision nor public disclosure provision barred the action.

Pfizer argued two previous complaints, which were resolved by an August 2009 settlement, contained essentially the same allegations regarding Geodon. But relators argued the two complaints were no longer “pending” at the time the instant whistleblower complaint was filed in July 2010.

The weight of authority was in relators’ favor, the court said in refusing to dismiss the complaint based on the first-to-file provision.

The court also held the public disclosure provision did not bar the action even though the prior two complaints seemingly disclosed the same allegations regarding Pfizer’s promotion of Geodon.

While noting the two complaints publicly disclosed “substantially the same allegations,” the court found relators escaped the bar as “original sources” who alleged the fraud was perpetrated for a different time period—i.e., after the August 2009 settlement.

“Engaging in a scheme to defraud cannot immunize a fraudulent action from qui tam suits regarding related forms of fraud in perpetuity,” the court observed. Here, the complaint alleged relator Booker, who worked for Pfizer through January 2010, “obtained knowledge that Pfizer had continued or resumed its off-label promotion of Geodon even after the company’s August 2009 settlement with the government.” Thus, relators “plausibly allege that they have ‘knowledge that is independent of and materially adds to the publicly disclosed allegations’ of those prior complaints,” the court said.

**Falsity of Claims**

Relators alleged four ways in which Pfizer’s off-label promotion of Geodon and Pristiq prescriptions induced the submission of false claims.

The court found relators were successful in two ways—with respect to their federal FCA claims, that the off-label promotion caused the submission of false claims for reimbursement of prescriptions for off-label, non-compendium Geodon or Pristiq uses and that Pfizer allegedly paid kickbacks to physicians to prescribe the two drugs.

The court did reject relators’ state FCA claims based on prescriptions for off-label, not compendium uses, noting some states permit reimbursement for such uses.

**Particularity**

Turning to its Rule 9(b) analysis, the court commented that the “complaint in many ways tests the limits of the ‘more flexible standard’ applied to allegations that a defendant induced third parties to file false claims.”

The court ultimately found relators pled with sufficient particularity allegations that Pfizer caused the filing of reimbursement claims for off-label prescriptions of Geodon to children and adolescents, for bipolar maintenance, and at excessive dosages.

“They have done so through the combination of particular alleged claims for reimbursement and allegations of off-label prescriptions by physicians with substantial (as much as 80%) Medicare/Medicaid patient populations,” the court said.

The court also held relators alleged with sufficient particularity a kickback scheme resulting in the submission of false claims.
The court rejected relators’ remaining allegations involving Geodon and Pristiq as insufficient under Rule 9(b).

**“Reverse” False Claims, Retaliation**

The court rejected relator’s allegation that Pfizer made “reverse” false claims by failing to comply with the CIA because the agreement did not impose on the company an “obligation” to pay the government.

Finally, the court agreed that relator Booker could proceed with his FCA retaliation claim, finding he reported more than mere regulatory failures, but also fraudulent conduct to encourage physicians to prescribe Geodon for off-label uses, adequately alleged Pfizer was aware of his activity, and his abrupt termination after years of positive job performance was sufficiently close in time to his protected activity.


**U.S. Court in Tennessee Holds FCA Public Disclosure Bar Applies to Claims Hospital Violated CIA**

On March 28, the U.S. District Court for the Eastern District of Tennessee dismissed with prejudice a relator’s qui tam complaint against a hospital because her allegations were based upon public disclosures of fraud in which substantial identity existed between the previously disclosed allegations or transactions and her qui tam suit. The court also found she was not an original source.

Relator Lisa Stratienko filed a qui tam action against defendant Chattanooga-Hamilton County Hospital Authority, d/b/a Erlanger Medical Center (Erlanger), in November 2010 alleging Erlanger violated its Corporate Integrity Agreement (CIA) (Count I), presented false claims in violation of the False Claims Act (FCA) (Count II), and made or used a false record or statement to cause a claim to be paid in violation of the FCA (Count III). The federal government declined to intervene.

The court previously dismissed Counts II and III based on the FCA’s public disclosure bar but gave relator leave to amend Count I. Relator’s amended complaint alleged Erlanger failed to report it entered into financial arrangements “in the absence of contemporaneously executed written contracts” with physicians, which constituted a material breach of the CIA. Relator also alleged Erlanger submitted claims for inpatient and outpatient hospital services provide to patients referred by certain teaching physicians and others. Erlanger moved to dismiss.

Granting the motion, with prejudice, the court concluded various public disclosures, including litigation materials from relator’s husband’s state court suit five years earlier that alleged Erlanger’s fraudulent activities from 1995-2003; a draft FCA complaint that the government used in settling the husband’s claim with Erlanger; and media attention about the case through two local newspapers were sufficient to put the government on notice about relator’s instant FCA allegations even though the government’s knowledge pertained to events that occurred at a different time and involved a different set of physicians.

The court explained that even though the details were not the same, relator’s allegations followed the same general pattern (i.e., Erlanger allegedly paying for services in the absence of executed written contracts and physicians referring patients to Erlanger) such that the public disclosures were sufficient to put the government on notice.
The court also concluded relator’s amended Count I action was based upon public disclosures of fraud as it derived from the same kind of conduct alleged in Counts II and III, which were dismissed because they also were based upon public disclosures.

Relator argued Count I of her second amended complaint was not based upon public disclosures as they did not disclose certain details, such as the existence of any “withheld reportable events,” overpayments to Erlanger by federal health care programs, Erlanger’s failure to repay overpayments, and Erlanger’s submission of false CIA certifications. The court disagreed, holding the essence of relator’s Count I allegations were based upon previously disclosed information.

Finally, the court held relator failed to establish she was an original source of the information and noted most if not all of her information appeared to come from her husband’s suit against Erlanger five years prior, which was covered extensively by the media.


**U.S. Court in Illinois Refuses to Dismiss Whistleblower Action Against Omnicare Alleging Illegal Inducements**

A federal district court in Illinois said April 14 a relator could proceed with the bulk of his allegations in a False Claims Act (FCA) whistleblower action that long term care pharmacy Omnicare Inc. submitted false claims by violating federal and Illinois anti-kickback statutes.

According to the U.S. District Court for the Northern District of Illinois, relator Alan J. Litwiller, who has worked for Omnicare since 1997, sufficiently pled the national pharmacy provider “knowingly set upon a course to develop and implement schemes for the purpose of inducing continued business from facilities” in violation of the anti-kickback statutes to survive a Fed. R. Civ. P. 12(b)(6) motion to dismiss.

The court also refused to dismiss relator’s complaint under Fed. R. Civ. P. 9(b). The court said allegations Omnicare submitted claim forms to Medicaid, which required certification of anti-kickback statute compliance, on a daily basis in Illinois between January 2009 and December 2011 was enough to avoid dismissal under Rule 9(b).

Relator alleged Omnicare, one of the nation’s largest providers of pharmaceutical products and services to various types of long term care facilities, engaged in a series of schemes to offer and pay illegal inducements to these facilities, including “forgiveness of accounts receivables,” “improper discounts for pharmaceutical services,” “improper refunds and credits,” “discounts and subsidies for third party services,” “free consulting and other services,” and using the “Omnicare Foundation” to make indirect payments to the owners of nursing facilities.

In seeking reimbursement from Medicaid for products and services purchased by these facilities as a result of the allegedly illegal inducements, Omnicare certified compliance with federal and state anti-kickback statutes rendering each claim false in violation of the FCA, according to the relator. The federal government and state of Illinois declined to intervene in the whistleblower action.

Omnicare moved to dismiss. The court agreed on two points—that the FCA first-to-file provision barred the allegations related to the accounts-receivable conduct and that the FCA public disclosure provision barred the allegations related to improper discounts for pharmaceutical services.

As to the improper discounts allegations, the court said relator could amend his complaint to show he was an “original source” of the publicly disclosed allegations.
As to the remaining allegations, the court found “Relator, a longtime employee of Omnicare, has laid out the schemes in detail and identified at least some of the major players on Omnicare’s end as well as the facilities that were allegedly offered remuneration in exchange for business.”

The court characterized Omnicare’s challenges as “more appropriate at the proof stage, when Relator will have to demonstrate—not merely allege—that the facilities at issue did not pay the fair market value for services and goods but instead received substantial discounts or credits in exchange for continuing to do business with Omnicare.”

Finally, the court refused to dismiss the complaint for failing to meet the Rule 9(b) pleading standard, noting “Relator has alleged that Omnicare submitted false claims daily from its offices in Illinois between January 2009 and December 2011 and explained the practice by which it was done, how and when payment was received, and why the claim was false.”


U.S. Court in New Jersey Rejects Whistleblower Action Against Bayer Alleging “Misbranding” of Drug Violated FCA

A federal court in New Jersey dismissed, without prejudice, a qui tam action under the False Claims Act (FCA) alleging a pharmaceutical manufacturer illegally promoted one of its drugs for off-label uses rendering the drug “misbranded” under the Food Drug and Cosmetic Act (FDCA).

The U.S. District Court for the District of New Jersey granted a motion to dismiss relator Laurie Simpson’s eighth amended complaint to defendants—Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare LLC (collectively, Bayer).

According to the court, Simpson’s action, which was brought under the federal FCA and the FCAs of 21 states and the District of Columbia, was based on an “implied false certification” theory of liability. The complaint’s major deficiency, the court found, was Simpson’s failure to show the misbranding provisions of the FDCA were a condition of payment for federal health care programs and therefore the existence of a false or fraudulent claim for payment.

Simpson, who worked for Bayer from April 1998 until January 2005, helped market its drug Trasylol, which the Food and Drug Administration (FDA) approved for patients undergoing coronary artery bypass graft surgery using a cardiopulmonary bypass pump to prevent excess bleeding. According to Simpson, Bayer marketed the drug, however, for a host of other non-FDA approved uses.

The court grouped Simpson’s 30 causes of action into three categories: allegations that Bayer’s misbranding of Trasylol resulted in the submission of false claims to the federal government, caused health care providers to submit false claims to the federal government, and violated various state FCAs.

As to the first two categories, the court found the complaint lacking because it failed to allege compliance with the misbranding provisions of the FDCA was a condition of payment under Medicare, Medicaid, or other federal health care programs.

With respect to Medicare specifically, the court noted a false certification of compliance with the Medicare statute can arise where a reimbursement claim is submitted for a drug that is not “reasonable and necessary for the diagnosis or treatment of illness or injury. . . .” 42 U.S.C. § 1395y(a)(1)(A).
While Simpson alleged each of the major drug compendia did not support the off label uses of Trasylol that Bayer promoted, the court said it could not reasonably infer that to be the case from the complaint’s lack of specificity as to which particular off-label uses were unsupported.

The court also agreed to dismiss Simpson’s claims under the state and District of Columbia FCAs based on a procedural defect—the fact that the various jurisdictions failed to notify the court individually of their decision not to intervene in the action.

Finally, the court said any of Simpson’s claims based on Trasylol-related violations occurring on or after August 5, 1999, and any claims based on alleged violations related to another drug Avelox occurring on or after July 24, 2000, were time-barred under the FCA’s applicable six-year statute of limitations.

The court said Simpson could submit another amended complaint but only if it alleged the existence of a condition of payment from the government, added allegations concerning the drug compendia, and removed time-barred allegations.


**U.S. Court in Virginia Dismisses Qui Tam Action Involving Health System’s Concierge Services**

A federal district court in Virginia dismissed April 14 a relator’s qui tam action alleging a health system violated the False Claims Act (FCA) through its “concierge program” offered to referring physicians.

The U.S. District Court for the Eastern District of Virginia found the relator, John Rector, who formerly worked as a “concierge” for Bon Secours Health System, Inc., failed to allege his FCA allegations with sufficient particularity.

The court said the complaint did not allege the submission of an actual false claim and therefore failed to meet the strict Fed. R. Civ. P. 9(b) pleading standard as interpreted by the Fourth Circuit. See *United States ex rel. Nathan v. Takeda Pharm. N. Am.*, Inc. 707 F.3d 451 (4th Cir. 2013).

According to the opinion, Bon Secours implemented the concierge program in 2006 at its various affiliates. Under the program, Bon Secours hired patient-physician practice liaisons—so called “concierges”—to provide services to physicians who referred patients to its hospital for diagnostic tests including scheduling, obtaining insurance pre-authorizations, communicating with patients and testing facilities, collecting patient copayments and deductibles, and performing other tasks as requested.

Rector, who started working for Bon Secours as a concierge in 2007 until he was fired in 2010, alleged concierges were instructed to use internal manuals and “cheat sheets” to enter medical coding when physicians failed to submit complete forms to the program even though the concierges were not qualified to do so.

Rector also contended Bon Secours directed its concierges to “cut and paste” physicians’ signatures from past orders if they failed to include them on a patient or order form. According to Rector, Bon Secours also systematically completed missing portions of physicians’ orders and other documentation that physician offices are required to complete.

Finally, Rector alleged Bon Secours assigned “onsite” concierges to work full time in “high-volume” referring physicians’ offices. These onsite concierges provided services that otherwise physicians would have to hire and pay staff to perform.
Relator estimated roughly half of the patients referred through the Bon Secours concierge department to its diagnostic and therapeutic facilities are Medicare patients and roughly a quarter are Medicaid patients.

Bon Secours terminated Rector in January 2010 for insubordination. One year later, Rector filed the instant qui tam action in which the federal government and Commonwealth of Virginia declined to intervene. Rector alleged violations of the FCA, Anti-Kickback Statute (AKS), and Stark Law, among other claims.

According to the court, Rector’s primary evidence to show that false claims were submitted to the government for payment was a patient log he created while working as a concierge for Bon Secours. In particular, Rector noted at least some of the patient’s on the log were Medicare or Medicaid beneficiaries.

Citing Nathan, the court said the patient log, by itself, was not enough to satisfy the heightened pleading standard of Rule 9(b).

Rector failed “to provide any billing information such as copies of a single actual bill or claim or payment, amounts of any charges, actual dates of claims, policies about billing or even second hand information about billing practices,” the court noted.

Given its finding that Rector failed to plead fraud with particularity, the court declined to address the merits of his AKS and Stark Law claims.

Rector also attempted to argue FCA liability could be premised on the fact that Bon Secours falsely certified compliance with Medicare requirements on its initial program enrollment form. “Multiple courts have held that CMS enrollment applications cannot serve as the basis for an FCA claim based on AKS allegations,” the opinion said.

The court also dismissed Rector’s FCA retaliation claim, finding little indication Bon Secours would have reasonably believed his complaints about “shoddy or suspicious business practices” were in furtherance of an FCA action or a related internal report.

The court dismissed Rector’s remaining claims but agreed he could file an amended complaint to address the pleading deficiencies.


First Circuit Finds FCA Claims Barred by First-to-File Rule

The First Circuit affirmed May 2 a lower court’s dismissal of certain False Claims Act (FCA) claims as barred by the FCA’s first-to-file rule. In so holding, the appeals court agreed the “essential facts” of the later-filed claim were identical to those in a suit previously filed.

Relator Michael A. Wilson, a former Bristol-Myers Squibb, Co. (BMS) sales representative, alleged in his first complaint that BMS violated the Anti-Kickback Statute and engaged in off-label promotion of its drugs Monopril, Plavix, and Pravachol, and that these actions caused false claims to be submitted to the government in violation of the FCA.

After the settlement of some of the claims, Wilson filed a second amended complaint containing the unsettled claims and adding Sanofi-Aventis U.S., LLC as a defendant. The complaint alleged BMS engaged in schemes to promote Plavix, Pravachol, and Monopril for certain off-label uses, and that Sanofi participated in those schemes that related to the promotion of Plavix only.
The district court denied Wilson leave to amend to file a third amended complaint and then dismissed the FCA claims relating to Plavix and Pravachol for lack of subject matter jurisdiction because they violated the FCA's first-to-file rule.

The court’s dismissal on first-to-file grounds was based on two complaints that were filed before Wilson filed his original complaint in September 2006, according to the opinion. On May 4, 2006, Daniel C. Richardson, a Senior District Business Manager for BMS, filed a complaint alleging BMS and Sanofi engaged in broad, nationwide schemes to promote and prescribe Plavix and Pravachol for off-label uses, the court noted.

A second relevant complaint was filed by Joseph Piacentile on June 7, 2005 against Sanofi. That complaint alleged Sanofi paid illegal kickbacks to physicians to push them to prescribe Plavix for certain off-label uses.

Using the "essential facts" test, the district court concluded "Wilson's complaint d[id] not alert the government to a new type of fraudulent scheme or even new aspects of an existing scheme allegedly being perpetrated by the defendants." The court therefore found the action was barred by the FCA's first-to-file rule.

The appeals court noted the differences between the first-filed Richardson complaint and Wilson’s complaint—the Richardson complaint referred to promotion of off-label uses of the two same drugs, but tied to certain diseases and symptoms, while Wilson’s complaint referred to promotion of off-label uses for different diseases and symptoms—“are not enough to reasonably conclude the earlier Richardson Complaint was not a related claim to the government based on the facts.”

The appeals court also affirmed the lower court’s refusal to allow Wilson to amend.


**U.S. Court in Florida Finds Lab’s Provision of Free Test Cups Constitutes Remuneration Where Physicians Could Not Bill for Them**

The U.S. District Court for the Middle District of Florida held May 5 that a laboratory’s provision of free point-of-care testing (POCT) cups to physicians could constitute prohibited remuneration under the Stark Law and Anti-Kickback Statute (AKS) under certain circumstances.

The court also found inapplicable the Stark Law exceptions to remuneration for the provision of items used solely to collect, transport, process, or store specimens for the entity providing the item and for items used solely to communicate the results of tests for the entity providing the item.

According to the court, the POCT cups included POC strips inside them that provide immediate preliminary results of the presence of certain drugs in patients’ urine and therefore were not used "solely" for collection or transportation purposes.

Based on the court's interpretation, “if the provision of the free device provides any additional benefit to the doctor, the device will not fall within the exceptions to the definition of remuneration.”

The underlying case involves a lawsuit for unfair competition brought by plaintiff Ameritox, a clinical laboratory that engages in screening urine specimens for the presence of drugs, against its competitor, defendant Millennium Laboratories.
Ameritox contended Millennium’s provision of free POCT cups to physicians who agree not to bill for the POC tests violates the AKS and the Stark Law, which Ameritox argued would form a basis for liability under its unfair competition claims.

Ameritox moved for partial summary judgment on the issue of whether Millennium’s provision of free POCT cups to physicians violates the AKS or Stark.

The court first addressed whether the provision of the free cups constituted remuneration under the Stark.

The court found a genuine issue of material fact precluding summary judgment as to whether the provision of free POCT cups constitutes remuneration where the physicians could bill for the POC testing done using a POCT cup but decline to do so because they agreed not to bill for the POC testing.

“[I]n such a situation, it appears that the doctors are giving up the ability to bill for POC testing, which is giving up the opportunity to net approximately $15 per specimen.” In this scenario, a jury must decide whether the free PCOT cups constitute remuneration.

To the extent physicians could not bill for the POC testing done using a POCT cup, however, “then Millennium’s provision of free POCT cups did provide a valuable benefit to the doctors in the form of the free preliminary test results that the doctors could not have obtained without purchasing a POCT cup,” the court noted.

“[I]n this situation,” the court said, “Millennium’s provision of free POCT cups constitutes remuneration under the Stark Law,” the court concluded.

The court found, under the same scenario, the provision of the free POCT cups could constitute remuneration under the AKS.

Thus, the court granted summary judgment to Ameritox to the extent it concluded the provision of free POCT cups constituted remuneration under Stark and the AKS where the physicians could not bill for the POC testing done using a POCT cup, but denied summary judgment when physicians could bill for the testing but agreed not to do so.


**Healthcare Reform**

**Fourth Circuit Refuses to Strike ACA Employer Mandate**

In a unanimous panel decision, the Fourth Circuit rejected July 11 a challenge to the employer mandate under the Affordable Care Act (ACA), finding the provision does not violate the Commerce Clause.

Under the employer mandate, “applicable large employers”—those with 50 or more full-time employees—may be required to make an “assessable payment” if they fail to provide affordable coverage to their full-time workers. The employer mandate was slated to go into effect in 2014, but the administration recently delayed the requirement until 2015. See related *item* in this issue.

Liberty University, a private Christian university in Virginia, along with two individuals, challenged the penalty provisions of the individual and employer mandates of the ACA, arguing
they were not a valid exercise of Congress' powers under the Commerce Clause and Necessary and Proper Clause.

In addition to these arguments, Liberty contended the mandates violate their religious freedom and equal protection.

The district court upheld the mandates. On appeal, the Fourth Circuit did not reach the merits of the case and instead ruled the Anti-Injunction Act (AIA) stripped the court of jurisdiction because the case was a pre-enforcement action seeking to restrain the assessment of a tax. *Liberty Univ., Inc. v. Geithner*, No. 10-2347 (4th Cir. Sept. 8, 2011).

Following its ruling in *National Federation of Independent Business v. Sebelius (NFIB)*, 132 S.Ct. 2566 (2012), which found the AIA did not preclude review of the ACA’s individual mandate, the U.S. Supreme Court vacated the Fourth Circuit decision and remanded to the appeals court for further consideration of the issues presented in the case. A majority of the Court found the individual mandate violated the Commerce Clause, but upheld the provision as a valid exercise of Congress’ tax power.

As a threshold matter, the appeals court determined Liberty had standing to assert its challenge because it alleged the employer mandate’s "burdensome regulations“ would increase the cost of providing healthcare coverage to its employees.

Liberty argued the employer mandate violates the Commerce Clause because it "compel[s] employers to engage in particular conduct or purchase an unwanted product,” contrary to *NFIB*.

But the appeals court disagreed, holding the employer mandate “is simply another example of Congress’s longstanding authority to regulate employee compensation offered and paid for by employers in interstate commerce.”

Unlike the individual mandate, the appeals court said, “the employer mandate does not seek to create commerce in order to regulate it.” Rather, “all employers are, by their very nature, engaged in economic activity.” Thus, the employer mandate does not compel them to engage in commerce; it merely regulates the existing commercial activity of employee compensation.

The employer mandate is a valid exercise of Congress’ Commerce Clause power, the appeals court observed, noting a long history of regulating the terms of employment that substantially affect interstate commerce. Health insurance is provided as part of employee compensation and has a substantial impact on interstate commerce, the appeals court reasoned.

“Requiring employers to offer their employees a certain level of compensation through health insurance coverage is akin to requiring employers to pay their workers a minimum wage,” the appeals court said.

Citing *NFIB*, the Fourth Circuit alternatively determined the employer mandate is a valid exercise of Congress’ taxing authority because it will produce some revenue for the government and has other hallmarks of tax.

Finally, the appeals court rejected plaintiffs’ religious-based challenges.


On December 2, 2014, the U.S. Supreme Court declined to review the Fourth Circuit decision.
Liberty petitioned for Supreme Court review on September 5. In a statement following the Court’s decision not to hear the case, Liberty Counsel, which represents the plaintiffs in the challenge, said “denial of review does not result in an opinion on the merits.”

According to the statement, the “Court could take up a similar challenge if a federal court of appeals strikes down the entire employer mandate, although no such challenge is currently pending.”

Liberty Counsel noted its case also challenged the contraceptive mandate, an issue the Court recently did agree to review.

“The High Court has decided to take up the HHS contraception and abortion drug mandate, but it is not ready yet to tackle the entire employer mandate. That challenge will wait for another day,” said Mat Staver, Founder and Chairman of Liberty Counsel.

“The Liberty University case would make strong arguments that the employer mandate could not be upheld as a tax because the penalties are exorbitantly high and punitive. Deciding the case would have highlighted the absurdity of the Supreme Court’s convoluted decision upholding the individual mandate as a tax,” he added.

Stayer said Liberty “will wait on the Court’s ruling next year to decide whether to file a new challenge.”


**U.S. Court in DC Tosses Challenge to IRS Rule Providing Subsidies Through Federal Exchange**

A federal trial court judge in the District of Columbia granted summary judgment to the government in a lawsuit alleging an Internal Revenue Service (IRS) final rule that allows individuals who purchase insurance through the federally facilitated exchanges to qualify for premium tax credits is contrary to the text of the Affordable Care Act (ACA), see 26 U.S.C. § 36B.

The lawsuit was filed May 2, 2013 in the U.S. District Court for the District of Columbia by individuals and several small businesses. *Halbig v. Sebelius*, No. 1:2013cv00623 (D.D.C. filed May 2, 2013). The lawsuit sought a declaratory judgment that the IRS rule is illegal under the Administrative Procedure Act (APA).

In October 2013, U.S. District Court Judge Paul L. Friedman refused to dismiss the action but also denied plaintiffs a preliminary injunction.

On cross-motions for summary judgment, however, Friedman found the government won the day.

Plaintiffs argued the plain text of the ACA indicates the tax credits should apply only to individuals enrolled in state-run exchanges, not those participating in the federally operated exchanges. Specifically, the statute provides that an individual’s tax credit is determined based on the cost of insurance purchased on “an Exchange established by the State.” According to plaintiffs, the subsidies were set up this way to incentivize states to run their own marketplaces rather than leave their operation to the federal government.

The government contended, however, that under the ACA “the federal government stands in the shoes of the Exchange that a state chooses not to establish” so the IRS reasonably interpreted
the law as extending the tax credits to individuals in every state regardless of the entity operating the exchange.

Judge Friedman agreed the plain language of the provision at issue appeared to support plaintiffs’ interpretation. In applying a *Chevron* analysis, however, the reviewing court should not consider a statutory provision in isolation, Friedman added. And when viewing the provision in the context of the ACA as a whole, Judge Friedman found plaintiffs’ interpretation clearly at odds with the remainder of the statute.

Other provisions of the ACA clearly reflect congressional intent to make tax credits nationally available regardless of whether the federal government or the state established the exchange, he said. In particular, Friedman pointed to the provisions establishing advance payment reporting requirements and requirements for “qualified individuals” who could purchase coverage through the exchanges.

In Judge Friedman’s view, if Congress intended the subsidies to be available only in state-based exchanges, these provisions also would not apply to the federal exchange, leading to absurd results.

Moreover, he wrote, plaintiffs’ interpretation conflicted with the purpose of the ACA—to expand access to affordable coverage.

Judge Friedman discounted plaintiffs’ argument that Congress intended to incentivize states to operate their own exchanges with the lure of federal subsidies for their residents. The problem with this argument, Friedman reasoned, is that there was no evidence Congress sought to compel states to operate their own exchanges. Instead, according to the Friedman, the legislative history indicated the opposite—i.e., that Congress was more interested in maximizing states’ flexibility regarding the exchanges.

For this reason, Friedman held Congress clearly expected the federal subsidies to be available on all the exchanges, whether run by the federal government or by the states.

In a January 15 statement, the Competitive Enterprise Institute (CEI), which is coordinating the case, called the ruling “a major blow to the states that chose not to participate in the Obamacare insurance exchange program.” The statement said the decision has been appealed to the D.C. Circuit, and CEI will move for expedited appeal.


**U.S. Court in Virginia Upholds IRS Rule Providing Subsidies Through Federal Exchange**

A federal trial court judge in Virginia agreed February 18 to dismiss a lawsuit challenging an Internal Revenue Service (IRS) final rule that allows individuals who purchase insurance through the federally facilitated exchanges to qualify for premium tax credits.

In his decision upholding the rule, the U.S. District Court for the Eastern District of Virginia Judge James R. Spencer found the regulation, which extends the availability of federal subsidies beyond the state-based exchanges, was a reasonable interpretation of the Affordable Care Act (ACA).

Plaintiffs in both lawsuits argued the plain text of the ACA indicates the tax credits should apply only to individuals enrolled in state-run exchanges, not those participating in the federally operated exchanges.

Specifically, the statute provides an individual’s tax credit is determined based on the cost of insurance purchased on “an Exchange established by the State.” According to plaintiffs, the subsidies were set up this way to incentivize states to run their own marketplaces rather than leave their operation to the federal government. See 26 U.S.C. § 36B.

According to the lawsuits, in extending the subsidies beyond the state-run exchanges, the IRS exceeded its statutory authority in violation of the Administrative Procedure Act.

The government contended, however, that “Exchange” as used in the ACA refers to both those established by the states, and those run by the federal government.

Applying a Chevron analysis, Judge Spencer said plaintiffs’ interpretation of the statute was “implausible” when considering the statutory context.

As did the Halbig decision, Judge Spencer highlighted a number of “anomalous results” that would flow from plaintiffs’ construction of the statutory provision at issue.

Moreover, Spencer wrote, “there is no direct support in the legislative history of the ACA for Plaintiffs’ theory that Congress intended to condition federal funds on state participation.” Citing Halbig extensively in his analysis, Judge Spencer noted the legislative intent of the ACA “evidence[s] congressional intent to ensure broad access to affordable health coverage for all,” not to coerce the states into establishing their own exchanges.

Even assuming ambiguity in Section 36B, Judge Spencer said the IRS’ interpretation was reasonable and therefore should not be disturbed.

U.S. Court in Oklahoma Says State Has Standing to Challenge IRS Rule Extending Tax Credits Beyond State-Run Exchanges

The U.S. District Court for the District of Oklahoma held August 12 that the state of Oklahoma has standing as a large employer to challenge an Internal Revenue Service (IRS) rule that extends the Affordable Care Act’s (ACA’s) premium-assistance tax credits to individuals purchasing insurance in federally facilitated insurance exchanges.

The case, brought in January 2011 by Oklahoma Attorney General E. Scott Pruitt challenges, among other things, the IRS’ authority to promulgate the rule, which he argued contradicts the plain text of the ACA indicating the tax credits should apply only to individuals enrolled in state-run exchanges, not those participating in the federally operated exchange.

After noting that states deserve “special solicitude” in standing analyses, the court held that at this stage in the litigation “under the extremely lenient pleading standards which are applicable,” the state has sufficiently demonstrated standing to challenge the IRS rule in its own capacity as an employer.

The court went on to find, however, that the state lacked standing on its claim asking the court to revisit the individual mandate provision of the ACA.

The state asserted standing based on state sovereignty under the Tenth Amendment, but the court agreed with the government’s argument that the state’s assertions constitute “parens patriae standing by another name.”
“The allegations in the amended complaint do not assert injury to the State’s proprietary interests,” the court found in dismissing that count.

The court also dismissed Count IV, under which plaintiff sought a declaration that the IRS rule is unconstitutional as applied to employees of the state.

Under Count III, in which the state sought to challenge the IRS rule pursuant to the Administrative Procedure Act (APA), the court found Oklahoma “has made sufficient plausible allegations supporting standing for the State of Oklahoma in its capacity as a large employer.”

The court also let stand Count V, which the state described as “an alternative claim for relief.”

**Anti-Injunction Act**

The government also relied as grounds for dismissal on the Anti-Injunction Act (AIA), which prohibits “any person” from maintaining a suit “for the purpose of restraining the assessment or collection of any tax.” 26 U.S.C. § 7421(a).

The court rejected this argument, however, choosing to follow the Fourth Circuit in finding the AIA does not bar the action. See *Liberty University, Inc. v. Lew*, 2013 WL 3470532 (4th Cir.2013).


**U.S. Court In D.C. Rejects Constitutional Challenge to ACA Individual Mandate Based on Origination Clause**

A federal district court in the District of Columbia held June 28 that the minimum essential coverage provision of the Affordable Care Act (ACA) did not violate the Origination Clause of the U.S. Constitution.

The U.S. District Court for the District of Columbia found the ACA provision requiring individuals to purchase health insurance or make a “shared responsibility payment,” known as the “individual mandate,” was not a “Bill[] for raising Revenue” subject to the Origination Clause, which requires such legislation to originate in the House of Representatives. U.S. Const. art. I, § 7, cl. 1.

Even assuming the individual mandate was a bill for raising revenue, the court held it was an amendment to a bill that “originated in the House of Representatives” and therefore was not unconstitutional.

Plaintiff Matthew Sissel is an individual who will be subject to the mandate when it goes into effect on January 1, 2014.

His initial complaint alleged the mandate violated the Commerce Clause. Following the Supreme Court’s decision in *National Fed. of Independent Bus. v. Sebelius*, 132 S.Ct. 2566 (2012) (*NFIB*), plaintiff amended his complaint to argue the Court’s ruling only upheld the shared responsibility payment under Congress’ taxing power, but that the actual purchase requirement could still be struck down on Commerce Clause grounds.

Rejecting this argument, the court said the individual mandate, under the Supreme Court’s decision, could not be read as two separate requirements—“but rather is to be read as a single provision for purposes of constitutional analysis under either the Commerce Clause or the Taxing Clause.”
Plaintiff also amended his complaint following *NFIB* to assert a violation of the Origination Clause. But the court likewise rejected that claim.

According to the court, the individual mandate’s primary purpose is not to raise revenue, but to expand health insurance coverage. Under Court precedent, legislation that “incidentally create[s] revenue” is not a bill for raising revenue under the Origination Clause, the district court said.

“Congress’ preference would be for the individual mandate to raise zero revenues,” the court observed, because the primary purpose of the provision is universal coverage; therefore, the Origination Clause requirement is not triggered.

Even assuming the individual mandate could be characterized as a bill for raising revenue, the court held it did in fact “originate” in the House, although the Senate struck the entire text of the House-passed measure, and substituted it with the text that ultimately became the ACA.


**U.S. Court in Texas Finds ACA Does Not Violate Origination or Takings Clauses**

A federal court in Texas rejected January 10 a challenge to the Affordable Care Act (ACA), holding plaintiffs failed to state a claim that the reform law violates either the Origination Clause or the Takings Clause of the U.S. Constitution. The U.S. District Court for the Southern District of Texas found, although plaintiffs had standing to challenge the law, their claims must be dismissed.

Plaintiffs Steven F. Hotze, M.D. and Braidwood Management, Inc. sought a declaratory judgment that the ACA is unconstitutional because it violates the Origination Clause and the Takings Clause.

As a threshold matter, the court found Braidwood had standing to challenge the law as it is subject to the ACA’s employer mandate as an “applicable large employer” with “approximately 73 full-time equivalent employees.”

**Origination Clause**

Under the Origination Clause of the U.S. Constitution, all revenue-raising bills must originate in the House of Representatives. To state a claim for the violation of the Origination Clause, a plaintiff must show both that the bill in question is one “for raising revenue,” and also that the bill “did not originate in the House of Representatives.”

Plaintiffs argued the individual mandate and the employer mandate levy taxes and thus “raise revenue” under the Origination Clause. After examining Supreme Court jurisprudence on the Origination Clause, the court disagreed with plaintiffs that the ACA is primarily a revenue-raising law. “While some revenue under these mandates will be paid to the general Treasury, those payments are only ‘incidental’ to the ACA’s ‘overarching purpose,’” the court held.

The court also found plaintiffs failed to show the bill did not originate in the House. The court acknowledged the argument that the version of H.R. 3590 that originated in the House was effectively superseded by the Senate’s “creation” of the ACA, and thus the ACA, though nominally titled under H.R. 3590, originated in the Senate.

But the court went on to find that “[t]his contention ignores the second half of the Origination Clause, which states that ‘the Senate may propose or concur with Amendments as on other bills.’”
Takings Clause

According to plaintiffs, the ACA compels private individuals and entities to make payments to other private entities without a public use and without just compensation and therefore violates the Takings Clause, which provides that “private property [shall not] be taken for public use, without just compensation.”

But the court was "unpersuaded" by that argument, noting the Supreme Court recently stated unequivocally that "it is beyond dispute that taxes and user fees . . . are not takings." *Koontz v. St. Johns River Water Mgmt. Dist.*, 133 S. Ct. 2586, 2600 (2013) (citing Justice Scalia’s dissent in *Brown v. Legal Found. of Wash.*, 538 U.S. 216, 242 n.2 (2003)).

“To permit Congress to tax certain conduct (i.e., the failure to purchase or provide health coverage), but then to require Congress to provide ‘just compensation’ because the collection is a ‘taking,’ would render Congress’s taxing authority nugatory,” the court held.


Developments in Challenges to Contraceptive Mandate

Challenges by for-profit, secular companies to the Affordable Care Act’s (ACA’s) preventative services mandate have continued to generate conflicting court opinions in recent weeks.

The preventative services mandate and its implementing regulations, issued by the Departments of Health and Human Services, Treasury, and Labor require non-grandfathered health plans to cover, among other things, contraception and sterilization procedures with no cost sharing.

The regulations specifically exempt “religious employers” from the mandate. The agencies at the end of June issued final rules simplifying the definition of a “religious employer” and providing an accommodation for nonprofit religious organizations, such as nonprofit religious hospitals or institutions of higher education, that object to contraception on religious grounds. The accommodation is not available to for-profit, secular corporations.

Plaintiffs in the lawsuits generally allege the coverage mandate, which includes drugs and devices such as the “morning-after pill,” “Plan B,” and “Ella,” places them in a position of either violating their religious beliefs or paying substantial penalties for noncompliance. Specifically, plaintiffs contend the rules violate the Religious Freedom Restoration Act (RFRA), the First Amendment’s Free Speech and Free Exercise Clauses, and the Administrative Procedure Act.

In a June 27 decision, the Tenth Circuit held Hobby Lobby Stores, Inc. and Mardel, Inc., had standing as corporations to bring their claim under the RFRA. The appeals court also found the two for-profit, secular corporations established a likelihood of success on the merits of their claims that the contraceptive-coverage requirement “substantially burdened” their rights under the RFRA and established irreparable harm. The Tenth Circuit remanded the case to the lower court to weigh the two remaining preliminary injunction factors—balance of equities and public interest. *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12–6294 (June 27, 2013).


In a July 11 decision, the U.S. District Court for the Eastern District of Michigan denied a preliminary injunction to plaintiff Mersino Management Company. Even assuming Mersino Management had standing, which the court doubted, it was unlikely to succeed on its claim.


Finally, the U.S. District Court for the Middle District of Florida granted June 25 a preliminary injunction to Beckwith Electric Co., Inc., also a for-profit, secular company, and its owner. The court found corporations have the right to exercise religion under the First Amendment and the RFRA and that plaintiffs were likely to prevail on the merits of their claims. *Beckwith Elec. Co., Inc. v. Sebelius*, No. 8:13-cv-0648-T-17MAP (M.D. Fla. June 25, 2013).

**Third Circuit Rejects Secular Corporation’s Challenge to Contraceptive Mandate**

The Third Circuit affirmed July 26 the denial of a preliminary injunction to a for-profit, secular corporation challenging the Affordable Care Act’s preventative services mandate and implementing regulations, which require non-grandfathered health plans to cover, among other things, contraceptives and sterilization procedures with no cost sharing.

In a split from a recent Tenth Circuit ruling, *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12–6294 (June 27, 2013), the 2-1 Third Circuit panel held that a for-profit, secular corporation cannot engage in religious exercise under the Free Exercise Clause of the First Amendment and the Religious Freedom Restoration Act (RFRA).

In a June 27 decision, the Tenth Circuit held Hobby Lobby Stores, Inc. and Mardel, Inc. had standing as corporations to bring their claim under the RFRA. The appeals court also found the two for-profit, secular corporations established a likelihood of success on the merits of their claims that the contraceptive-coverage requirement “substantially burdened” their rights under the RFRA and showed irreparable harm.

Plaintiffs in this case Conestoga Wood Specialties Corporation (Conestoga), which has 950 employees, and its owners, who practice the Mennonite religion, alleged the coverage mandate, which includes drugs and devices such as the “morning-after pill,” “Plan B,” and “Ella,” violates their religious rights under the RFRA and the First Amendment. The district court refused to grant them a preliminary injunction.

Affirming the decision below, the appeals court majority acknowledged the Supreme Court recognized a corporation’s free speech rights in *Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 365 (2010), but concluded that case was not a fitting analogy because it rested on “a long history of protecting corporations’ rights to free speech.”

By contrast, the majority said, there is no similar precedent finding corporations have free exercise rights. “Such a total absence of caselaw takes on even greater significance when compared to the extensive list of Supreme Court cases addressing the free speech rights of corporations.”
The appeals court went on to say that even disregarding the “lack of historical recognition of the right, we simply cannot understand how a for-profit, secular corporation—apart from its owners—can exercise religion.”

The appeals court majority also rejected plaintiffs’ argument that Conestoga could assert their free exercise claims of their owners under the Ninth’s Circuit “pass through theory.” See EEOC v. Townley Engineering & Manufacturing Company, 859 F.2d 610 (9th Cir. 1988), and affirmed in Stormans, Inc. v. Selecky, 586 F.3d 1109 (9th Cir. 2009) (holding for-profit corporations can assert the free exercise claims of their owners).

The Third Circuit declined to adopt the “pass through theory,” saying it “rests on erroneous assumptions regarding the very nature of the corporate form.”

Given its conclusion that a for-profit, secular corporation cannot exercise religion under the First Amendment, the appeals court held Conestoga also could not assert a RFRA claim.

A dissenting opinion argued plaintiffs did have a likelihood of success on the merits of their claim. The dissent took issue with the majority’s conclusion that the lack of precedent on corporation’s free exercise of religion dictated the result. “While authority is admittedly scanty, that is in all probability because there has never before been a government policy that could be perceived as intruding on religious liberty as aggressively as the Mandate, so there has been little reason to address the issue,” the dissent said.

“[T]he conclusory assertion that a corporation has no constitutional right to free exercise of religion is [also] unsupported by any cited authority,” the dissent pointed out.


Sixth Circuit Denies Preliminary Injunction in Contraceptive Mandate Challenge

The Sixth Circuit September 17 became the latest federal appeals court to weigh in on the challenges to the Affordable Care Act’s preventative services mandate, rejecting a for-profit, secular company’s bid for a preliminary injunction.

The preventative services mandate and its implementing regulations, issued by the Departments of Health and Human Services, Treasury, and Labor, require non-grandfathered health plans to cover, among other things, contraception and sterilization procedures with no cost sharing.

The regulations specifically exempt “religious employers” from the mandate. The agencies at the end of June issued final rules simplifying the definition of a “religious employer” and providing an accommodation for nonprofit religious organizations, such as nonprofit religious hospitals or institutions of higher education, that object to contraception on religious grounds. The accommodation is not available to for-profit, secular corporations.

Plaintiffs in the lawsuits, which have been filed in federal district courts across the country, generally allege the coverage mandate, which includes drugs and devices such as the “morning-after pill,” “Plan B,” and “Ella,” places them in a position of either violating their religious beliefs or paying substantial penalties for noncompliance. Specifically, plaintiffs contend the rules violate the Religious Freedom Restoration Act (RFRA), the First Amendment’s Free Speech and Free Exercise Clauses, and the Administrative Procedure Act.
In this case, plaintiffs are Autocam Corporation and Autocam Medical, LLC, manufacturers for the automotive and medical industries, and the family that owns them, all of whom are practicing Roman Catholics. The district court denied their motion for a preliminary injunction.

As a threshold issue, the Sixth Circuit found the individual plaintiffs lacked standing to assert a RFRA claim based on a legal obligation of their closely held company. “The decision to comply with the mandate falls on Autocam,” not the individual plaintiffs, the appeals court said.

Turning to the merits of Autocam’s claim, the appeals court held the corporation is not a “person” capable of “religious exercise” under the RFRA and therefore affirmed the district court’s judgment on that basis. While religious groups organized as corporations have been allowed to assert RFRA claims, it does not necessarily follow that “for-profit, secular corporations can exercise religion,” the appeals court said.

In a June 27 decision, the Tenth Circuit reached a different conclusion, holding two for-profit, secular corporations had standing to bring their claim under the RFRA. The appeals court also found the companies established a likelihood of success on the merits of their claims that the contraceptive-coverage requirement “substantially burdened” their rights under the RFRA and established irreparable harm. The Tenth Circuit remanded the case to the lower court to weigh the two remaining preliminary injunction factors—balance of equities and public interest. *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12–6294 (June 27, 2013).


The Third Circuit, however, in a July 26 decision held a for-profit, secular corporation cannot engage in religious exercise under the Free Exercise Clause of the First Amendment and the RFRA. *Conestoga Wood Specialties Corp. v. Secretary of the United States Dep’t of Health and Human Servs.*, No. 13-1144 (3d Cir. July 26, 2013). On September 19, the company in that case filed a petition with the Supreme Court asking it to review the Third Circuit's decision on whether the mandate violates the free exercise rights of a closely held family business with religious owners.


**Tenth Circuit Affirms Injunction in Contraceptive Mandate Challenge**

On October 3, the Tenth Circuit affirmed a district court’s decision to grant a preliminary injunction barring enforcement of a Department of Health and Human Services (HHS) regulation that required a for-profit corporation’s employer-provided group health plan to cover certain contraceptive drugs and services.

Plaintiffs, for-profit corporation Hercules Industries, Inc. (Hercules), and five of its shareholders and/or officers, brought suit in district court seeking an exemption from the HHS regulation, which requires employer-provided health plans to cover all contraceptive drugs and services approved by the Food and Drug Administration. Plaintiffs contended compliance with the regulation would violate their sincerely held religious beliefs. The district court granted plaintiffs’ motion for preliminary injunction, and HHS appealed.

The Tenth Circuit reviewed the district court’s decision for abuse of discretion and affirmed.

Although the district court did not determine whether plaintiffs had a substantial likelihood of succeeding on the merits of its claim under the Religious Freedom Restoration Act (RFRA), the Tenth Circuit noted this issue was resolved by its intervening decision in *Hobby Lobby v.*
Sebelius, 723 F.3d 1114 (10th Cir. 2013). In *Hobby Lobby*, the appeals court held a corporation is a “person” within the meaning of the RFRA, HHS’ regulation substantially burdened religious exercise, and the regulation failed to satisfy strict scrutiny.

The Tenth Circuit also found the district court did not abuse its discretion in concluding plaintiffs’ religious liberties would be harmed if forced to comply and that equitable relief was needed to prevent irreparable harm.

In granting the preliminary injunction, the district court found the balance of harms tipped in plaintiff’s favor. Although the district failed to address the government’s interest in making this determination, the Tenth Circuit nonetheless found no abuse of discretion in light of its decision in *Hobby Lobby*.

The district court also determined the public interest in the free exercise of religion supported the injunction, while reasoning exemptions from the regulation for many employers diluted the government’s stated interest in improving women's health and equalizing preventative services coverage. The appeals court held this reasoning was not an abuse of discretion.

The appeals remanded the case to the district court and ordered it to abate further proceedings until the Supreme Court acted on the *Hobby Lobby* case.


**D.C. Circuit Reverses Denial of Injunctive Relief to Company Owners in Contraceptive Mandate Challenge**

The owners of two closely held for-profit, secular companies were likely to succeed on the merits of their challenge to the Affordable Care Act’s preventative services mandate and therefore the lower court erred in denying them a preliminary injunction on that basis, according to a D.C. Circuit panel.

Two of the three judges on the panel held in a November 1 opinion that the mandate, which requires non-grandfathered health plans to cover, among other things, contraception and sterilization with no cost sharing, substantially burdened the owners’ free exercise of religion and the government regulation failed to survive strict scrutiny. One judge would have ruled the mandate did not constitute a substantial burden on the owners’ religious exercise because they were not directly required to do something in violation of their religious beliefs.

The panel majority reversed the U.S. District Court for the District of Columbia’s denial of a preliminary injunction and remanded for further proceedings on the remaining preliminary injunction factors.

Two of the judges also concluded that, based on existing case law, the secular corporations themselves could not exercise religion, while the third judge would have declined to reach this issue at all.


The preventative services mandate and its implementing regulations, issued by the Departments of Health and Human Services, Treasury, and Labor, specifically exempt “religious employers” from the mandate. The agencies at the end of June issued final rules simplifying the definition of a “religious employer” and providing an accommodation for nonprofit religious organizations, such as nonprofit religious hospitals or institutions of higher education, that object to
contraception on religious grounds. The accommodation is not available to for-profit, secular corporations.

Plaintiffs in the lawsuits, which have been filed in federal district courts across the country, generally allege the coverage mandate, which includes drugs and devices such as the “morning-after pill,” “Plan B,” and “Ella,” places them in a position of either violating their religious beliefs or paying substantial penalties for noncompliance. Specifically, plaintiffs contend the rules violate the Religious Freedom Restoration Act (RFRA), the First Amendment’s Free Speech and Free Exercise Clauses, and the Administrative Procedure Act.

The Third, Sixth, and Tenth Circuits have issued conflicting opinions in the cases, which are now pending before the Supreme Court for review.

In a similar lawsuit, the Sixth Circuit ruled in September that individual plaintiffs lacked standing to assert a RFRA claim based on a legal obligation of their closely held company. The appeals court also held a corporation is not a “person” capable of “religious exercise” under the RFRA and therefore affirmed the district court’s denial of an injunction on that basis. Autocam Corp. v. Sebelius, No 12-2673 (6th Cir. Sept. 17, 2013).

The Third Circuit in a July decision also held a for-profit, secular corporation cannot engage in religious exercise under the Free Exercise Clause of the First Amendment and the RFRA. Conestoga Wood Specialties Corp. v. Secretary of the United States Dep’t of Health and Human Servs., No. 13-1144 (3d Cir. July 26, 2013).

In a June 27 decision, however, the Tenth Circuit reached a different conclusion, holding two for-profit, secular corporations had standing to bring their claim under the RFRA. The appeals court also found the companies established a likelihood of success on the merits of their claims that the contraceptive-coverage requirement “substantially burdened” their rights under the RFRA and established irreparable harm. Hobby Lobby Stores, Inc. v. Sebelius, No. 12–6294 (10th Cir. June 27, 2013).

Seventh Circuit Says Companies Entitled to Injunction in Contraceptive Mandate Challenge

The Seventh Circuit held November 8 that business owners and their closely held secular corporations were entitled to injunctive relief from the Affordable Care Act’s preventative services provision requiring non-grandfathered health plans to cover contraceptives with no cost sharing.

In so ruling, the appeals court reversed two lower court decisions denying preliminary injunctions to the plaintiffs in the case, two Catholic families and their closely held corporations. The appeals court previously enjoined enforcement of the mandate pending appeal. The Seventh Court remanded with instructions to enter preliminary injunctions in both cases.

The 2-1 panel decision found for-profit, secular companies and their owners had free exercise rights and therefore could assert a religious objection to the contraception mandate. The panel also concluded the mandate substantially burdened those rights and failed the strict scrutiny analysis under the Religious Freedom Restoration Act (RFRA).

Korte v. Sebelius, No. 12-3841 (7th Cir. Nov. 8, 2013).

The Seventh Circuit is the second federal appeals court to rule that for-profit, secular companies have standing to bring their claim under the RFRA. The Tenth Circuit also reached this conclusion in Hobby Lobby Stores, Inc. v. Sebelius, No. 12–6294 (10th Cir. June 27, 2013). The Tenth Circuit likewise found the companies established a likelihood of success on the merits of their
claims that the contraceptive-coverage requirement “substantially burdened” their rights under the RFRA.

Most recently, the D.C. Circuit held owners of two closely held the owners of two companies were likely to succeed on the merits of their challenge to the mandate, but concluded, based on existing case law, the secular corporations themselves could not exercise religion. *Gilardi v. United States Dep’t of Health and Human Servs.*, No. 1:13-cv-00104 (D.C. Cir. Nov. 1, 2013).

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The preventative services mandate and its implementing regulations, issued by the Departments of Health and Human Services, Treasury, and Labor, specifically exempt “religious employers” from the mandate. The agencies at the end of June issued final rules simplifying the definition of a “religious employer” and providing an accommodation for nonprofit religious organizations, such as nonprofit religious hospitals or institutions of higher education, that object to contraception on religious grounds. The accommodation is not available to for-profit, secular corporations.

Plaintiffs in the lawsuits, which have been filed in federal district courts across the country, generally allege the coverage mandate, which includes drugs and devices such as the “morning-after pill,” “Plan B,” and “Ella,” places them in a position of either violating their religious beliefs or paying substantial penalties for noncompliance. Specifically, plaintiffs contend the rules violate the RFRA, the First Amendment’s Free Speech and Free Exercise Clauses, and the Administrative Procedure Act.

**High Court Will Hear Preventative Services Mandate Cases; Notre Dame Re-Files Challenge in Indiana**

The U.S. Supreme Court agreed November 26 to hear two cases challenging the so-called preventative services mandate in the Affordable Care Act (ACA).

The Tenth and Third Circuits split on this issue, with the Third Circuit in *Conestoga Wood Specialties Corp. v. Secretary of the United States Dep’t of Health and Human Servs.*, No. 13-1144 (3d Cir. July 26, 2013), affirming the denial of a preliminary injunction to a for-profit, secular corporation. The 2-1 Third Circuit panel held that a for-profit, secular corporation cannot engage in religious exercise under the Free Exercise Clause of the First Amendment and the Religious Freedom Restoration Act (RFRA).

In contrast, the Tenth Circuit in *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12–6294 (June 27, 2013), held Hobby Lobby Stores, Inc. and Mardel, Inc. had standing as corporations to bring their claim under the RFRA. The appeals court also found the two for-profit, secular corporations established a likelihood of success on the merits of their claims that the contraceptive-coverage requirement “substantially burdened” their rights under the RFRA and showed irreparable harm.
The ACA and its implementing regulations, issued by the Departments of Health and Human Services, Treasury, and Labor require non-grandfathered health plans to cover preventative services including contraception and sterilization procedures with no cost sharing.

Regulations implementing this requirement included a narrow exemption for “religious employers.” Following objections to the rules, the agencies issued a temporary enforcement safe harbor until August 1, 2013 for nonprofit employers that did not qualify for the exemption but that professed religious objections to providing coverage for contraceptives. The agencies issued an advance notice of proposed rulemaking in March 2012, before issuing proposed rules in February, which were finalized in June.

The final rules simplify the definition of a “religious employer” and provide an accommodation for nonprofit religious organizations, such as nonprofit religious hospitals or institutions of higher education, that object to contraception on religious grounds. Under the accommodation, enrollees would be provided separate contraceptive coverage at no cost.

The High Court consolidated the two cases and allotted one hour for oral argument.

In a White House blog post, the administration expressed its expectation that the High Court would affirm the ACA requirement. “We are confident the Supreme Court will agree that health decisions in this country should remain with individuals, in consultation with their doctors, families, faiths, and whomever else they personally trust,” the post said.

“No corporate entity should be in position to limit women’s legal access to care, or to seize a controlling interest over the health care choices of women,” said Valerie Jarrett, who authored the post.


Notre Dame Re-Files Challenge

Meanwhile, on December 3, the University of Notre Dame re-filed its challenge to the mandate under the First Amendment and RFRA.

Notre Dame said in its complaint that although a narrow exemption from the mandate was given to religious institutions, organizations like Notre Dame--schools, universities, hospitals, and charitable organizations that serve and employ people of all faiths--do not fall under the exemption.

According to the University, the accommodation issued by the administration in June does not relieve the "unlawful burdens placed on Notre Dame."

The complaint alleges the University should not be forced to "pay for, facilitate access to, and/or become entangled in the provision of products, services, practices, and speech that are contrary to its sincerely held religious beliefs."

The U.S. District Court for the Northern District of Indiana dismissed the University's initial suit, indicating that the regulation was not ripe for judicial review because of a temporary enforcement safe harbor until August 1, 2013 for nonprofit employers that did not meet the regulatory definition of a “religious employer” but that professed religious objections to the mandate. University of Notre Dame v. Sebelius, No. 3:12CV253RLM (N.D. Ind. Dec. 31, 2012).

But the University said December 3 that its third-party administrator is required to notify all females of child-bearing age among the University’s employees and their dependents of the
availability of the objectionable services by January 1, 2014; accordingly, the University said it believes its suit is proper at this time.

**Supreme Court Enjoins Government from Enforcing ACA Contraceptive Mandate Against Religious Group**

The U.S. Supreme Court enjoined January 24 the government from enforcing the contraceptive coverage requirements under the Affordable Care Act (ACA) against a religious group pending a final decision by the Tenth Circuit. *Little Sisters of the Poor Home for the Aged v. Sebelius*, No. 13A691.

On December 31, 2013, Justice Sonia Sotomayor enjoined the government from enforcing the so-called “contraceptive mandate” against plaintiffs when it took effect January 1.

Although the order warned the injunction “should not be construed as an expression of the Court’s views on the merits,” it enjoined the government from enforcing the mandate if plaintiffs inform the Secretary of the Department of Health and Human Services in writing “that they are non-profit organizations that hold themselves out as religious and have religious objections to providing coverage for contraceptive services.”

“To meet the condition for injunction pending appeal, applicants need not use the form prescribed by the Government and need not send copies to third-party administrators,” the order specified.

At issue in the case is Employee Benefit Security Administration Form 700. Plaintiffs, The Little Sisters of the Poor and others, are nonprofit religious employers that would be exempt under the ACA from its requirement that non-grandfathered group health plans cover certain preventive health services, including contraceptives, without cost sharing.

Form 700 requires such employers to “certify that, on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered; the organization is organized and operates as a nonprofit entity; and the organization holds itself out as a religious organization.”

According to plaintiffs, Treasury Regulations cited in the Form state that third-party administrators who receive the Form “shall provide or arrange payments for contraceptive services.” Thus, The Little Sisters claim in their suit that signing the form will violate their religious freedom “because they cannot deputize a third party to sin on their behalf.”

On January 28, the University of Notre Dame renewed its motion before the Seventh Circuit for injunction pending appeal in light of the *Little Sisters* decision. According to the motion, both cases “address similar legal questions, have nearly identical factual predicates, and are in the same procedural posture.” Thus, Notre Dame argued in its motion, “there is no legitimate basis upon which an injunction could be granted to the Little Sisters of the Poor but denied to Notre Dame.”

Still pending before the Court is *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-354, cert. granted (U.S. Nov. 26, 2013), which presents a different side of the issue.

In that pair of cases, plaintiffs are for-profit, secular organizations arguing they should be exempt from the contraceptive mandate because it would require the family-owned businesses to act contrary to their religious convictions in violation of the Religious Freedom Restoration Act (RFRA).
On January 28, a group of 15 lawmakers filed an amicus brief with the Court arguing the mandate violates RFRA.

The lawmakers, including Senator Orrin Hatch (R-UT), who was the lead Republican sponsor of RFRA, argued in the brief that the “government’s refusal to apply RFRA throughout the administrative process has resulted in a mandate that violates RFRA and turns the law of religious freedom upside down.”

“RFRA places a heavy burden on the government and protects religion by default. But the [Health and Human Services] mandate places a heavy burden on religion and protects the government by default,” the brief said.

Seventh Circuit Finds Requirement to Opt Out of ACA Contraceptive Mandate Not a Substantial Burden on Religious Employer Under RFRA

The Seventh Circuit in a two-to-one panel decision February 21 affirmed the denial of preliminary injunctive relief to the University of Notre Dame in its challenge to contraceptive coverage requirements under the Affordable Care Act (ACA), finding Notre Dame’s duty to fill out a form opting out of the requirements was not a substantial burden under the Religious Freedom Restoration Act (RFRA).

The University of Notre Dame is a nonprofit religious employer that would be exempt under the ACA from its requirement that non-grandfathered group health plans cover certain preventive health services, including contraceptives, without cost sharing.

By statute, an exempt employer must fill out Employee Benefit Security Administration Form 700, which requires such employers to “certify that, on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered; the organization is organized and operates as a nonprofit entity; and the organization holds itself out as a religious organization.”

On December 3, 2013, Notre Dame moved for the entry of a preliminary injunction arguing the regulation’s requirements violate its rights under RFRA. The district court denied the motion on December 20, 2013, and Notre Dame filed its appeal from that denial the same day. On December 31, 2013, the last day before it would be penalized for violating the regulations, Notre Dame signed Form 700 and thereby opted out of paying for contraceptive coverage for its employees. Notre Dame was required to give copies of the form both to Aetna, with whom it contracts to provide insurance to students, and to its third-party administrator, Meritain.

The narrow question before the appeals court then was whether the district court abused its discretion in refusing to grant a preliminary injunction.

According to the appeals court, “while a religious institution has a broad immunity from being required to engage in acts that violate the tenets of its faith, it has no right to prevent other institutions, whether the government or a health insurance company, from engaging in acts that merely offend the institution.”

Notre Dame’s principal argument was that by requiring it to fill out Form 700 and give copies to Aetna and Meritain, the government “substantially burden[ed] a person’s exercise of religion” and no “compelling governmental interest” justified that burdening.

“But the university has not yet shown that there is a substantial burden,” the appeals court found, pointing out the form is only two pages long.
According to the appeals court, the only colorable burden Notre Dame complains of “is that by filling out the form and sending it to the companies it ‘triggers’ their coverage of the contraception costs of the university’s female employees and students, and that this makes the university an accomplice in the provision of contraception, in violation of Catholic doctrine, which in the name of avoiding ‘scandal’ forbids the encouragement (equivalent to aiding and abetting) of sinful acts.”

But the court found no merit in this argument, noting federal law, not the religious organization’s signing and mailing the form, requires health care insurers, along with third-party administrators of self-insured health plans, to cover the contraceptive services.

“And refusing to fill out the form Notre Dame would subject itself to penalties, but Aetna and Meritain would still be required by federal law to provide the services to the university’s students and employees unless and until their contractual relation with Notre Dame terminated,” the appeals court noted.

Notre Dame argued, however, that had it not filled out the form, Meritain and Aetna would not have been authorized to provide contraceptive services because neither would have been a “plan administrator” under Section 3(16) of the Employee Retirement Income Security Act and thus would not have been plan fiduciaries entitled to make expenditures (as for costs of contraceptives) on behalf of the plan.

The appeals court rejected this argument as well, noting it was made for the first time at oral argument and therefore was forfeited.

“In any event it’s unconvincing,” the appeals court commented. “If the government is entitled to require that female contraceptives be provided to women free of charge, we have trouble understanding how signing the form that declares Notre Dame’s authorized refusal to pay for contraceptives for its students or staff, and mailing the authorization document to those companies, which under federal law are obligated to pick up the tab, could be thought to ‘trigger’ the provision of female contraceptives,” the appeals court said.

The appeals court then turned to Notre Dame’s argument that the regulations violated the free-speech clause of the First Amendment by providing that an exempt organization, such as Notre Dame, “must not, directly or indirectly, seek to interfere with a third party administrator’s arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries, and must not, directly or indirectly, seek to influence the third party administrator’s decision to make any such arrangements.” 29 C.F.R. § 2590.715-2713A(b)(1)(iii); 26 C.F.R. 54.9815-2713A(b)(1)(iii).

While “troubled by the seeming vagueness of the regulation,” the court said more facts were needed to rule on the merits of the claim.

Lastly, the court noted that on January 28 the university filed a renewed motion for an injunction pending appeal based on the Supreme Court’s January 24 decision in Little Sisters of the Poor Home for the Aged v. Sebelius, No. 13A691.

The Court’s order enjoined the government from enforcing the contraceptive coverage requirements against the religious group pending a final decision by the Tenth Circuit conditioned on the Little Sisters’ sending a letter to the government declaring its opposition to paying for contraceptive services. The Seventh Circuit noted “at the oral argument of our case Notre Dame told us that it would consider sending such a letter an infringement of its religious freedom.”

Another distinction, the appeals court said, was that unlike Meritain, Little Sisters’ third-party administrator, Christian Brothers, is a “church plan” administrator and so would not provide
contraceptive services anyway, or be required to do so. Accordingly, the appeals court denied the renewed motion for an injunction pending appeal “as moot because the appeal has been resolved.”

The lone dissenting judge argued Notre Dame made out a credible claim under RFRA.

“I therefore would grant the university a preliminary injunction forbidding the government from penalizing Notre Dame for refusing to comply with the self-certification requirement,” the dissent said.

*University of Notre Dame v. Sebelius*, No. 13-3853 (7th Cir. Feb. 21, 2014).

**D.C. Circuit Upholds Dismissal of Challenges to ACA Mandate, Medicare Rules**

The D.C. Circuit affirmed March 7 a lower court decision rejecting a challenge to the Affordable Care Act’s (ACA’s) individual mandate brought by plaintiffs Association of American Physicians & Surgeons, Inc. and Alliance for Natural Health USA.

Plaintiffs argued the mandate violated the Takings Clause of the Fifth Amendment by taking property from some individuals to subsidize health care coverage for others.


The appeals court agreed, noting no suggestion “that any redistributive purpose sweeps an otherwise valid tax into the narrow group of measures” condemned by the Court.

Plaintiffs’ action challenging the individual mandate had been stayed pending the Court’s ACA decision, which was issued in June 2012 and upheld the individual mandate as a proper exercise of Congress’ taxing power. *See National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012).

The appeals court also denied plaintiffs’ origination clause claim—i.e., that the ACA is unconstitutional because its revenue-raising provisions originated in the Senate, rather than the House. The district court held, and the appeals court agreed, that the argument was conceded.

**Medicare Rules**

Plaintiffs also challenged Social Security Program Operations Manual System (POMS) provisions that provide that individuals who receive Social Security benefits are automatically enrolled in Medicare Part A. According to plaintiffs, the POMS provisions exceeded the Social Security Administration’s statutory authority and required notice-and-comment rulemaking under the Administrative Procedure Act (APA).

Affirming the district court’s dismissal of this claim, the appeals court said the challenge to the POMS provisions “is clearly foreclosed” by its decision in *Hall v. Sebelius*, No. 11-5076 (D.C. Cir. Feb. 7, 2012), which held seniors who receive Social Security cannot disclaim their legal entitlement to Medicare Part A even if they decline the program’s benefits in favor of private insurance.

The appeals court also found the APA claim failed because notice-and-comment rulemaking would not change the outcome in light of the *Hall* decision.
Plaintiffs also challenged Medicare rules put in place by provisions of the Centers for Medicare & Medicaid Services manual and accompanying change requests, and a Department of Health and Human Services (HHS) interim final rule that requires physicians and other eligible professionals to obtain a national provider identifier and an HHS-approved enrollment or opt-out record in the Provider Enrollment, Chain, and Ownership System to make covered referrals under Medicare Part B.

The appeals court noted a final rule issued in April 2012 superseded the interim final rule, which made the challenge moot.

Finally, plaintiffs claimed the Social Security Commissioner and the Secretary violated their "fiduciary and equitable duties" by failing to provide an "honest accounting" of Social Security's and Medicare's financial position.

The appeals court found no foundation for the fiduciary duties plaintiffs alleged and therefore dismissed for lack of jurisdiction.


**U.S. Court in Wisconsin Finds Plaintiffs Lack Standing to Challenge Employer Mandate Delay**

A federal court in Wisconsin dismissed March 18 an action challenging the constitutionality of the administration’s decision to delay implementation of the Affordable Care Act’s (ACA’s) employer mandate while allowing the individual mandate to take effect in 2014.

The U.S. District Court for the Eastern District of Wisconsin held plaintiffs—the Association of American Physicians & Surgeons, Inc. and Robert T. McQueeney, MD—lacked standing because the injury they alleged was too speculative.

According to plaintiffs, the Internal Revenue Service (IRS) violated constitutional separation of powers and the Tenth Amendment by implementing the individual mandate—which requires individuals to obtain "minimum essential coverage" or make a "shared responsibility payment"—in 2014 while delaying the employer mandate until 2015 for employers with 100 or more full-time workers and until 2016 for employers with 50 or more full-time workers.

Plaintiffs alleged Congress intended both mandates be implemented at the same time.

The IRS moved to dismiss for lack of subject matter jurisdiction, arguing plaintiffs lacked standing to sue.

The court granted the motion, noting plaintiffs relied "on a series of discretionary acts by third parties" as the basis for their claims.

Plaintiffs alleged they would lose patients and revenues because the delay to the employer mandate would cause large employers not to offer ACA-compliant health insurance for 2014; would cause these employees to pay out-of-pocket for insurance plans that plaintiffs either would not or could not accept payment from; which ultimately would cause these employees to purchase fewer services from plaintiffs.

The court found this causal chain too attenuated to establish an “imminent” or “impending” injury for standing purposes.
“The ACA does not prohibit employers from providing health insurance in 2014, and it is reasonable to conclude that many will still provide it in 2014 for the same reasons they provided it in the past,” the court observed.

The court also found it “speculative” that plans employees purchased would not cover the services provided by plaintiffs or that those employees would not pay for the services out of pocket.

Finally, the court said it also was too uncertain that employees would have less discretionary income and therefore stop seeking services from plaintiffs.


HIPAA

U.S. Court in Florida Finds Hospital Properly Terminated Business Associate Contract for HIPAA Breach

The U.S. District Court for the Southern District of Florida found June 20 that a hospital system properly terminated its contract with a business associate staffing company for a violation of the Health Insurance Portability and Accountability Act (HIPAA).

Defendant Community Health Systems, Inc. (CHS) was sued by a business associate Managed Care Solutions, Inc. (MCS) for breach of contract, but the court found MCS was unable to present “more than a mere scintilla of evidence” in support of its argument that its employee did not improperly obtain protected health information (PHI) from the hospital in contravention of the HIPAA Addendum to the parties’ contract.

Nichole Scott worked at CHS' Salem Hospital through a temporary employment agency employed by MCS.

After Delaware State Police executed a warrant to search Scott’s home and arrested her, CHS terminated its contract with MCS citing, “the arrest of MCS employee, Nichole Scott for identity theft” related to PHI of Salem patients.

MCS claimed CHS breached the contract because it immediately terminated the contract without knowledge of any material breach.

Turning first to the question of whether Scott improperly used Salem PHI in violation of the contract, the court found “[t]he testimonies of Detectives Widdoes and Wysock combined with the circumstances under which specific evidence was discovered at Scott’s home do not lead to any reasonable conclusion other than that Scott improperly obtained PHI in violation of the HIPAA Addendum.”

“While the totality of the Defense's pleadings presents a strong case for summary judgment against the Plaintiff, it is Scott's inability to assert a plausible alternative to the Defense's contentions that ultimately renders summary judgment proper in this case,” the court continued.

According to the court, although Scott denied taking patient checks, credit card, and social security information while working at Salem Hospital, “her testimony reveals that patient information was at her home, but she could not explain how it got there. Scott's best explanation for the presence of patient information at her home was that she could not account for her husband's actions and that he was 'a snake'”
The court next found the totality of the evidence showed MCS knew of Scott's actions prior to the termination of the contract.

In fact, the court highlighted, Salem's termination letter "provides no alternative explanation than that Salem terminated the contract with knowledge of Scott's actions." Finally, the court found Scott's conduct was clearly a material breach of the HIPAA Addendum.

*Managed Care Solutions, Inc. v. Community Health Sys., Inc.*, No. 10-60170 (S.D. Fla. June 20, 2013).

**U.S. Court in Michigan Holds HIPAA Does Not Bar Ex Parte Interviews of Treating Physicians**

On October 28, the U.S. District Court for the Eastern District of Michigan agreed to allow ex parte interviews of a plaintiff's treating physicians in a personal injury action subject to a qualified protective order.

Defendants are a trucking company and truck driver from whom plaintiff allegedly sustained injuries in an automobile accident. Defendants filed a motion for a qualified protective order so they could obtain plaintiff's medical records and conduct ex parte interviews of plaintiff's treating medical providers.

Under Michigan state law, physician-patient privilege is waived if "the patient brings an action against any defendant to recover for any personal injuries . . . and the patient produces a physician as a witness in the patient's own behalf who has treated the patient for the injury . . ." The court held Michigan law was not "more stringent" than HIPAA and therefore the state law was preempted by the federal law. HIPAA does not allow for automatic waiver of the physician-patient privilege and "unfettered" access to a patient's medical providers to conduct ex parte interviews just because a lawsuit is filed, the court noted.

At the same time, the court said HIPAA and its implementing regulations include some exceptions to the prohibition against disclosing protected health information without a patient's consent. For example, the court pointed to the exception allowing disclosures for purposes of judicial and administrative proceedings in certain instances, including where a physician receives "satisfactory assurance" from the party seeking the information that reasonable efforts have been made to secure a qualified protective order.

The court noted in this case that plaintiff failed to offer reasons as to why access to his treating medical providers should be restricted and there was no indication his medical records contained sensitive or privileged information or treatments for conditions irrelevant to the lawsuit. The court said defendants' were entitled to all the relevant medical records, which they could obtain by subpoena with notice to the plaintiff as required by HIPAA. The court also refused to restrict access to plaintiff's treating medical providers to the formal discovery process. Instead, the court agreed defendants could interview potential medical witnesses who treated plaintiff subject to the limitations of a qualified protective order.
The court was not persuaded by plaintiff’s argument that defendants should not be able to obtain written communications from his treating physicians, finding no basis for such a restriction. The court stated defendants’ need to interpret illegible chart notations was a justifiable reason as to why written translation would serve the purpose of conveying accurate information for the fact finder. The court also said HIPAA prohibited defendants from using protected health information for any purpose outside of litigation but it did not restrict what defendants may use, the questions they wanted to ask, or the form in which they could gather information in connection with this lawsuit.


**U.S. Court in Wisconsin Declines to Issue HIPAA Protective Order Allowing Fraud Defendant Access to Patient’s Medical Records**

The U.S. District Court for the Eastern District of Wisconsin declined November 5 to allow a health care fraud defendant access to medical records of a patient in order to show other physicians may have issued similar prescriptions to the ones at issue in the case.

The court also found the fraud defendant need not admit in her answers to interrogatories that the prescriptions she wrote were “off label.”

Jennifer King-Vassel was accused by relator Toby Watson of submitting false claims to Medicaid for off-label prescriptions that she provided to N.B., a minor patient. Watson contended the off-label prescriptions were not issued for a use approved under the Food, Drug, and Cosmetic Act (FDCA), nor were they written for a use supported by one of the drug compendia.

King-Vassel moved for entry of a Health Insurance Portability and Accountability Act (HIPAA) protective order that would allow her to access the medical records of N.B. to ascertain whether his other treating doctors also wrote similar prescriptions.

The court denied this motion, however, finding the instant case “has nothing to do with what other treatment N.B. might have received outside of King-Vassel’s care.” The court further said it could not “envision any material matter on which the requested information would bear that could possibly be relevant to this case.”

Watson also requested entry of a modified HIPAA order. The court noted that it previously granted another of Watson’s motions for a HIPAA order, finding that Watson should be allowed access to the records of King-Vassel, Wisconsin Medical Assistance Program, Wisconsin BadgerCare System, and Wisconsin Forward Health, to determine whether King-Vassel wrote any allegedly off-label prescriptions constituting false claims for any minors aside from N.B.

Watson sought a modified protective order to clarify that he was entitled to receive King-Vassel's records, which are in the hand of a records custodian, rather than in King-Vassel’s own possession. The court agreed to grant the order, finding “Watson is entitled to receive this information because additional off-label prescriptions may constitute false claims.”

Finally, Watson asked the court to compel King-Vassel to: (1) provide "complete non-evasive responses" to his discovery requests; and (2) supplement her initial disclosures "with respect to her defense that prescriptions presented to Medicaid that were not issued for a medically accepted indication . . . are not false claims."
The court noted Watson’s request called for King-Vassel to admit not only that the prescriptions were issued for a use that was not approved by the FDCA, but further that the use was "off-label."

Although it already “has been conclusively decided [in this case] that the prescriptions at issue were not written for indications covered under the FDCA,” King-Vassel need not admit that the prescriptions were written for off-label purposes to the extent that the term "off-label" is intended to mean anything other than non-FDCA-approved uses, nor must she admit that the "uses" were not approved by the FDCA, the court held.

Rejecting Watson’s request for King-Vassel to admit that her prescriptions were not approved uses in any drug compendia, the court noted “it is Watson’s duty to examine the compendia as compared to the record and determine for himself whether there is evidence that would support his false claim contentions.”


**U.S. Court in Florida Finds Plaintiff May Challenge Whether State Statute Preempted by HIPAA in Declaratory Judgment Action**

The U.S. District Court for the Southern District of Florida found December 10 that a declaratory judgment action was the correct legal mechanism in which to challenge the validity of a state law that plaintiff claimed was preempted by the Health Insurance Portability and Accountability Act (HIPAA).

Plaintiff Janice Lee in her action for a declaratory judgment stated she was contemplating filing a medical malpractice action against defendant Bethesda Hospital, Inc. for injuries sustained as a result of medical care that did not meet the prevailing standard of care.

Under a Florida Statute, designated as Chapter 2013-108, plaintiff would be required to provide a release authorizing defendant to have ex parte communications with all of her treating health care providers. Plaintiff asserted this requirement would violate her federal rights under HIPAA.

The state statute requires plaintiff to authorize defendant to engage in ex parte interviews with her health care providers during the 90-day presuit period, before any action may be filed and when no state court has jurisdiction over the dispute. If plaintiff withholds her authorization for ex parte interviews, her failure to comply with all the requirements of the 90-day presuit notice will allow the statute of limitations to continue to run. See Florida Statute § 766.106. Therefore, according to plaintiff, she either must forfeit her privacy rights under HIPAA or her medical malpractice claim.

Defendant moved to dismiss the action arguing it did not establish a case or controversy.

But the court agreed with plaintiff that the declaratory judgment action is the appropriate mechanism to resolve the dispute and determine whether the new state statute interferes with and is inconsistent with her rights under federal law.

In its holding, the court relied on *Khodara Envt’l, Inc. v. Blakey*, 376 F.3d 187, 195 (3d Cir. 2004), and *Triple G Landfills, Inc. v. Board of Commissioners*, 977 F.2d 287 (7th Cir. 1992), which found similar suits ripe for declaratory judgment.

South Carolina Supreme Court Rejects Hospital’s Bid for Review of Urgent Care Center’s CON Exemption

On May 29, the South Carolina Supreme Court held an agency’s denial of a hospital’s request for a final review conference regarding a competitor’s exemption from the Certificate of Need (CON) or Non-applicability Determination (NAD) process did not give rise to a final agency decision subject to a contested case hearing before an administrative law court (ALC), and the competitor’s status as a licensed private practitioner did not require a formal, written determination of its exemption.

Plaintiff Amisub of South Carolina is a hospital that conducts business as Piedmont Medical Center (Piedmont) in South Carolina. Piedmont’s competitor, Carolinas Physicians Network (CPN), is a wholly owned subsidiary of Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System (CHS).

In October 2007, the South Carolina Department of Health and Environmental Control (DHEC) informed CHS by letter that its proposed construction of a medical office building did not require CON review because it was an expense by a healthcare facility for a non-medical project as provided in S.C. Code Ann. Regs. 61-15 § 104(2)(f).

CHS thereafter built its medical office building and on January 12, 2009, CPN opened an urgent care center in that building and classified it as a licensed private practitioner’s office.

A few days earlier on January 5, Piedmont’s counsel (counsel) met with DHEC staff to discuss the center’s opening. On January 16, counsel requested in writing that DHEC immediately require CHS to submit either a non-applicability request or CON application for the urgent care center, pointing to a 2007 letter from CHS to DHEC where CHS assured the agency it would not open an urgent care center without first obtaining a CON or NAD.

On January 28, counsel spoke with DHEC’s CON director by telephone who said DHEC would not require CHS to apply for a NAD or CON for the urgent care center. Two days later, counsel prepared an affidavit summarizing his phone conversation with DHEC’s CON director and stated he had not received anything in writing from DHEC “memorializing its decision to not take any action against CHS for the opening of its urgent care center.”

On February 2, counsel requested a final review by the DHEC Board. On February 4, the Board’s clerk declined the request, stating Piedmont filed its request 464 days after DHEC’s decision was mailed to Piedmont. According to the DHEC Board, any request for review is due within 15 days following notice of decision. This letter, however, referenced DHEC’s October 26, 2007 determination that construction of the medical office building was exempt from CON requirements. The letter did not reference Piedmont’s question about the urgent care center.

Counsel wrote back clarifying it sought review of DHEC’s decision regarding the urgent care center, including the “unwritten decision made in January or February 2009 and communicated to [counsel] verbally on January 28, 2009, as described in [counsel’s] affidavit of January 30, 2009.” Counsel also asked for clarification on whether the DHEC Board’s February 4 letter represented its final decision to deny Piedmont’s request for review. The clerk informed Piedmont the DHEC Board met on February 12 and declined to conduct a final review.

On March 5, Piedmont filed a request with the ALC for a contested case hearing, challenging DHEC’s failure to require CHS to apply for and obtain a CON or NAD. Piedmont argued the
physician office exemption under S.C. Code Ann. § 44-7-170 was inapplicable because the urgent care center was marketed as a CHS facility rather than a physician practice and CHS controlled the urgent care center through its wholly owned subsidiary, CPN.

The ALC granted summary judgment to CHS and CPN, stating the urgent care center qualified as a licensed private practitioner’s office that was exempt from CON review.

Piedmont appealed to the court of appeals, which reversed the ALC’s ruling. The South Carolina Supreme Court granted certiorari as to DHEC’s argument that the appeals court erred in finding the ALC had subject matter jurisdiction. The issue before the high court was whether Piedmont’s challenge was properly before the ALC as a contested case.

DHEC argued the ALC did not have subject matter jurisdiction because DHEC did not issue a formal “staff decision” pursuant S.C. Code Ann. § 44-1-60(C), which would have required notice and an opportunity for Piedmont to be heard. Under Section 44-1-60(C), DHEC’s “initial decision involving the issuance, denial, renewal, suspension, or revocation of permits, licenses, or other action of the department shall be a staff decision.” DHEC also contended neither the telephone conversation between DHEC’s director and counsel nor counsel’s affidavit recounting that conversation constituted a staff decision within the purview of Section 44-1-60.

DHEC further argued neither CPN nor CHS sought a CON because in their case, one was not required by law for a licensed private physician’s office, and CPN’s physician’s office status was not one of the 12 exemptions that required written proof of exemption under S.C. Code Ann. Regs. 61-15 § 104. According to DHEC, it never issued a formal staff decision that qualified for a contested case hearing before the ALC as no approval or permission was required by law by way of a CON, NAD, or other formal exemption.

Piedmont countered DHEC’s unwillingness to communicate its staff decision in writing prompted Piedmont to take the unusual step of relying on counsel’s affidavit to memorialize the decision to seek a contested case hearing. Piedmont also maintained this unwritten staff decision became a final agency decision under Section 44-1-60(D) when the DHEC Board denied Piedmont’s request for review in February 2009. Under Section 44-1-60(D), a “department decision” is issued when the staff decision is made. The department decision becomes final 15 days after notice of its decision is mailed to the applicant unless the applicant files with DHEC a written request for final review. The DHEC Board then has 60 days following receipt of the applicant’s request to conduct a final review conference. If it does not, the department decision becomes the final agency decision and the applicant may then request a contested case hearing before the ALC within 30 days after the deadline for the final review conference has passed.

The high court agreed with DHEC that a staff decision had been made pursuant to Section 44-1-60(C) when DHEC granted CHS exemption in 2007 for the construction of its medical office building. The high court held, however, that neither the 2007 exemption nor DHEC’s February 13, 2009 letter declining Piedmont’s request for final review constituted a formal staff decision on the subsequent opening of the urgent care center. The high court also found the phone conversation between Piedmont’s counsel and DHEC’s CON director was not a “staff decision” that fell “within the statutory parameters for a contested case.”

The high court ultimately concluded the appeals court erred in finding DHEC issued a formal staff decision that could be the subject of a contested case hearing before an ALC. The high court pointed out since DHEC was not legally bound to issue a formal, written staff decision given CPN’s status as a licensed private physician’s office that also exempted CPN from the CON process, “there was no corresponding obligation that Piedmont be afforded a contested case hearing before the ALC.” With no formal staff decision that was required by law, there was no staff decision that could be properly subjected to the ALC’s review.
Mississippi Supreme Court Says Hospital Has No Claim to Patient’s Third-Party Settlement Proceeds

The Mississippi Supreme Court affirmed September 12 a lower court’s dismissal of a hospital’s claim to settlement proceeds received by a patient who was treated at the hospital following a car accident. According to the high court, the hospital had no legal basis on which to stake a claim to the funds.

A minor was treated at Memorial Hospital at Gulfport after being injured in a car accident. His guardians settled his personal-injury claim for $50,000 and petitioned the court to dismiss claims against the settlement proceeds made by several medical providers, including Memorial.

Memorial argued it was entitled to a pro rata share of the settlement funds because the minor is a Medicaid beneficiary and a provider cannot bill Medicaid until all available third-party sources of payment have been exhausted.

The lower court rejected this argument and dismissed Memorial’s claim because it exceeded the amount of the settlement and the minor would not be made whole if Memorial’s claim were paid from the settlement funds.

On appeal, the high court said it need not reach Memorial’s argument as to whether the “made whole” doctrine applied because the hospital had no legal right to any recovery from the settlement proceeds.

Unlike some other states, Mississippi has no statutory hospital lien, nor has the court recognized a common law lien under these circumstances, the opinion noted.

Memorial did not claim a right to recovery under a lien, an assignment, or a contractual theory, but rather that it had a legal duty to seek recovery from any legally liable third party prior to billing Medicaid, the high court observed.

But in this case the third-party coverage at issue was general liability coverage, not medical-pay coverage that reimburses the hospital for medical bills. Because no law entitled Memorial to payment from the settlement proceeds, the high court affirmed the lower court’s dismissal.


Ninth Circuit Says Washington State CON Requirements for Cardiac Procedure Do Not Violate Dormant Commerce Clause

The Washington State Department of Health’s Certificate of Need (CON) regulations did not violate the dormant Commerce Clause because they did not significantly impact interstate commerce and any effect they did have did not outweigh the safety benefits of the regulations, the Ninth Circuit held September 23.

Under Washington State CON regulations, hospitals without onsite cardiac surgical facilities can perform elective percutaneous coronary interventions (PCIs), which are nonsurgical procedures used to treat coronary heart disease, only if they obtain a CON demonstrating sufficient need in the region to support an annual minimum volume.

Yakima Valley Memorial Hospital (Memorial) in February 2011 filed an application for a CON to perform elective PCIs. Because another hospital, Yakima Regional Medical and Cardiac Care
Center, has onsite surgery facilities, the state Department of Health found Memorial had not demonstrated a need for a second elective PCI program in the relevant planning area.

Memorial sued, arguing the regulations unreasonably discriminate against interstate commerce in violation of the dormant Commerce Clause.

The Ninth Circuit observed at the outset that the “PCI regulations do not treat in-state and out-of-state actors differently, nor are they an even-handed law that incidentally makes it harder for out-of-state actors to do business in the state.”

In addition, the regulations do not “impair the free flow of materials and products across state borders,” the appeals court said. Instead, “[w]hat really is at issue is the shifting of business from one competitor to another, not a burden on interstate commerce,” according to the court.

Memorial also argued the regulations burden interstate commerce by reducing the total number of PCIs performed, but this “speculative downstream impact” is “highly attenuated” and a reduction in the total number of elective PCIs performed in the Yakima Valley does not place a significant burden on interstate commerce, the appeals court held.

In addition to being nondiscriminatory, the appeals court found the challenged regulations “are predicated on a safety-related purpose.” And Memorial offered no evidence to support its argument that the benefits of the 300-PCI minimum are illusory or manufactured, the appeals court noted.


**Sixth Circuit Finds Qualified Immunity Protects Hospital Secretary from Liability for Failing to Protect Patient**

A hospital unit secretary is shielded from liability based on qualified immunity for failure to protect a patient from harm, the Sixth Circuit held October 21 in an unpublished opinion. According to the appeals court, the plaintiff failed to assert a plausible violation of her husband’s rights to defeat an immunity defense.

Michael Minick was taken to Nashville General Hospital after he was tasered during his arrest. After being treated, he was transferred to the hospital’s “lock-up” floor and detained.

Later after Minick became combative, Unit Secretary Mailena Mason left her desk to investigate noise coming from Minick’s room. She met a county deputy outside of the room who told her “that everything was fine” so Mason returned to her desk. Minick was later found unconscious and subsequently died.

Plaintiff Heather Minick sued Mason and others (defendants) under 42 U.S.C. § 1983 for failing to protect her husband. Mason moved to dismiss for failure to state a claim and argued she was entitled to qualified immunity. The district court denied the motion on both grounds, and Mason appealed.

The appeals court first noted qualified immunity protects government officials performing discretionary functions from liability when their “conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known.”

According to the appeals court, to defeat a qualified immunity defense, Minick had to plead a plausible violation of her husband’s rights, and show that right was clearly established at the time of the incident.
Here, the appeals court found Minick failed “to carry her burden of showing that Mason violated a clearly established constitutional right.” The appeals court noted Minick cited no law establishing constitutional liability for a hospital unit secretary failing to protect a patient under another’s care. In addition, Minick also failed “to provide authority for the proposition that such an employee has a duty—or even would have been permitted—to intervene in a situation similar to what Mason faced,” the court said.

The appeals court said the case relied on by the lower court in finding the complaint stated a facially plausible constitutional violation was not analogous to the present case. In that case, Durham v. Nu’Man, 97 F.3d 862 (6th Cir. 1996), the defendant nurse both initiated the encounter that led to the beating of a patient in her care and also watched security officers attack him, facts not present in this case, the appeals court held.

Accordingly, the appeals court found qualified immunity shielded Mason from liability.


Utah High Court Says Statute Barring Negligent Credentialing Does Not Apply Retroactively

A statute prohibiting negligent credentialing claims does not retroactively bar a negligent credentialing claim that accrued before the enactment of the statute, the Utah Supreme Court held November 1.

On May 24, 2010, Melissa Waddoups underwent several procedures performed by Dr. Barry Noorda at Logan Regional Hospital, an Intermountain Health Care (IHC) facility. Mr. and Mrs. Waddoups (plaintiffs) subsequently sued alleging Noorda negligently performed those procedures and they suffered harm as a result.

At issue in the instant case was plaintiffs’ claim alleging negligent credentialing against IHC. Utah Code § 78B-3-425, which was passed on May 10, 2011, prohibits negligent credentialing as a cause of action in the state. The district court certified the question to the high court regarding whether the statute would bar plaintiffs’ negligent credentialing claim retroactively.

The high court noted the state statute barring retroactive application of new laws contained a single exception, "[a] provision of the Utah Code is not retroactive, unless the provision is expressly declared to be retroactive."

"Thus, absent clear legislative intent to the contrary, we generally presume that a statute applies only prospectively," the high court said. Here, Section 78B-3-425 contains no words indicative of retroactive application, the court found.

The court recognized a distinction between substantive and procedural laws as it relates to retroactive application of newly enacted statutes in that purely procedural laws may be given retrospective effect.

Here, “[i]n purporting to eliminate the cause of action of negligent credentialing, section 78B-3-425 cannot be said to be merely procedural, but rather is clearly substantive in nature,” the high court found.

Lastly, IHC argued Section 78B-3-425 is merely a clarifying amendment and thus subject to a judicially created exception that "when the purpose of an amendment is to clarify the meaning of an earlier enactment, the amendment may be applied retroactively in pending actions." The high court rejected this argument, however, noting during the pendency of the instant case it decided another case that repudiated the exception.
Eleventh Circuit Finds Percentage-Based Collection Fee Imposed on Patient Violates FDCPA

The Eleventh Circuit reversed in part January 2 a district court ruling granting summary judgment in favor of the defendant in a debt collection case, finding the fee imposed on a patient violated the Fair Debt Collection Practices Act (FDCPA).

Plaintiffs Melvin Bradley and Kevin Calma incurred medical debts at North Alabama Urology P.C. and University of Alabama at Birmingham Health System West, respectively. Both failed to pay these debts, and had their accounts referred to Franklin Health Services, Inc. As part of the referrals, Bradley’s account was charged an additional 33 1/3%, while Calma’s account was charged an additional 30% as a collection fee. Plaintiffs sued, arguing the additional fee violated Alabama state law, the FDCPA, and the Racketeer Influenced and Corrupt Organizations Act (RICO).

Plaintiffs and defendant each moved for summary judgment, which was granted in favor of the defendants on all claims except Calma’s unjust enrichment claim. Defendants then filed a motion to dismiss the unjust enrichment claim with prejudice, which the trial court granted. Plaintiffs appealed.

The appeals court agreed with the trial court’s decision granting summary judgment to defendant, except with regard to Bradley’s FDCPA claim. The FDCPA prohibits “collection of any amount . . . unless such amount is expressly authorized by the agreement creating the debt or authorized by law.” Bradley argued the collection fee violated the FDCPA because it was liquidated damages rather than cost of collection. The appeals court agreed, citing an Eighth Circuit opinion finding the FDCPA was violated when a collector charged a fee based on a percentage of the balance rather than the cost of collection.

The appeals court also noted Bradley’s patient registration with Urology specified that in the event of delinquency he would pay “costs of collection.” This was in contrast with Calma’s agreement with UAB West, in which he agreed to pay “reasonable collection fees,” or other cases in which the original contract explicitly permitted a percentage-based fee.

As a result, the appeals court held Bradley had contracted only to pay the actual costs. Furthermore, the appeals court ruled Urology and Franklin’s subsequent collection agreement could not alter Bradley’s contractual obligations. Since there was no showing that the collection fee had any correlation to the actual costs, the appeals court found the fee violated the FDCPA.

Georgia Supreme Court Finds Hospital Liens Timely Filed

The Georgia Supreme Court held January 27 that hospital plaintiffs timely filed their action for a hospital lien within the two-year statute of limitations. In reversing the judgment below, the high court found the limitations period began to run from the date of final release and not from the date the insureds agreed to settlement.

After providing treatment in March 2010 to a patient who was injured in a car accident with Geico insureds, the Hospital Authority of Clarke County and Athens Regional Medical Center (plaintiffs) filed three hospital liens totaling $66,999.22. The patient subsequently settled with Geico in September 2010 but never paid the liens.
When Geico did not satisfy the liens, plaintiffs sued on October 6, 2011. Geico moved for summary judgment, arguing that plaintiffs’ action was untimely under Ga. Code Ann. § 44–14–473 (a). The trial court denied the motion, but the appeals court reversed. The appeals court found the trial court erred in denying summary judgment because the hospitals failed to file their action to enforce their liens within one year of the September 10, 2010 settlement between Geico and the patient. Plaintiffs appealed.

The appeals court held an agreement to settle may be enforced in the absence of a formal release where there is evidence that the terms of the agreement were sufficiently finalized and agreed upon. However, the parties here executed the settlement and signed a general release on October 8, 2010, according to the high court.

The statute makes clear that the limitations period begins to run one year from the date of liability being finally determined by a settlement or release, the high court said. “In this case, because the settlement agreement progressed into a final release, as explicitly contemplated by the parties, we find that the statute of limitations began to run on the date that the release was executed—October 8, 2010,” the high court concluded.

Reversing the appeals court’s decision, the high court found plaintiffs timely filed their action.


**Texas Supreme Court Finds Insurance Settlement Did Not Satisfy Hospital Lien**

The Texas Supreme Court held May 16 that an insurer’s delivery of settlement checks, jointly payable to a hospital and two of its patients, did not satisfy the hospital’s statutory lien where the hospital lacked notice of the settlement funds and where the patients deposited the checks without the hospital’s endorsement.

To secure payment for the treatment of two car accident victims, plaintiff McAllen Hospitals, L.P. d/b/a McAllen Medical Center (Hospital) filed hospital liens under Tex. Prop. Code ch. 55 (Hospital Lien Statute), which invalidates any release of a patient’s cause of action against the person whose negligence caused his or her injury, until payment of the charges secured by the lien is received.

After receiving treatment, the two patients received checks from defendant State Farm Mutual Insurance Company of Texas (State Farm) pursuant to a settlement agreement with another motorist involved in their accident. Although the checks were payable to the Hospital as a copayee, State Farm did not notify the Hospital of the settlement funds, and the two patients deposited the checks without the Hospital’s endorsement, leaving the charges for their treatment outstanding.

The Hospital sued State Farm to enforce its hospital liens, seeking recovery of the two patients’ outstanding treatment costs up to the amount of the settlements. The appeals court affirmed the trial court’s grant of summary judgment to State Farm, finding the patients’ settlement was valid under the Hospital Lien Statute.

The Texas Supreme Court first determined that, because possession of a draft by one joint payee constitutes constructive possession by the other under the Uniform Commercial Code (UCC), State Farm constructively delivered the settlement checks to the Hospital by physically delivering them to its two patients.

However, the high court also found that, because payment to one nonalternative copayee without the endorsement of the other is not payment to a “holder” under the UCC, the Hospital
was not “paid” in accordance with the UCC or the Hospital Lien Statute when the checks were
delivered by State Farm and deposited by the patients. Thus, the patients’ causes of action had
not been released by the settlement and the Hospital’s liens remained intact.

The high court noted that holding otherwise would provide “no assurance that all the joint
payees would receive payment,” and would “dissolve any distinction between drafts made out to
alternative copayees and drafts made out to nonalternative copayees.”

By concluding neither State Farm’s liability nor its underlying obligation under the Hospital Lien
Statute was discharged under the UCC, the court abrogated prior case Benchmark Bank v. State
Farm Lloyds, 893 S.W.2d 649 (Tex. App. 1994), and joined those jurisdictions citing with
approval the Massachusetts Supreme Judicial Court’s reasoning in General Motors Acceptance

Because the issue of whether the Hospital Lien Statute permitted a hospital to recover directly
from a negligent third party or its insurer was not raised in State Farm’s summary judgment
motion, the court declined to decide whether the Hospital had a separate cause of action against
State Farm.


Insurance

Sixth Circuit Upholds Health Plan’s Benefits Denial After Auto Insurer Paid
Medical Expenses

On August 8, the Sixth Circuit, in an unpublished decision, held Blue Cross Blue Shield of
Michigan (BCBS) did not err when it denied plaintiff benefits as plaintiff’s employer-sponsored,
self-funded health care plan and plaintiff’s individual automobile insurance policy allowed for
coordination of benefits.

Plaintiff had medical coverage through two self-funded health care benefit plans governed by the
Employee Retirement Income Security Act. Plaintiff’s employer provided the Chrysler Hourly
Active Plan (HAP). Plaintiff’s second plan was an individual uncoordinated no-fault automobile
insurance policy that he purchased from Farmers Insurance Company (Farmers). The HAP is
governed by three documents: the Chrysler UAW Health Care Administrative Manual (Manual);
the Chrysler Hourly Active Summary Plan Description; and the Chrysler collective Bargaining
Agreement Manual (CBA).

After plaintiff retired, his HAP coverage switched to the Chrysler Hourly Retiree Plan (HRP) in
2007. Three years later, plaintiff’s coverage changed again to the UAW Retiree Medical Benefits
Trust for Chrysler (URMBT). BCBS administered both the HRP and URMBT but Chrysler paid any
claims that were paid to the beneficiaries.

In the meantime, plaintiff continued receiving medical treatment for injuries sustained in 2006
when struck by a motor vehicle. Farmers paid for plaintiff’s medical expenses in full, resulting in
BCBS denying those claims. Plaintiff argued Chrysler’s policy barred coordination of benefits with
Farmers, thereby entitling him to recover money from Chrysler, through BCBS, that it would
have had to otherwise pay had plaintiff not been covered by Farmers.

Plaintiff’s claim asserted the Manual’s non-coordination clause did not contradict the CBA’s terms,
which stated benefits payable under Chrysler’s program would be “coordinated with and
secondary to benefits provided or required by any group of individual automobile . . . insurance.”
The district court disagreed, finding a clear contradiction as the CBA contained an “unambiguous
provision” allowing coordination of Chrysler’s plan benefits with the very type of insurance that plaintiff had with Farmers. The court of appeals affirmed.

The appeals court was not persuaded by plaintiff’s argument that the CBA intended coordination only when another plan was obtained as part of a group health care plan. The appeals court held plaintiff failed to identify any authority indicating that “plan” necessarily meant a group plan and could not include an individually purchased plan like the one plaintiff had with Farmers.

The appeals court also held plaintiff failed to reconcile “the clear, unequivocal language employed” in the CBA regarding “any group or individual automobile . . . insurance” with his claim that the CBA did not coordinate with individual plans. According to the appeals court, plaintiff’s Farmers policy fell within the scope of the CBA’s provision that allowed coordination.

Lastly, the appeals court held the BCBS administrator’s decision to deny plaintiff benefits was not “arbitrary and capricious” as it was not irrational in light of the plan’s provisions. 


New York Appeals Court Says Computer Fraud Insurance Policy Does Not Cover Medicare Fraud

A New York appeals court held October 1 that a computer fraud insurance policy covered losses resulting from unauthorized users hacking into the system, not fraud perpetrated by authorized health care providers on a Medicare managed care plan.

The decision affirmed a January 7 ruling by a New York trial court, which granted summary judgment to defendant National Union Fire Company of Pittsburgh, PA in an action brought by plaintiff Universal American Corp., a health insurance company that provides Medicare managed care plans and other insurance products.

Universal contended a “computer systems fraud” rider National issued in 2008 covered a portion of the $18 million in losses that resulted from fraudulent claims submitted by health care providers to one of the company’s Medicare Advantage plans that were processed and paid through its computer system.

The rider provided up to $10 million in coverage for “loss resulting directly from a fraudulent . . . entry of Electronic Data” into Universal’s computer system. National argued the policy only covered access to the computer system by unauthorized users, i.e., hackers. Universal said even if the language was ambiguous on this point, it should be construed in favor of coverage.

In January, the New York Supreme Court held the policy was unambiguous and did not extend coverage to fraudulent claims entered by authorized users of the computer system. Universal Am. Corp. v. National Union Fire Ins. Co. of Pittsburgh, PA, 969 N.Y.S.2d 849 (2013). According to the court, coverage under the rider clearly was directed at misuse or manipulation of the computer system, not fraudulent medical claims submitted by authorized users. The court said nothing in the policy suggested coverage extended to instances where an authorized user—a health care provider submitting claims—used the computer system as intended, even if the claims themselves were fraudulent.

The New York Supreme Court, Appellate Division, agreed with the trial court, upholding its interpretation of the policy as a matter of law. The fraud rider “was intended to apply to wrongful acts in manipulation of the computer system, i.e., by hackers, and did not provide coverage for fraudulent content consisting of claims by bona fide doctors and other health care providers authorized to use the system for reimbursement for health care services that were not provided,” the appeals court said.
A commercial general liability policy issued by Hartford Casualty Insurance Company covers defense costs and damages that may arise from two lawsuits brought by patients who alleged a data breach exposed their personal medical information to public view for over a year, a federal court in California held October 7.

The U.S. District Court for the Central District of California rejected Hartford's argument that the policy's exclusion of statutory causes of action was triggered because the litigation was brought under the California Confidentiality of Medical Information Act (CMIA). The court found the exclusion did not apply because the state's common law has long recognized a right to medical privacy.

Plaintiffs in the underlying litigation sued Stanford Hospital and Clinics and Corcino & Associates alleging the private medical information of almost 20,000 emergency room patients was posted on a public website for almost a year. The lawsuits alleged violations of plaintiffs' constitutional and common law privacy rights, as well as statutory causes of action under the CMIA.

Corcino has a general liability policy issued by Hartford that covers damages stemming from the "electronic publication of material that violates a person's right of privacy." When Corcino sought defense and indemnification under that provision, Hartford argued the policy specifically excluded coverage for injuries "arising out of the violation of a person's right to privacy" created by statute. Hartford asserted this argument in a lawsuit it filed in federal district court seeking declaratory relief from having to defend and indemnify Corcino in the state court actions.

The federal district court agreed, however, to dismiss Hartford's action after finding another clause in the policy, when construed in favor of coverage, made the exclusion inapplicable where the insured could be liable for damages under the common law. In other words, the exclusion only applied in instances where a claim arising out of an invasion of privacy is created by statute. In California, however, the courts have long recognized a right to privacy and allowed tort actions for violations of that right.

Hartford attempted to argue the exclusion was triggered because plaintiffs sought statutory remedies under the CMIA. According to the court, however, these remedies merely codified relief already available for a violation of medical privacy under the common law. "The statutes thus permit an injured individual to recover damages for breach of an established privacy right, and as such, fall squarely within the Policy's coverage," the court held.

New York Appeals Court Holds Provider, Patient May Sue Insurer Under Prompt Pay Law

On March 5, the New York Supreme Court, Appellate Division, held the Prompt Pay Law created an implied private right of action by a health care provider or patient against an insurer that allegedly violated its obligations under the law.

Plaintiff is a not-for-profit hospital that provided services to six patients who assigned their Medigap benefits to plaintiff. The patients' Medigap polices were with defendant First United
American Life Insurance Company (First United). Plaintiff billed First United more than $19 million for services rendered to the patients but received only slightly more than $4 million.

Plaintiff sued to recover the balance, plus 12% interest per annum, alleging breach of contract, violation of the Prompt Pay Law, and unjust enrichment. Plaintiff also alleged First United never provided written notice, as required by the Prompt Pay Law, that it was not obligated to pay in full the amounts billed by plaintiff for services provided to the six patients.

First United moved to dismiss arguing the Prompt Pay Law provided no express or implied private right of action. First United further alleged only the New York Superintendent of Insurance could impose penalties for violation of the Prompt Pay Law, including an award of 12% interest per annum.

The trial court disagreed and held the New York Insurance Law § 3224 revealed an “express legislative intent to confer a private right of action upon the intended beneficiary patients and their providers to seek payment directly from an insurer.”

While disagreeing that the Prompt Pay Law “expressly” provided a private right of action, the appeals court did find an implied right of action under the statute. In reaching this conclusion, the appeals court noted the statute imposed specific duties on insurers like First United and created rights in patients and health care providers; “thus [militating] in favor of the recognition of an implied private right of action to enforce such rights.”

The appeals court noted the Prompt Pay Law was similar to other statutes where a private right of action was found in that it was not merely remedial in nature but gave health care providers and patients certain rights, including the right to full payment of the claim plus interest, and imposed an affirmative duty or obligation on insurers like First United to pay or dispute claims in a timely manner.

The appeals court also found support for its conclusion in the legislative history of the Prompt Pay Law.


U.S. Court in New Jersey Denies Renewed Motion to Certify Subscriber Class Alleging Insurer Used Flawed UCR Data

A federal trial court in New Jersey refused for a second time to certify a class of plan subscribers in an action alleging Cigna (defendant) violated the Employee Retirement Income Security Act (ERISA) and the Racketeer Influenced and Corrupt Organization Act (RICO) by relying on faulty data on usual, customary, and reasonable (UCR) amounts for reimbursing services performed by out-of-network (ONET) providers.

In a January 2013 decision, the U.S. District Court for the District of New Jersey denied the named plaintiffs ERISA class certification for failure to establish predominance and superiority, and for defining the class in an overly broad and indeterminate manner. The court also denied plaintiffs’ request for RICO class certification for failure to show defendant’s alleged wrongdoing could be established based on evidence common to the class. Franco v. Connecticut Gen. Life Ins. Co., No. 0-cv-6039 (SRC)(PS), (D.N.J. Jan. 16, 2013) (Franco I).

The court this time found while plaintiffs “correct[ed] some of the problems identified in Franco I,” including “injecting greater precision into the definitions of their two proposed classes” and “narrow[ing] the UCR language to two basic formulations widely used in the CIGNA plans during
the relevant time period,” they still failed to show the pared down classes “present common liability issues that will predominate over individual ones.”

Named plaintiffs are participants or beneficiaries of employer-sponsored health benefit plans that are insured and/or administered by Cigna. Plaintiffs had services performed by ONET providers.

Plaintiffs alleged Cigna violated its ERISA plan and statutory obligations when it made benefit determinations based on flawed UCR data that was contributed by major health insurance companies such as Cigna, self-funded groups, managed care organizations, and other payers. Plaintiffs sought relief for Cigna’s alleged misconduct of “systematically making UCR determinations that reduced the allowable amount without valid or compliant data to support such determinations.”

As to their RICO claims, plaintiffs alleged the insurance companies that contributed data to Ingenix were the same payers to which Ingenix sold the information for claims processing. Plaintiffs further alleged Ingenix did not audit its data despite knowing it was flawed and provided discounts to payers depending on the volume of data they provided to Ingenix.

Plaintiffs adequately narrowed the ERISA class definition in their second motion for certification to address issues raised in Franco I, but the court said the motion still failed under the stringent Fed. R. Civ. P. 23(b) predominance analysis.

The court zeroed in on the lack of a uniform UCR definition in the plans, and the fact the plans included multiple qualifiers, clauses, and administrator discretion that created “a fractured landscape for the ERISA claims of the putative class” and, therefore, “an inappropriate setting for class action litigation.”

Plaintiffs also failed to show predominance with respect to establishing injury on a classwide basis as they presented no evidence Ingenix data was consistently depressed or biased downward.

In addition, the court said plaintiffs failed to demonstrate damages could be tried without relying on individualized proof as to each class member and each ONET claim.

The court devoted “very little discussion” to the renewed attempt to certify a RICO class, as plaintiffs “have not demonstrated that either the occurrence of fraud or existence of any injury redressable by RICO could be proven as to the entire class based on common proof.”


**Ninth Circuit Finds Insurer May Exclude Coverage of Certain Device**

The Ninth Circuit May 8 found in an Employee Retirement Income Security Act (ERISA) action that an insurer’s exclusion of myoelectric prosthetics from a health insurance plan did not violate California Health & Safety Code § 1367.18.

In so holding, the appeals court agreed with the insurer that the statute did not require such coverage.

Plaintiff Martha Garcia was fitted while she was in high school for myoelectric upper-extremity prostheses. Since 2006, Garcia worked for the Regional Center of Orange County, which provided health care coverage through PacifiCare.

In 2009, Garcia’s myoelectric prostheses began to fail, and her physician submitted a replacement request to Memorial Healthcare, the independent practice association under contract
with PacifiCare for Regional Center employees. Memorial denied the physician’s request because “myoelectronic prosthetics are not a benefit covered under [Garcia’s] health plan.”

In January 2010, Garcia filed a grievance with the California Department of Managed Health Care, which “did not find a violation of the California health plan law regarding this issue.”

Garcia then sued under ERISA alleging PacifiCare’s benefit exclusion was contrary to Section 1367.18. The district court granted summary judgment to PacifiCare. Garcia appealed.

Although Garcia agreed the plan expressly excluded coverage for myoelectric prosthetic devices, she argued Section 1367.18(a) requires plans to cover any prosthetic device if it is medically necessary and prescribed by a physician.

Despite several amendments, PacifiCare argued Section 1367.18 always has required—and continues to require—that prosthetic coverage must be offered on terms and conditions mutually agreed upon, and that the relevant amendment made in 1991 only requires that whatever coverage is offered must extend to both original and replacement devices.

Garcia argued the 1991 amendment transformed the statute from a “mandate to offer” into a “mandate to cover.”

But the appeals court said the 1991 amendment “must be viewed in the context of the original statute because the legislature did not replace the 1985 language; it retained the original statutory language and added a new provision to it.”

“For this reason, the parties’ agreement that the original statute only required plans to offer coverage for prosthetics on mutually agreeable terms—an interpretation with which we agree—informs the meaning to be given to the amendment,” the appeals court explained.

Read in conjunction with the original language, the 1991 amendment only requires that, whatever type or types of prosthetic devices a plan offers to cover, the coverage must extend to original and replacement devices, the appeals court held.

The appeals court pointed out that one problem with Garcia’s interpretation was that Section 1367.18(a) retains language stating that plans “shall offer coverage” for prosthetic devices under terms and conditions that may be agreed upon by the group subscriber and the plan.

“If the legislature intended the 1991 amendment to transform the statute from a ‘mandate to offer’ into a ‘mandate to cover,’ as Garcia suggests, we can see no reason for retaining the original ‘mandate to offer’ language from the 1985 version of the statute,” the appeals court held.

Garcia v. PacifiCare of Cal., Inc., No. 13-55468 (9th Cir. May 8, 2014).

**Life Sciences**

**D.C. Circuit Finds Stem Cell Mixture Violated FDCA Manufacturing, Labeling Requirements**

The D.C. Circuit affirmed a lower court decision that three physicians and their corporation violated federal laws governing the manufacturing and labeling of drugs by mixing stem cells with an antibiotic as part of an orthopedic procedure they performed on patients.

The appeals court upheld a permanent injunction enjoining the defendants from further violating the law.
The case involves three physicians and their company, Regenerative Services, LLC, which developed a procedure to treat patients’ orthopedic conditions. The procedure involves extracting and isolating patients’ stem cells, cultivating the cells, combining them with an antibiotic, and then re-injecting the “mixture” at the site of the damaged tissue.

In August 2011, the government sought a permanent injunction against defendants arguing the mixture is a drug and a biological product that is adulterated and misbranded in violation Section 331(k) of the Federal Food, Drug & Cosmetic Act (FDCA) and Section 262(j) of the Public Health Service Act (PHSA).

The district court granted the government’s motions for summary judgment, finding defendants violated the FDCA and the PHSA and entered a permanent injunction to prevent further violations.

On appeal, the D.C. Circuit rejected defendants’ primary argument that the mixture is a medical procedure and therefore should not be regulated as a drug or biological product under the FDCA or PHSA.

According to the appeals court, the FDCA’s and PHSA’s broad definitions of a drug and biological product clearly encompassed the mixture, “an article derived mainly from human tissue and intended to treat orthopedic diseases and to affect musculoskeletal function.”

Defendants argued under Colorado law the procedure constitutes the “practice of medicine” and therefore should not be regulated under the FDCA. But the court disagreed, noting first that the Food and Drug Administration was not attempting to regulate the procedure used to administer the mixture, but the mixture itself and, second, “that the scope of the FDCA depends on state-by-state definitions of the ‘practice of medicine.’” Classifying the distribution of drugs by physicians as the practice of medicine essentially would “gut” the FDCA, the court observed.

The D.C. Circuit also agreed with First and Ninth Circuit precedent that the inclusion of the antibiotic, an ingredient that travelled in interstate commerce, brought the mixture within the scope of regulation under Section 331(k) and Section 262(j).

The appeals court also found the mixture did not qualify for a regulatory exemption from the FDCA’s manufacturing and labeling requirements as human cells, tissues, and cellular or tissue-based products (HCT/Ps) that are “minimally manipulated.” See 21 C.F.R. § 1271.10(a). Defendants had the burden of proving the regulatory exemption applied and failed to do so, the court found.

The appeals court also rejected defendants’ argument that the mixture was exempt from the FDCA’s requirements as a compounded drug.

Having concluded the FDCA’s manufacturing and labeling provisions applied, the appeals court next held the mixture was “adulterated” under the statute because defendants’ facilities and production methods did not conform with current good manufacturing practice. The appeals court also found the mixture “misbranded” because it failed to meet FDCA labeling requirements.

Finally, the appeals court upheld the permanent injunction, noting defendants admitted they did not improve their manufacturing process even after receiving warnings from the FDA.

Long Term Care

U.S. Court in Tennessee Refuses to Enjoin Nursing Facility’s Termination from Medicare, Medicaid

On May 31, the U.S. District Court for the Eastern District of Tennessee denied a preliminary injunction sought by Bristol Health Care Investors, LLC (Bristol), a nursing home facing termination from participating in the Medicare and Medicaid programs as a result of repeated non-compliance with patient quality and safety standards under federal conditions of participation.

According to the opinion, on May 1, CMS notified Bristol, which was designated as a Special Focus Facility in January 2012, that it “was not in substantial compliance with the participation requirements” of Medicare and Medicaid and that conditions “constituted immediate jeopardy and substandard quality of care” to patients. As a result, Bristol’s Medicare provider agreement would be terminated on May 15, 2013, and that Medicare and Medicaid payments for services rendered to those residents would continue “up to a 30 day period in order to facilitate the orderly transfer/relocation of residents.”

Bristol also was informed of its right to request a hearing before an administrative law judge of the Department of Health and Human Services. Bristol petitioned for and was granted a temporary restraining order in state court enjoining the Tennessee Department of Finance and Administration (Department) from revoking its Medicaid billing privileges, terminating its Medicaid provider agreements, or taking steps to relocate its Medicaid residents.

The Department removed the action to federal court, alleging Bristol’s healthcare claims arise under federal law, and the case presents federal questions. The federal district court agreed to extend the temporary restraining order entered by the state court until May 30.

After reviewing the previously filed affidavits and declarations and hearing oral arguments, the court found Bristol was not entitled to a preliminary injunction. First, Bristol could not demonstrate a strong or substantial likelihood or probability of success on the merits because it failed to exhaust its administrative remedies and therefore the court lacked subject matter jurisdiction. Bristol’s claims “arise under” the Medicare statute and must be channeled through administrative review procedures per Section 405(h) of the Social Security Act, the court said.

Citing a line of cases, Bristol argued the court could order preliminary injunctive relief to maintain the status quo while its administrative appeal was pending. But the Sixth Circuit rejected this argument in Cathedral Rock of N. College Hill, Inc. v. Shalala, 222 F.3d 354 (6th Cir. 2000), which found a dually certified nursing facility facing termination of its Medicare and Medicaid provider agreements could not seek a temporary restraining order in court before exhausting its administrative remedies.

The court then examined the other factors for granting a preliminary injunction, finding next that Bristol failed to show irreparable harm. Bristol argued its residents are ill and debilitated and that “involuntary relocation” could be harmful to them. Relying on the U.S. Supreme Court’s decision in O’Bannon v. Town Court Nursing Center, 447 U.S. 773, 787-90 (1980), the court held that alleged injuries to residents alone does not establish the kind of irreparable harm necessary for granting injunctive relief.
The court also rejected Bristol’s argument that facility staff would suffer irreparable harm absent the injunction. Instead, the court agreed with the Department that “staff can stand in no better position than the residents and that the staff, aside from its economic interest in employment at the facility, share the public interest that Medicaid and Medicare recipients receive appropriate care in a certified facility.” Finally, although termination of its agreement would have an adverse financial effect on Bristol, the court did not feel a negative business impact was sufficient to establish irreparable harm.

The court also considered the potential for substantial harm to the Department and to the facility’s residents if the status quo was preserved. Bristol argued the Department would suffer no harm because it had to pay for the care of the Medicaid recipients regardless of the facility where they resided. But the court said this argument missed the point that the potential for substantial harm arose from keeping the Medicaid recipients in a facility with a history of noncompliance with quality and safety standards and the recent identification of “immediate jeopardy” deficiencies and “actual harm” to residents. Further delay, in and of itself, in relocating the residents might well result in increased risk of harm to the residents, and as a result, to the Department, the court reasoned.

Finally, the court cited the clear public interest in having Medicare and Medicaid funds spent on quality care and in avoiding placing vulnerable populations at risk of harm.

Having weighed all four factors, the court denied the preliminary injunction and vacated the temporary restraining order.


**Fifth Circuit Vacates Order Holding CMS in Contempt**

The Fifth Circuit vacated July 17 a lower court’s contempt order put in place after it determined the government violated a preliminary injunction regarding Medicare and Medicaid payment to a nursing home. The appeals court found the government did not violate the preliminary injunction and thus the contempt order was improper.

After the Centers for Medicare & Medicaid Services (CMS) determined Oaks—a nursing facility—was no longer eligible to participate in the Medicare and Medicaid programs, the agency sent a letter dated April 9, 2010 informing Oaks that its “Medicare and Medicaid agreements [would] terminate May 9, 2010.”

On May 5, 2010, Oaks sued the government seeking injunctive relief and mandamus. The district court preliminarily enjoined the government from terminating Oaks. The government agreed to a temporary restraining order, which lapsed July 8, 2011.

On July 22, 2011, CMS contacted Oaks “to confirm that [Oaks] was terminated from participation in the Medicare/Medicaid programs effective May 9, 2010.” Between May 5, 2010 and August 9, 2011, the government paid Oaks over $2 million.

Oaks moved to initiate contempt proceedings, arguing it was not paid for services described in a 2010 cost report that it submitted in May 2011; the government discontinued Oaks’ access to CMS’ electronic billing system around July 22, 2011, denying it the ability to submit billing information for some services provided during the effective period of the injunction; and the government refused to pay for services provided after June 8, 2010.

The district court held the government in contempt “for failure to abide by the terms of the preliminary injunction previously issued in this case.” The contempt order required the
government to reimburse Oaks in the amount of $704,728 for services rendered during the effective period of the injunction.

The government appealed, arguing the injunction only required it to “delay . . . effectuation of the termination of a provider agreement,” and that it complied with this requirement.

The Fifth Circuit agreed with the government and reversed the contempt order. “[G]iven the showing required for a civil contempt order, contempt was appropriate only if Oaks proved, by clear and convincing evidence, that the Notice affected the government’s conduct while the injunction was in effect,” the court explained.

But Oaks had not made that showing because the injunction did not require the government “to pay for services,” but rather “forbids the government from ’refusing to pay’” based on the disputed notice to Oaks.

The appeals court found the government “[maintained] the status quo” during the effective period of the injunction: “a status quo in which Oaks would not have received full, non-preliminary payment for services rendered. Whether the government would have later made additional payments (but for the Notice) was beside the point; acting ‘on the basis of’ the Notice after the injunction lapsed is not contemptuous.”


**U.S. Court in Kansas Denies Temporary Restraining Order to SNF Facing Medicare, Medicaid Decertification**

On July 23, the U.S. District Court for the District of Kansas denied a skilled nursing facility (SNF) facing termination of its Medicare and Medicaid certification a temporary restraining order (TRO) because it failed to show it would suffer irreparable harm if the status quo was not preserved until its appeal could be heard through the appropriate administrative channels.

Plaintiff is an 82-bed skilled nursing facility that was certified to participate in Medicare and the Kansas Medicaid program. In the summer of 2013, the Kansas Department of Aging and Disability Services (KDADS) conducted complaint surveys at the SNF that identified deficiencies, including one that qualified as “immediate jeopardy.”

As a result, the Centers for Medicare & Medicaid Services (CMS) informed plaintiff that payment for new Medicare and Medicaid admissions would be denied starting July 13, and plaintiff’s Medicare agreement would be terminated on August 12. KDADS also issued its intent to revoke plaintiff’s license for failing to comply with Medicare and Medicaid participation requirements and informed plaintiff its Medicaid agreement likewise would be terminated on August 12.

Plaintiff appealed the survey deficiencies and KDADS’ intent to revoke its license and discontinue its Medicaid provider agreement. Plaintiff also requested that CMS consider alternative plans for facility performance improvement, opportunity to demonstrate corrective actions implemented, and additional time to address the deficiencies. CMS denied plaintiff’s requests and on July 10, plaintiff filed a request with the Department of Health and Human Services Departmental Appeals Board to expedite its appeal.

Plaintiff sought injunctive relief in federal court and filed a motion for an expedited hearing. The court denied plaintiff a TRO, but granted an expedited hearing on a preliminary injunction to address issues related to subject matter jurisdiction, the scope of plaintiff’s claims, and whether plaintiff had a right to a pre-termination hearing. The court set the hearing for July 25, 2013, “well in advance of the August 13, 2013 decertification date.”
In denying the TRO, the court found plaintiff failed to present evidence showing it would incur irreparable injury absent injunctive relief. According to the court, irreparable harm requires a plaintiff to show significant risk it will experience harm that cannot be compensated after the fact by monetary damages. In this case, plaintiff's argument that its patients would be harmed without the injunction was insufficient as the patients themselves did not have standing to challenge the federal and state agencies' decisions.

The court found unpersuasive plaintiff's economic argument that it would not be able to operate if decertification occurred on August 13 as plaintiff failed to provide evidence about the likelihood of an expedited hearing before then or how long it would take for plaintiff's facility to stop operating after decertification.

The court also pointed out it had to go beyond identifying plaintiff's alleged harm if an injunction was denied. According to the court, it also had to consider the potential damage to the adverse parties involved. In this case, the court found the risk of harm resulting from plaintiff's delayed hearing did not outweigh the government's interests in protecting elderly and disabled Medicare patients and minimizing the Medicare program's administrative expenses.


**U.S. Court in Ohio Dismisses Nursing Facility’s Challenge to Medicare, Medicaid Termination**

On August 6, the U.S. District Court for the Southern District of Ohio held termination of a skilled nursing facility’s (SNF’s) Medicare and Medicaid provider agreements was appropriate given its long history of Medicare noncompliance, failure to exhaust all administrative remedies, the low risk of erroneous deprivation, and the government’s interest in protecting Medicare beneficiaries.

In June 2013, the Department of Health and Human Services (HHS) notified plaintiff, a Medicare and Medicaid certified SNF, that the agency was terminating the facility’s Medicare provider agreement effective August 2, 2013 due to its documented history of noncompliance with Medicare requirements. When the Centers for Medicare & Medicaid Services (CMS) first moved to terminate plaintiff’s Medicare and Medicaid provider agreements in May 2012, the parties negotiated and entered into a Systems Improvement Agreement that gave plaintiff an additional year to “graduate” from its Special Focus Facility status. In consideration of continued Medicare and Medicaid reimbursement during the additional year plaintiff attempted to secure compliance, plaintiff waived its right to appeal to federal and state courts on any termination imposed as a result of surveys conducted during that additional year.

On June 21, 2013, plaintiff requested a hearing from an administrative law judge (ALJ) regarding HHS’ August 2 termination but later moved for an expedited hearing before the ALJ could rule on several motions. On June 22, plaintiff filed this action against HHS and Secretary Kathleen Sebelius, asserting the Secretary violated constitutional due process by failing to provide plaintiff with a hearing prior to termination of the agreements and that the doctrine of unconstitutional conditions prohibited the government from conditioning receipt of government benefits on waiver of constitutional rights. That same day, plaintiff filed its motion for a temporary restraining order requesting that its Medicare and Medicaid provider agreements not be terminated until all administrative hearings and judicial appeals were completed, and that CMS continue to reimburse plaintiff for Medicare and Medicaid services rendered until after such hearings and appeals took place.

On June 30, Secretary Sebelius filed a motion to dismiss for lack of subject matter jurisdiction. The court denied plaintiff's motion for a temporary restraining order and dismissed plaintiff’s claim for lack of subject matter jurisdiction.
The court relied on *Cathedral Rock of North College Hill, Inc. v. Shalala*, 223 F.3d 354 (6th Cir. 2000), concluding plaintiff, like the one in *Cathedral Rock*, failed to exhaust its administrative remedies as required by the Medicare Act, which requires plaintiff to channel all legal challenges through the Secretary’s administrative process before judicial review can be available. The court also held that claims dismissal predicated on the Medicare Act necessitated dismissal of Medicaid claims as well.

The court also found no exceptions to the exhaustion requirement in this case. Plaintiff’s private interest was “weak” as the facility was not the Medicare program’s intended beneficiary and the adverse economic impact plaintiff might experience as a result of the terminated agreements was incidental to the “purpose and design of the [Medicare] program,” the court said.

The court further held no exhaustion exception existed as risk was low regarding the “erroneous deprivation” of plaintiff’s private interest because the Secretary’s decision to terminate plaintiff’s provider agreements was well documented; was based on multiple survey reports conducted by unbiased health care professionals over a four-year period that applied well-defined criteria; and plaintiff had opportunity to submit written materials in response to the survey findings.

Finally, the court held no exhaustion exception existed for plaintiff because the Secretary’s responsibility to ensure elderly and disabled Medicare beneficiaries is of primary importance and the government has a strong interest in minimizing the program’s administrative expenses. According to the court, the government’s strong interest in an expeditious termination procedure against plaintiff outweighed plaintiff’s “less significant” private interest and the “relatively small risk for erroneous termination.” Consequently, plaintiff failed to make a colorable claim that it was entitled to a pre-termination hearing under the Due Process Clause.

The court also found it did not have jurisdiction under the Medicaid Act. Under 42 C.F.R. § 498.3(2)(I), “a Medicaid facility is treated as a Medicare provider subject to the Medicare administrative appeals procedures when it has agreed to participate in both Medicare and Medicaid and Medicare is the subject of a compliance action following review of a state’s survey findings.”

Finally, the court was not persuaded by plaintiff’s argument that a provision in the Systems Improvement Agreement, which required plaintiff to waive its rights to judicial review and to sue, constituted an unconstitutional condition. The court referenced several Supreme Court and Sixth Circuit cases that held “many constitutional rights may be knowingly and voluntarily waived as part of the settlement of disputes,” as was the case here.


**U.S. Court in New York Enjoins Termination of Nursing Home from Medicare**

With no evidence of immediate jeopardy to residents, the U.S. District Court for the Western District of New York enjoined the imminent termination of a nursing home’s Medicare provider agreement.

The court found the circumstances warranted granting Blossom South, LLC a preliminary injunction. Defendants in the action are the Department of Health and Human Services (HHS) Secretary and the New York State Commissioner of Health.

First, the court noted the real possibility that plaintiff could be put out of business before an administrative hearing was held. “The total destruction of a business has been held to constitute irreparable harm,” the court said.
The court also cited the likelihood of harm to plaintiff’s residents, who would have to be moved on short notice.

Next, the court found no likelihood of harm to defendants in granting the injunction, noting Medicare and Medicaid would likely be paying the same fees regardless.

“The balance of harms, then, weighs heavily in favor of plaintiff,” the court concluded.

The court also was moved by the fact that the most recent state survey documented no “immediate jeopardy” violations and, as recently as May 2013, an HHS official indicated plaintiff was “in substantial compliance” with federal and state requirements.

Noting “serious questions” about the merits, the court said “defendants have precipitously ordered the closure of Blossom South, in a short time frame, notwithstanding the steady improvement in [its] performance as reflected in recent surveys.”

The court acknowledged concerns about the deficiencies cited at plaintiff’s facility and therefore ordered Blossom South to continue to implement its current plan of correction.

The court plans to consider oral arguments on whether to extend the preliminary injunction on October 8. In the meantime, the court prohibited defendants from terminating plaintiff’s provider agreement; requiring plaintiff to submit a closure plan; taking any steps to relocate residents; denying payments for new Medicare/Medicaid admissions, or for existing residents; and preventing plaintiff from admitting residents.


**U.S. Court in New York Rejects Nursing Home’s Challenge to Medicare Termination**

A nursing home challenging the termination of its Medicare provider agreement lost on the merits of its claims after a federal district court in New York determined December 17, 2013 that a pretermination hearing was not required to satisfy due process.

The court also found the Department of Health and Human Services (HHS) Secretary did not violate the Administrative Procedure Act (APA) by implementing a special program to focus on facilities with a history of noncompliance with federal requirements.

The U.S. District Court for the Western District of New York in August 2013 agreed to enjoin the imminent termination of Blossom South, LLC’s Medicare provider agreement citing the real possibility that it could put the facility, located in Rochester, NY, out of business and harm residents who would have to be moved on short notice. The court also was moved by the fact that the most recent state survey documented no “immediate jeopardy” violations.

At that time, the court prohibited defendants, the HHS Secretary and the New York State Commissioner of Health, from terminating plaintiff’s provider agreement; requiring plaintiff to submit a closure plan; taking any steps to relocate residents; denying payments for new Medicare/Medicaid admissions, or for existing residents; and preventing plaintiff from admitting residents. _Blossom South, LLC v. Sebelius_, No. 13-CV-6552L (W.D.N.Y. Aug. 30, 2013).

On November 27, 2013, an Administrative Law Judge heard Blossom’s administrative appeal, upheld survey deficiency findings, and sustained the termination decision.

After determining it had subject matter jurisdiction to hear the case under the “entirely collateral” exception to the exhaustion requirement, the court found the complaint failed on the
merits, agreeing with other courts to consider the issue that nursing facilities, like Blossom, have no constitutional right to a hearing before the termination of their Medicare or Medicaid provider agreement.

“[T]he Due Process Clause generally requires only notice and an opportunity to be heard; it does not mandate either the availability or completion of any appeals before the deprivation of a protected interest,” the court observed.

The court also found “meritless” Blossom’s contention that it was not given adequate notice of the requirements to avoid termination. According to the court, the record, which included extensive notice of the alleged deficiencies and the implications of failing to correct them, proved otherwise.

Citing again to extensive case law on another challenge Blossom advanced, the court held the Secretary acted within her authority in adopting regulations that allow termination of a Medicare provider agreement absent a finding of immediate jeopardy.

Finally, the court rejected Blossom’s claim that the Secretary violated the APA in adopting the Special Focus Facility (SFF) program without notice and comment rulemaking. Blossom was designated as a SFF in March 2011. Nursing homes designated as SFFs are subject to heightened scrutiny under HHS rules.

In the court’s view, the SFF program was not “substantive” or “legislative” rulemaking subject to notice and comment APA requirements. According to the court, the SFF program “constitutes no more than a set of procedural rules,” which do not change the substantive nursing home participation requirements.

Nursing homes designated as SFFs “may be subject to heightened scrutiny, but they are not required to meet more stringent substantive requirements than other nursing homes,” the court observed.


Sixth Circuit Upholds CMP Imposed on SNF

On September 6, the Sixth Circuit affirmed the imposition of a three-month civil monetary penalty (CMP) of over $4,000 per day on a skilled nursing facility (SNF) for noncompliance with Medicare and Medicaid participation requirements.

Plaintiff Life Care Center of Bardstown is a SNF that participates in the Medicare and Medicaid programs. In April 2007, the Centers for Medicare & Medicaid Services (CMS) found plaintiff was in substantial non-compliance with several participation requirements that put resident health and safety in “immediate jeopardy.”

The January 3, 2007 death of one of plaintiff’s residents was central to CMS’ finding of non-compliance with three participation requirements: the physician consultation requirement under 42 C.F.R. § 483.10(b)(11); the quality of care requirement under 42 C.F.R. § 483.25; and the facility administration requirement under 42 C.F.R. § 483.75. As a result, CMS imposed a CMP of $4,050 per day, effective January 3, 2007 through March 27, 2007.

Plaintiff appealed to an administrative law judge (ALJ) in July 2008 who initially found plaintiff substantially complied with 42 C.F.R. §§ 483.10(b)(11), 483.25, and 483.75, thereby making the CMP unwarranted. CMS appealed the ALJ’s decision to the Department of Health and Human Services Departmental Appeals Board (DAB), which vacated the ALJ’s initial decision and remanded so that the ALJ could address conflicting evidence. On remand, the ALJ upheld CMS’
findings and further upheld the $4,050 CMP per day. The DAB sustained the ALJ’s final decision and plaintiff appealed to the Sixth Circuit.

The appeals court upheld the ALJ’s final decision that plaintiff did not comply with the physician consultation requirement as plaintiff’s nurse who was taking care of the now deceased resident failed to contact a physician when the resident vomited a second time in one night. According to the physician consultation requirement, “a facility must immediately inform the resident, consult with the resident’s physician . . . when there is . . . [a] significant change in the resident’s physical, mental, or psychosocial status.” In this case, the nurse’s failure to contact the resident’s physician following the second vomiting incident constituted a failure to substantially comply with 42 C.F.R. § 483.10(b)(11).

The appeals court further upheld the ALJ’s final decision regarding plaintiff’s noncompliance with the quality of care requirement as plaintiff failed to implement the physician’s order that the resident’s oxygen saturation levels be taken daily. Under 42 C.F.R. § 483.25, “[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.” According to the DAB, this quality of care standard requires facilities to “carry out every applicable [physician] order and ensure the sufficiency of resident care plans . . . .” In this case, the appeals court found plaintiff’s failure to comply with the physician’s order constituted a failure to substantially comply with the quality of care requirement.

The facility administration requirement provides that facilities “must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being for each resident.” The appeals court affirmed the ALJ’s final determination, stating that because plaintiff failed to substantially comply with both the quality of care and physician participation requirements, it also violated the facility administration requirement.

In January 2007, CMS found plaintiff complied with the facility administration requirement; plaintiff therefore argued the ALJ’s final determination of noncompliance was not sound. The appeals court disagreed, stating a mere finding by CMS that plaintiff’s policy complied with the facility administration requirement did not also mean all of plaintiff’s staff were properly trained to administer that policy. In this case, for example, the nurse’s training was deficient as she failed to immediately notify the resident’s physician when the resident’s condition worsened.

The appeals court upheld the CMP duration as plaintiff failed to show “a definite and firm conviction that the Secretary committed a clear judgment error in reaching its conclusion . . . .” In this case, CMS did not deem the “immediate jeopardy canceled” until plaintiff conducted additional in-services regarding physician notification, documentation, and carrying out of physician orders.

Life Care Ctr. of Bardstown v. Secretary of Dep’t of Health and Human Servs., No. 12-4420 (6th Cir. Sept. 6, 2013).

U.S. Court in Wyoming Allows Negligence, Punitive Damages Claims Against Nursing Home to Go Forward

The U.S. District Court for the District of Wyoming refused November 1 to dismiss negligence per se and punitive damages claims against a nursing home, finding the plaintiff was able to support her allegations with facts sufficient to sustain her claims at this point in the litigation.

Plaintiff Susan Feinman, as personal representative of the Estate of Theresa Jo Witt, filed a negligence action against defendant Kindred Healthcare, Inc. alleging Witt suffered injuries
during her stay at defendant’s Sage View Care Center nursing home. Defendant moved to
discard plaintiff’s negligence per se claim and her request for punitive damages.

Plaintiff claimed defendants violated at least 24 U.S. Department of Health and Human Services
regulations falling within 42 C.F.R. pt. 483 and one Wyoming Department of Health Aging
Division regulation and alleged the violation of these regulations constituted negligence per se.

Defendants argued plaintiff could not circumvent the lack of a private right of action under those
regulations by bringing a negligence per se claim, but the court found this argument “misplaced.”

Because Witt’s alleged injuries were of the type the regulations were intended to prevent and
Witt belonged to the class of persons the regulations were intended to protect, the court “may
adopt those regulations as the Defendants’ standard of care,” the opinion said.

Defendants next argued plaintiff failed to allege sufficient facts to support a punitive damages
award. But the court pointed out that “the allegations as a whole indicate a continuing course of
conduct that lasted for nearly two years during which Ms. Witt was injured, ignored, and allowed
to physically decline.”

Accordingly, the allegations in the complaint “cross the threshold of making a plausible claim for
punitive damages,” the court held.

The court also said it would allow plaintiff to pursue punitive damages under her respondeat
superior cause of action, rejecting defendants’ argument that plaintiff failed to allege any facts in
support of this claim.

Instead, the court found defendants’ alleged control of the facility and the ongoing nature of
defendants’ alleged misconduct gave rise to the inference that defendants either authorized the
doing and manner of their agents’ actions or that they approved of the acts.


U.S. Court in Pennsylvania Finds No Private Right of Action Under Federal
Nursing Home Reform Act

On November 7, the U.S. District Court for the Western District of Pennsylvania held that
Congress did not intend to create a private remedy or private cause of action under the Federal
Nursing Home Reform Act (FNHRA).

Plaintiff Solomon White sued defendant Jewish Association on Aging, among others, alleging the
nursing facility it operates violated the FNHRA by requiring him to become a third-party financial
guarantor for his mother’s bills as a condition of admitting her.

Defendant argued plaintiff lacked standing to to enforce the FNHRA. Alternatively, defendant
contended even if plaintiff had standing, he failed to state a claim under the FNHRA as he was
not a guarantor under the admissions agreement. According to defendant, plaintiff’s consent to
become the responsible party as defined in the nursing home’s admissions agreement simply
meant he was obligated to apply his mother’s financial resources (her income and assets) to pay
for her care, and he would only be personally liable if he misappropriated his mother’s funds.

The court noted the Third Circuit has found the FNHRA is not enforceable via an action under 42
U.S.C. § 1983, but has not ruled on whether there is a direct cause of action.
After analyzing relevant case law, the court held FNHRA does not implicitly create a cause of action against a private nursing facility as Congress did not intend to create a private remedy under the Act.

Even if plaintiff could assert a FNHRA violation, he still failed to state a claim for relief because the agreement he signed did not create a guarantor obligation, nor violate the relevant regulation, the court said.

The court also held defendant’s method of assessing charges did not violate 42 C.F.R. § 483.10(b)(5) and (6), which sets forth requirements that nursing facilities must comply with to participate in Medicare and Medicaid. The court ruled that the regulation does not create a private cause of action in light of Third Circuit precedent.

The court declined to exercise supplemental jurisdiction over plaintiff’s state claims.


U.S. Court in South Carolina Refuses to Enjoin Termination of Nursing Home’s Medicare Provider Agreement

A federal trial court in South Carolina denied November 13 a preliminary injunction to a nursing home that argued it was entitled to a pre-deprivation hearing before the Department of Health and Human Services (HHS) terminated its Medicare provider agreement.

The court acknowledged the nursing home could suffer potential irreparable harm without injunctive relief, but found plaintiffs “have not and cannot make the requisite ‘clear showing’ of likelihood of success on the merits of their procedural due process claim seeking a pre-termination hearing.”

Marion Nursing Center, Inc., a Medicare and Medicaid provider, sought injunctive relief after receiving notice that HHS was terminating its Medicare provider agreement following survey findings of substandard conditions at the nursing home that posed “immediate jeopardy” to resident health and safety.

Marion initiated an administrative appeal of the findings and also filed the lawsuit to block the termination of its provider agreement pending the outcome of the administrative process. Marion alleged, among other things, a violation of its due process for failure to provide a pre-termination hearing.

While agreeing the court had subject matter jurisdiction because the exhaustion requirement was waived with respect to its procedural due process claim, the U.S. District Court for the District of South Carolina refused to grant injunctive relief because Marion failed to show a substantial likelihood of success on the merits.

Marion did have a property right in its Medicare/Medicaid provider agreements, but “it is equally well established that property interests of this sort rarely, if ever, merit the protection of a pre-termination or pre-deprivation hearing,” the court said.

Moreover, the “general rule that pre-deprivation hearings are not required to satisfy procedural due process has been applied in the specific Medicare provider context of this case,” the court observed.
The court agreed Marion, whose residents included a substantial percentage of Medicare and Medicaid beneficiaries, could suffer irreparable harm if its provider status was terminated without an administrative hearing. The potential for irreparable harm, however, was outweighed by Marion’s inability to show a likelihood of success on the merits, the Secretary’s interest in ensuring the safety of Medicare patients and properly administering the program, and the public’s interest in the “efficient, safe and economical administration of a large public program.”


**Seventh Circuit Affirms Dismissal of Nursing Home’s Lawsuit Involving Mistaken Star Rating**

The Seventh Circuit agreed April 7 with a lower court that a nursing home was not entitled to a hearing to challenge deficiencies that led to a mistaken Centers for Medicare & Medicaid Services (CMS) star rating.

Plaintiff Bryn Mawr Care operates a nursing home in Chicago occupied exclusively by Medicaid patients. The Illinois Department of Public Health (IDPH) surveyed the facility and provided plaintiff written notice of several deficiencies.

Plaintiff initially challenged the deficiencies through informal dispute resolution, but eventually opted to “correct” the alleged “deficiencies” under a “plan of correction,” the opinion said. IDPH ultimately imposed no remedies on plaintiff, however, after it determined the deficiencies had been cured. The deficiency findings remained on plaintiff’s record.

CMS mistakenly rated the nursing home as two, rather than four stars, and the rating was posted on the agency’s website for two years. The nursing home argued the mistake damaged its reputation and cost it patients.

Plaintiff sued the Department of Health and Human Services Secretary in her official capacity and the Acting Director of IDPH alleging violations of federal Medicaid regulations and its procedural due process rights under the Fifth and Fourteenth Amendments.

Both defendants moved for summary judgment, which the U.S. District Court for the Northern District of Illinois granted, finding plaintiff was not entitled to a hearing to challenge the deficiency findings. *Bryn v. Sebelius*, No. 11 C 734 (N.D. Ill. Sept. 26, 2012).

On appeal, plaintiff argued it was entitled to a hearing before a state administrative law judge because the record of the alleged deficiencies and the mistaken star rating amounted to a “public shaming” that constituted an “other alternative remedy” under applicable regulations.

But the appeals court found the Secretary’s interpretation of the regulations on this point was not plainly erroneous or inconsistent and therefore rejected this argument.

The appeals court also held plaintiff did not have a constitutional right to a hearing because it failed to show a change in legal status in addition to its alleged reputational harm. Plaintiff argued its rights were altered in three ways—that it now was exposed to the potential of enhanced penalties based on past noncompliance; that it no longer had the opportunity to correct “actual harm” deficiencies before remedies were imposed; and that past non-compliance would be factored into its ratings.

But the appeals court held plaintiff failed to show any of its legal rights were altered for purposes of constitutional due process.
“Bryn Mawr has been stigmatized, and as a facility completely filled with Medicaid patients, it is at the mercy of regulators entrusted by statute with enormous discretion,” the appeals court commented.

“However, Bryn Mawr has failed to show that any of its rights have been altered. At worst, regulators may keep a stigmatizing record of noncompliance to guide the exercise of their discretion,” but this does not amount to a due process violation, the appeals court held.

*Bryn Mawr Care, Inc. v. Sebelius*, No. 12-3678 (7th Cir. Apr. 8, 2014).

**U.S. Court in Illinois Holds Federal Nursing Home Reform Act Does Not Create Private Right of Action**

A federal district court in Illinois rejected May 12 a lawsuit brought by a nursing home resident against Alden Long Grove Rehabilitation and Health Care Center, Inc. after the facility discharged her involuntarily. The court held the federal Nursing Home Reform Act (NHRA) did not create a private right of action or a private remedy.

The U.S. District Court for the Northern District of Illinois also found plaintiff Theresa Schwerdtfeger could not maintain a due process claim against the Director of the Illinois Department of Health (Department) because plaintiff failed to avail herself of the state process in place for reviewing her discharge.

The court declined to exercise supplemental jurisdiction over plaintiff’s state law claim and dismissed the case.

Plaintiff was a resident of Alden, a private nursing home, starting in 2007. In August 2012, Alden staff told plaintiff she had to leave the facility and issued an Emergency Notice of Involuntary Transfer or Discharge (IVD), citing the safety of individuals in the nursing home as the reason.

Plaintiff requested an administrative hearing with the Department. The administrative law judge reviewing the action ultimately dismissed the case after Alden withdrew the IVD. Alden did not, however, readmit plaintiff to the facility.

Plaintiff sued Alden and its administrator, Lesley Hieras, alleging her discharge from the facility violated the NHRA. She also asserted a due process claim against the Director of the Department, Lamar Hasbrouck, in his official capacity for failure to ensure she received a proper administrative hearing upon her discharge. Defendants moved to dismiss.

As to Alden and Hieras, the court agreed with their argument that the NHRA does not create private rights or remedies that are enforceable by an individual.

While the NHRA speaks in terms of “transfer and discharge rights,” these statutory provisions are aimed at imposing obligations on the nursing homes, and the federal and state governments that oversee them, not at creating rights enforceable by nursing home residents themselves, the court said.

Even assuming the NHRA provisions created private rights in favor of nursing facility residents, the statute does not provide a private remedy, the court added. The NHRA instead calls for “separate administrative enforcement mechanisms” in state court, which signal congressional intent to preclude other enforcement methods.

The court also discounted plaintiff’s reference to cases finding private rights of action under other Medicaid provisions. In those cases, the defendants were state actors subject to the remedies
created by 42 U.S.C. § 1983. Alden, as a private nursing facility, is not a state actor subject to Section 1983, the court said.

Finally, the court dismissed plaintiff's due process claim against Hasbrouck, noting she failed to pursue an appeal of the administrative decision in state court. That appeal, the court observed, would have reviewed the adequacy of the administrative process she received, not whether the discharge itself was proper.

_Schwerdtfeger v. Alden Long Grove Rehabilitation and Health Care Ctr., Inc.,_ No. 13C8316 (N.D. Ill. May 12, 2014).

**Medicaid**

**Iowa Supreme Court Reverses State Agency’s Disallowance of Certain Costs from Nursing Home Cost Reports**

The Iowa Supreme Court found June 28 the state health agency erroneously interpreted its rules on certain Medicaid reimbursement. According to the high court, the agency’s abrupt change of heart regarding its enforcement of the rules was improper and not supported by the text of the relevant statute.

Several nursing homes submitted an annual report disclosing their income and expenses to the Iowa Department of Human Services (DHS), which is used by the agency to calculate a Medicaid per diem reimbursement rate for each participating facility.

In submitting their cost reports for the fiscal year ending December 31, 2008, some long term care facilities (plaintiffs) included costs incurred for services provided to residents whose primary source of payment was Medicare Part A. DHS deemed some of these costs disallowed, which was a departure from prior practice.

Until the 2008 adjustments, DHS allowed the facilities to include in the cost reports the costs paid to third parties for lab services, x-rays, and prescription drugs provided to Medicare patients. Plaintiffs appealed the adjustments and an administrative law judge concluded the nursing homes properly reported the costs.

After the DHS director issued a final decision disallowing the costs, plaintiffs sought judicial review. The district court affirmed the disallowance, but the appeals court reversed, concluding DHS’ rules did not support the agency’s determination that the costs in question were not allowable. DHS appealed.

After reviewing the text of the state rules at issue and the director’s interpretation of them, the state high court concluded: “Given the agency’s abrupt about-face in its practice regarding exclusion of certain costs from reports, and the substantial disparity between what the rules plainly say and what the director now suggests they mean, we think DHS’s new interpretation of rule 81.6’s cost reporting and per diem calculation procedures is akin to the creation of a new rule.”

Accordingly, the high court found the director’s conclusion affirming the agency’s exclusion of the facilities’ lab, x-ray, and prescription drug costs from the nursing homes’ reports was erroneous.
Instead, the high court affirmed the decision of the appeals court. The high court instructed the district court to “enter judgment remanding this matter to DHS for further proceedings consistent with this opinion.”

Sunrise Retirement Community v. Iowa Dep’t of Human Servs., No. 11-1145 (Iowa June 28, 2013).

Ninth Circuit Says Medi-Cal Coverage Limits Violate Medicaid Requirements for FQHCs, RHCs

On July 5, the Ninth Circuit held a California law eliminating Medi-Cal coverage of certain healthcare services, including those provided by dentists, podiatrist, optometrists, and chiropractors, conflicted with a provision of the Medicaid Act, 42 U.S.C. § 1396a(bb), obligating state plans to reimburse services furnished by federally qualified health centers (FQHCs) and rural health clinics (RHCs).

In so holding, the appeals court found FQHCs and RHCs have a private right of action to challenge the state law under 42 U.S.C. § 1983. The appeals court also concluded the Medicaid Act was unambiguous in requiring state plans to reimburse FQHCs and RHC for a broader category of “physicians services,” as defined in the Medicare statute, than the narrower category of services rendered by medical and osteopathic physicians.

Facing a budget crisis, California enacted in February 2009 legislation, Cal. Welf. and Inst. Code § 14131.10, eliminating certain Medi-Cal benefits, including adult dental, podiatry, optometry, and chiropractic services, it deemed optional. As a result, the state’s Department of Health Services (Department), which administers Medi-Cal, submitted a state plan amendment (SPA) to the Centers for Medicare & Medicaid Services (CMS). While awaiting CMS approval, the Department discontinued reimbursement for the services.

The California Association of Rural Health Clinics and Avenal Community Health Center, an FQHC, (collectively, the Clinics) sought declaratory and injunctive relief in district court to stop implementation of Section 1413.10, arguing the statute violated federal Medicaid requirements and therefore was preempted. The Clinics also contended the Department violated federal law by failing to obtain SPA approval before discontinuing reimbursement.

The district court found Section 1413.10 was consistent with federal law, but granted the Clinics declaratory relief on the SPA claim and enjoined further enforcement of the statute pending CMS approval. After the district court entered judgment but prior to appeal, CMS approved the SPA with a July 1, 2009 retroactive effective date.

On appeal, the Department argued Congress did not intend to confer on the Clinics a private right of action to challenge state law as violating Section 1396a(bb).

The appeals court disagreed, finding the language in Section 1396a(bb)(1), which provides a state plan “shall provide for payment for services . . . furnished by a [FQHC] and services . . . furnished by a [RHC] in accordance with the provisions of this subsection,” showed Congress intended to “confer individual rights” upon the Clinics with specific rights-creating language.

The appeals court reasoned the statutory text specifically referred to RHCs and FQHCs, making the Clinics named beneficiaries; the Clinics’ right to payment for services was neither “vague nor amorphous” as the statute plainly required state plans like Medi-Cal to pay for services furnished by FQHCs and RHCs; and the statute clearly imposed a mandatory obligation on the state plans to pay for RHC and FQHC services.
Turning to the question of whether the California law violated the Medicaid Act, the appeals court declined to accord *Chevron* deference to CMS’ approval of the SPA. The Department argued CMS' approval amounted to an implicit finding that the state law, which interpreted the Medicaid Act as permitting reimbursement to RHCs and FQHCs for only those physicians’ services performed by medical or osteopathic doctors, did not violate federal requirements. But the appeals court determined Congress unambiguously defined the scope of physicians services for which the Clinics must be reimbursed, and therefore no deference was due CMS’ approval of the SPA.

The parties' conflicting interpretations centered on which source of law—Medicaid or Medicare—defined “physicians’ services” for which RHCs and FQHCs are entitled to reimbursement. The Clinics argued Medicare’s expansive definition controlled because in defining RHC and FQHC services, the Medicaid Act specifically refers to the Medicare Act, which defines a physician as a medical doctor, osteopathic doctor, dentist, podiatrist, optometrist, or chiropractor. The Department, on the other hand, argued Medicaid’s narrower definition of physician—a medical doctor or osteopath—controlled as “there was no basis” for referring to Medicare’s definitions to determine what Medicaid requires.

The appeals court agreed with the Clinics, pointing out the Medicaid statute specifically requires coverage for RHC and FQHC services and, *separately*, for physicians’ services furnished by a physician. With respect to RHC and FQHC services, the Medicaid Act unambiguously references the Medicare statute. As a result, the RHC services and FQHC services Medicaid requires states to cover are “coequal” to those services as defined by the Medicare statute. “Medicaid imports the Medicare definitions wholesale,” which define the Clinics services to include those provided by dentists, podiatrists, optometrists, and chiropractors in addition to those provided by medical or osteopathic physicians.

Lastly, the appeals court held CMS’ approval of the SPA rendered the Department’s cross-appeal moot. The appeals court reversed without discussion, however, the district court’s ruling that the Clinics had a private right of action to challenge the Department’s implementation of the SPA before CMS’ approval.


**U.S. Court in Arizona Upholds HHS’ Approval of Arizona Medicaid Demo with Higher Copayments**

A federal court in Arizona granted July 23 summary judgment to the Department of Health and Human Services (HHS) Secretary in a class action challenging the approval of an Arizona Medicaid demonstration that increased cost-sharing on low-income childless adults who would otherwise not be eligible for the program.

The court in February remanded to HHS to reconsider its approval of the demo. See *Wood v. Betlach*, No. CV-12-08098-PCT-DGC (D. Ariz. Feb. 6, 2013). The Secretary in April confirmed her approval of the demo.

The U.S. District Court for the District of Arizona found this time that the Secretary adequately considered the necessary factors before approving the demo and therefore her decision was not arbitrary or capricious.

Plaintiffs are a class of “medically needy” Arizonans who receive coverage through the state’s Medicaid agency, the Arizona Health Care Cost Containment System (AHCCCS), under a Section 1115 waiver.
In 2003, AHCCCS sought to modify the existing demo to increase mandatory cost sharing on this “expansion population” for doctor’s visits, non-emergency use of emergency rooms, and prescription drugs. HHS approved the modification. The demo was set to expire at the end of September 2011. In October 2011, HHS approved a new demonstration project, which continued to cover the expansion population and also included the higher copayment requirements.

Plaintiffs challenged the 2003 modification as a violation of the Medicaid Act. The Ninth Circuit held the increased mandatory copayments did not violate Medicaid cost-sharing restrictions because plaintiffs were part of an “expansion population.” *Newton-Nations v. Betlach*, No. 10-16193 (9th Cir. Aug. 24, 2011).

But the Ninth Circuit went on to find the cost-sharing requirements did not comply with Section 1115 because the Secretary failed to consider certain factors before granting a waiver, including whether a “project has a research or a demonstration value.” On remand, the district court found the Secretary’s 2003 approval of the modified copayments had expired and “the copayments currently in effect are due to a new program based on a new administrative record.” Accordingly, the court found the case moot.

Plaintiffs then filed the instant action, challenging HHS’ 2011 approval of the new demonstration project, arguing, among other things, that the Secretary violated the Administrative Procedure Act (APA).

The court in its previous decision determined the Secretary violated the APA by not addressing in the administrative record plaintiffs’ objections to the higher copayments—namely, an expert opinion they offered suggesting the impact of cost-sharing on low-income populations has been widely studied and the demo was unlikely to yield any new information or result in substantial savings for the state.

Following the HHS Secretary's April 2013 approval decision, both parties again moved for summary judgment.

Granting judgment in the Secretary’s favor, the court this time found she adequately considered whether the project had a research or a demonstration value.

Specifically, the Secretary stated the demo “will address existing gaps in the research or otherwise strengthen the research literature on cost sharing with respect to low-income adults by testing the impact of the childless adults’ copayments on access, outcomes, and costs of care.”

“Plaintiffs may disagree with the Secretary’s conclusion, but the Secretary has demonstrated that her consideration of the project’s experimental purpose was not arbitrary and capricious.”

The court likewise found the Secretary’s determination that the demo as a whole furthered the objectives of the Medicaid Act—i.e., that the demo provides plaintiffs with medical benefits they would not otherwise be eligible for—was not arbitrary and capricious.


**U.S. Court in Wisconsin Finds State’s Medicaid Lien Statute Conflicted with Federal Law**

On July 19, the U.S. District Court for the Western District of Wisconsin held a federal statute, 42 U.S.C. § 1396p, which limits the circumstances under which state and local governments can impose a lien on property or otherwise attempt to recover Medicaid expenses from a recipient, preempted a state statute that allowed a government entity to impose a lien on a settlement that the recipient obtained related to his or her injury, illness, or death.
Defendant Portage County of Wisconsin paid plaintiff $35,000 in Medicaid assistance benefits for medical expenses incurred from a car accident. When plaintiff also obtained a $25,000 settlement from his insurance company, defendant sought $12,500 in reimbursement under Wis. Stat. § 49.89(5). Plaintiff sought declaratory relief, contended Section 49.89(5) conflicted with Section 1396p, and that defendant was entitled to a much lower amount.

The court granted in part plaintiff’s motion for summary judgment, finding Section 1396p preempts the portion of Section 49.89(5) that allocates medical expenses in a settlement. Plaintiff’s motion was denied with respect to his request for an allocation of medical and nonmedical expenses and his request for attorney fees. The parties also were directed to schedule a hearing date to determine how plaintiff’s settlement should be allocated.

In this case, Section 49.89(5) would allow defendant to have a lien on the settlement plaintiff obtained that would be equal to the amount of medical assistance provided as a result of plaintiff’s injury. Defendant contended Section 49.89(5) would allocate the settlement so that collection and attorney fees were deducted first, followed by the amount of assistance granted as a result of plaintiff’s injuries, with the remainder being paid to the plaintiff.

The parties agreed the $12,500 should be allocated to attorney fees; however, defendant argued it was entitled to the remaining $12,500 of the $25,000 insurance settlement under Section 49.89(5) as it paid $35,000 in medical expenses on plaintiff’s behalf. Plaintiff countered Section 49.89(5) conflicted with Section 1396p and therefore was preempted.

Defendant argued the state was entitled to determine how a settlement allocates medical and nonmedical expenses when there is no express allocation in the settlement or no stipulation between the government and the beneficiary. Defendant further argued Section 49.89(5) allocated all of a settlement for attorney fees and medical expenses unless the settlement was greater than the total of those two amounts. In this case, according to defendant, applying Section 49.89(5) was not inconsistent with Section 1396p because it paid more than $12,500 of medical expenses on plaintiff’s behalf.

Plaintiff disagreed, contending the pro-rata allocation method used in Arkansas Dep’t of Health and Human Servs. v. Ahlborn, 547 U.S. 268 (2006), should be applied, which would require the court to determine the total value of plaintiff’s claim, divide that total value by the amount of the settlement, and multiply the amount defendant paid by the resulting fraction.

During plaintiff’s suit against defendant, the Supreme Court decided Wos v. E.M.A. ex rel. Johnson, 133 S.Ct. 1391 (2013), which held Section 1396p preempted a North Carolina statute that defined the portion of the settlement that represents payment for medical expenses as the lesser of the state’s past medical expenditures or one-third of the plaintiff’s total recovery. The Supreme Court held the North Carolina statute failed to provide a process for determining what portion of a beneficiary’s tort recovery was attributable to medical expenses.

According to the court in the instant case, Section 49.89(5) was no different from the North Carolina statute as Section 49.89(5) not only failed to provide an individualized procedure for allocating medical and nonmedical expenses, but allocated all settlements minus attorney fees for medical expenses unless the settlement exceeded the amount owed to the defendant.

Defendant attempted to distinguish the North Carolina statute from Section 49.89(5) as the former picked an arbitrary percentage of damages allocable to medical expenses. The court was not persuaded as defendant’s number of 100% of settlement not devoted to attorney fees was just as arbitrary as North Carolina’s cap at 33.33%.

Defendant also argued Section 49.89(5) did not require a beneficiary to pay 100% of his settlement in all cases because the actual amount deducted for medical expenses depended on
costs, fees, the amount of the settlement, and the amount of funds available. Again, the court
was not persuaded and pointed out the North Carolina statute in Wos required the beneficiary to
use his settlement to pay the state all of what he owed but that amount could not exceed one-third of the settlement. In this case, Section 49.89(5) allocated as medical expenses the lesser of
defendant’s past medical expenses or 100% of the plaintiff’s total recovery minus attorney fees.

In determining how plaintiff’s settlement should be allocated, the court held plaintiff’s “modest
appraisal” using the Ahlborn pro-rata allocation method was inadmissible as the only evidence
plaintiff provided for his estimate was a conclusory affidavit from his attorney. Citing a Seventh
Circuit case, the court held plaintiff’s counsel was ethically prohibited from acting as a witness in
his own case. The court also stated because defendant and plaintiff could not agree on allocation,
there was no stipulation or determination by the court regarding allocation, and the state of
Wisconsin did not provide a mechanism for resolving such disputes administratively, the court
was required under Wos to hold a hearing on the matter.


**Third Circuit Sets Aside HHS Approval of Nursing Facilities Medicaid Rate
Reductions in Pennsylvania**

The Department of Health and Human Services (HHS) improperly approved a Pennsylvania state
plan amendment (SPA) that reduced Medicaid payment rates to nursing facilities because it failed
to consider how the cuts would affect quality of care, the Third Circuit ruled September 19.

Reversing in part a district court decision, the Third Circuit found the record HHS had before it in
approving the SPA in 2008 did not satisfy the “equal access” provision of the Medicaid Act, 42
U.S.C. § 1396a(a)(30)(A), which requires “methods and procedures” necessary to “assure”
payments to providers are “‘consistent with’ efficiency, economy, quality of care, and adequate
access to providers.”

According to the appeals court, HHS seemed to base its approval of the SPA on the fact that
nursing facility reimbursement rates actually went up in the 2008-2009 period relative to the
previous year.

But the appeals court said the critical piece that the agency failed to consider was that the
state’s cost-based reimbursement system called for a much higher increase in per diem rates,
which instead were reduced based on a budget adjustment factor (BAF) applied under the SPA.
Although a BAF had been applied in previous years, the appeals court said that still did not
excuse HHS from considering how further, even more substantial rate cuts, would affect quality
and access to care.

The appeals court stressed it was not concluding the reduction in fact compromised quality and
access, but held HHS did not provide a reasoned basis for approving the SPA and therefore
violated the Administrative Procedure Act.

Since 1996, Pennsylvania has paid nursing facilities participating in the state’s Medicaid program
using a “case-mix rate” that produces an individualized per diem reimbursement rate for each
facility based on “allowable costs.”

Facing rate increases under this payment system that were outpacing inflation, Pennsylvania’s
Department of Public Welfare (DPW) proposed in June 2005 applying a BAF to serve as a cap on
payments to nursing facilities. The BAF is determined by the funds appropriated by the
legislature for nursing facility payments. DPW applied a BAF for each year between 2005 and
2008, which effectively reduced the case-mix rate between 4.9% to 6.8% during those years.
In 2008, DPW submitted a SPA to HHS for approval of a proposed BAF that would reduce the case-mix rate by over 9% in the 2008-2009 rate year. Even applying the BAF to the case-mix rate, nursing facility payments still went up by about 1% in 2008-2009 from the previous year. HHS, through the Centers for Medicare & Medicaid Services, approved the SPA.

Plaintiff private nursing facilities challenged HHS’ approval of the SPA, arguing it violated Section 30(A) equal access requirements and 42 U.S.C. 1396a(13)(A) public process requirements. The district court granted summary judgment to HHS, finding its approval of the SPA was not arbitrary and capricious.

While finding SPA approvals warranted deference, and that DPW satisfied the public process requirements of Section 13(A), the Third Circuit held HHS improperly concluded the SPA complied with Section 30(A) based on the evidence it had before it.

The Third Circuit characterized the record DPW submitted with its SPA as “remarkable thin” and rejected arguments that the approval was justified because payments to nursing facilities increased slightly from the previous year under the proposed SPA; that the state previously applied BAFs without harming quality of care; and that state statutes mandating nursing facilities meet quality standards provided independent assurances of quality.

The state never argued the case-mix rate methodology was flawed just that it had to reduce rates for budgetary reasons. The appeals court pointed out that methodology called for much higher rates based on escalating costs. Thus, although the per diem rate actually increased slightly, it went up far less than what the cost-based system demanded, which could negatively affect quality.

Likewise, the fact that previous reductions did not impact quality was not a sufficient basis for concluding additional steep reductions would not have such an effect. “It is simply not reasonable to conclude that, because prior cuts did not seem too painful, a deeper could would not hurt.”

Finally, HHS could not reasonably rely on state statutes as “independent assurances of quality of care” when approving the SPA. “[S]imply passing a statute saying that nursing homes will provide quality care does not make it so,” the appeals court observed.

Plaintiffs also sought declaratory and injunctive relief against the Secretary of DPW, arguing the rate revisions violated Section 30(A) and Section 13(A) and therefore were preempted by federal Medicaid law.

The Third Circuit affirmed the district court’s grant of summary judgment to the state defendant on the ground the Eleventh Amendment deprived the court of jurisdiction to grant the requested relief.

The SPA has not been in effect since July 1, 2009, and plaintiffs did not claim the state’s current rate-calculation methodology violated federal law, the appeals court said. Plaintiffs failed to allege any “ongoing conduct by the Secretary of DPW that must be enjoined to ensure the supremacy of federal law.” Thus, their case seeking compensation for the prior action of a state official “seems precisely the kind of suit that is barred by the Eleventh Amendment.”

Christ the King Manor, Inc. v. Secretary United States Dep’t of Health and Human Servs., Nos. 12-3401, 12-3501 (3d Cir. Sept. 19, 2013).
U.S. Court in California Allows Case Alleging Inflated Drug Prices to Go Forward

On September 20, the U.S. District Court for the Northern District of California held a three-year limitations period applied to Virginia's claims under the Virginia Fraud Against Taxpayers Act (VFATA) against prescription drug wholesaler McKesson Corp.; therefore, the claims were not time-barred.

The court also denied both parties' motion for partial summary judgment, finding genuine issues of material fact as to the state's knowledge of drug price inflation and whether it received a windfall.

Plaintiff, the Commonwealth of Virginia, alleged McKesson engaged in a conspiracy with First DataBank (FDB) to inflate the amount that Virginia's Medicaid program paid for brand-name prescription drugs. Virginia alleged that starting in late 2001, McKesson constructed a scheme with FDB to mark up drugs’ average wholesale prices (AWP) to extract excess payments from Virginia's Medicaid agency to McKesson's pharmacy customers. Virginia contended that because the margin between the wholesale average costs (WACs) and the average wholesale prices represented the pharmacies’ profits for the pharmacies, the artificial mark-up resulted in increased profits for the pharmacies at Virginia's expense.

In June 2011, Virginia filed a complaint against McKesson. Both parties filed cross motions for partial summary judgment. McKesson argued the VFATA claims were barred by Cal. Code Civ. P. § 340(a), which provides a one-year statute of limitations. Virginia contended the three-year statute of limitations applied under Cal. Code Civ. P. § 338(d).

The court was not persuaded by McKesson's argument that VFATA is a statute for a penalty or forfeiture, analogizing it to the California Private Attorneys General Act, which has applied Section 340(a)'s one-year limitations period. According to the court, the VFATA, like the federal False Claims Act, was enacted to prevent and punish fraud on the government and to recoup for the government damages sustained by the Commonwealth of Virginia. In other words, the focus is not on the individual, thereby making a VFATA claim "an action for relief on the ground of fraud or mistake" under Section 338(d).

Virginia moved for partial summary judgment on McKesson's argument that Virginia's VFATA claims were barred by the doctrine of consent, ratification, and unjust enrichment. On the issues of consent and ratification, the court found McKesson raised genuine issues of material fact as to Virginia's knowledge of the drug price inflation, the extent of Virginia's knowledge as to the true facts, and the determination of whether Virginia actively approved of the underlying facts.

On McKesson's unjust enrichment affirmative defense, the court held disputed issues of material fact remained as to whether the FDB rollback was independent of a related settlement and whether Virginia obtained a windfall when AWPs fell to 20% above WAC following the FDB rollback.


U.S. Court in Oklahoma Refuses to Order State to Pay Plaintiff Medicaid Benefits

The U.S. District Court for the Western District of Oklahoma refused October 11 to grant a plaintiff a preliminary injunction instructing the Oklahoma Department of Human Services to grant him Medicaid eligibility and immediately start paying benefits.
In so holding, the court found plaintiff Lawrence Ira Clayton failed to show irreparable injury to himself if the injunction was denied.

Clayton sued Ed Lake, Director of the Oklahoma Department of Human Services, and others alleging he was wrongfully found ineligible for Medicaid benefits under Oklahoma’s Advantage Waiver Program.

Plaintiff asked the court for preliminary and permanent injunctions that would grant him Medicaid eligibility and asked for a preliminary injunction directing defendants to place him in Medicaid pay status for the pendency of the case, and for all other relief deemed just and equitable.

The court first noted a movant seeking a disfavored preliminary injunction—i.e., preliminary injunctions that alter the status quo, mandatory preliminary injunctions, or preliminary injunctions that afford the movant all the relief he could recover at the conclusion of a full trial on the merits—must satisfy a heightened burden.

Here, plaintiff’s complaint alleged “Clayton’s family is being forced to utilize its own funds to pay for Clayton’s care. Because Clayton’s only remedy in this case is prospective injunctive relief (or an order requiring the state to provide medical services going forward), there is no way Clayton’s family can recover out-of-pocket expenses for his care.”

“While plaintiff may have shown irreparable injury to his family, none of whom are parties in this case, plaintiff has not shown any irreparable injury to himself,” the court held in denying the requested relief.


West Virginia High Court Rejects Hospital’s Challenge to Medicaid Rates Under State Law

On November 21, the West Virginia Supreme Court of Appeals affirmed the dismissal of a hospital’s lawsuit challenging allegedly inadequate Medicaid reimbursement rates under state law. The high court found neither of the state statutes—W. Va. Code §§ 9-15-16 (1988) and 16-29B-20 (1997)—the hospital relied on provided an express or implied private cause of action by a Medicaid provider for judicial review of reimbursement rates for medical services.

Plaintiff Beckley Appalachian Regional Hospital (Beckley ARH) filed a lawsuit in December 2010 against the West Virginia Department of Health and Human Resources and the West Virginia Bureau of Medical Services (BMS) (collectively, the Department), alleging the Medicaid rates being paid by the Department were “grossly inadequate” to cover the cost of providing acute care inpatient and psychiatric services to Medicaid patients.

Medicaid requires that a single state agency be established or designated as the administrator of the state plan. In this case, the administering state agency was BMS. One of BMS’ statutory duties was to establish Medicaid reimbursement rates in compliance with federal law for medical and laboratory services rendered to Medicaid patients.

The high court concluded Sections 9-5-16(a) and 16-29B-20 did not provide a statutory basis, either express or implied, to challenge the Medicaid reimbursement rates.

As to Section 9-5-16(a), the court found nothing that provided an explicit judicial remedy. To determine if Section 9-5-16 included an implied private cause of action, the court applied a four-prong test enumerated in Hurley v. Allied Chemical Corporation, 164 W. Va. 268, 262 S.E.2d 757 (1980).
Although the court concluded Beckley ARH was a health care provider within the meaning of Section 9-5-16(a) and therefore a member of the class for whose benefit the statute was enacted, it found the remaining factors weighed against finding an implied cause of action—namely, nothing in the statute indicated legislative intent to provide a private cause of action for rate setting; a private cause of action would be inconsistent with the statute’s underlying and express purpose of information gathering for rate setting; and a private cause of action would not intrude into an area delegated exclusively to the federal government because the federal government relegated rate-setting for Medicaid reimbursements to the states.

As to Section 16-29B-20, Beckley AHR contended the statute provided a basis for judicial review of Medicaid reimbursement rates as it related to the West Virginia Health Care Authority’s (HCA) duty to review rate proposals by hospitals like Beckley AHR and establish hospital rates throughout the state. Upon review of applicable authority, however, the court found the setting of reimbursement rates was delegated by statute to the Department, not HCA. The court pointed out that BMS was the single state agency designated by the Centers for Medicare and Medicaid Services to administer the Medicaid program for the state, so while the HCA rate-setting statutes addressed the HCA’s role in setting Medicaid reimbursement rates, W. Va.Code § 9-2-6(10) (2005) clearly delegated that duty to the Department.

The Department argued that federal law preempted the statutes on which Berkley AHR relied. The court held the Medicaid rate-setting was “field preempted” by federal law. With BMS acting as the single state agency that administered all aspects of the state’s Medicaid program, CMS’ designation necessarily precluded HCA’s involvement. Moreover, W. Va.Code § 9-2-3 (1970) provided direct support for preemption by acknowledging the state’s participation in Medicaid required compliance with applicable federal laws, rules, and regulations. The court therefore concluded Beckley ARH could not maintain a cause of action related to rate-setting under W. Va.Code § 16-29B-20.


U.S. Supreme Court Denies Review of Cases Challenging California Medicaid Rate Cuts

The U.S. Supreme declined to review January 13 two cases in closely watched litigation involving provider challenges to California Medicaid rate reductions. The action leaves intact a Ninth Circuit decision allowing the rate cuts to go forward.

Various provider groups challenged the rate cuts in federal district court after Assembly Bill 97, enacted in March 2011, called for a host of Medi-Cal rate reductions. See Cal. Wealth and Inst. Code § 14105.192. In late October 2011, the Centers for Medicare & Medicaid Services (CMS) approved a number of provider reimbursement cuts in California’s Medicaid program to help address the significant budget shortfall the state is facing.

Plaintiffs asserted claims against the Department of Health and Human Services Secretary under the Administrative Procedure Act (APA) and against the Director of the California Department of Health Care Services under the Supremacy Clause of the U.S. Constitution.

Among other things, the lawsuits alleged the cuts violated the federal Medicaid Act, specifically 42 U.S.C. § 1396a(a)(30)(A), which requires a state Medicaid plan provide payments that “are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,” as interpreted in Orthopaedic Hosp. v. Belshe, 103 F.3d 1491.
But the appeals court found the Secretary’s interpretation that states are not required to follow any specific procedural steps before reducing rates was entitled to *Chevron* deference. The appeals court therefore did not find a violation of the APA.

The appeals court also found it unlikely plaintiffs would succeed on their Supremacy Clause claims, assuming they had a private right of action to assert them, given the Secretary’s determination that the state complied with Section 30(A).


**First Circuit Rejects Legal Aliens' Challenge to Discontinuation of Maine’s Medical Assistance Benefits**

The First Circuit found April 28 that Maine did not violate equal protection when it terminated in 2011 a state-funded medical assistance program for legal aliens who were ineligible for Medicaid.

The appeals court affirmed the district court’s denial of a preliminary injunction to a class of Medicaid-ineligible aliens residing in Maine and instructed the lower court, on remand, to dismiss the action.

In 1996, Congress enacted the Personal Responsibility and Work Opportunity and Reconciliation Act (PRWORA), which prohibited states from extending federal Medicaid benefits to most legal aliens residing in the United States for less than five years. The legislation also authorized states, however, to extend medical assistance benefits to this population using exclusively state funds.

In 1997, the Maine legislature enacted legislation that permitted the state’s Department of Health and Human Services (Department) to provide medical assistance benefits to PRWORA-ineligible aliens residing in the state. Due to budgetary constraints, the legislature in 2011 terminated state-funded non-emergency medical assistance benefits for this group of legal aliens.

Hans Bruns and Kadra Hassan, as representatives of a class of individuals who lost their medical assistance benefits under the 2011 law, filed a class action complaint against Mary Mayhew in her official capacity as the Department’s Commissioner alleging an equal protection violation.

The district court denied plaintiffs’ motion for a preliminary injunction in March 2013, finding the state effectively operated two separate medical assistance programs and therefore PRWORA-ineligible residents were not similarly situated to federal Medicaid recipients.

On appeal, plaintiffs argued in practice Maine operated a single state health care program, MaineCare, which did not distinguish between eligible citizens and aliens on the one hand and PRWORA-ineligible aliens on the other. In particular, plaintiffs noted the state applied the same eligibility criteria, used the same application form, and provided the same benefits.

The First Circuit held, however, that the “veneer of a single MaineCare program” did not change the fact that “MaineCare recipients received benefits from two distinct programs: one funded jointly by the federal and state governments; and the other fully funded and controlled by the state government.”

Given this finding, the appeals court held the repeal of the supplemental program for PRWORA-ineligible aliens did not deprive plaintiffs of a benefit the state continued to provide to citizens and aliens who have resided in the United States more than five years.
To the extent there was any discrimination, it was based on federal Medicaid eligibility requirements that were subject only to rational basis review under Congress’ broad authority over immigration and naturalization.

“The fact that Congress discriminated on the basis of alienage in enacting PRWORA does not also establish alienage-based discrimination by Maine merely because of its continued Medicaid participation and required compliance with PRWORA,” the First Circuit concluded.


**Fifth Circuit Holds Louisiana Must Return Federal Share of Medicaid Overpayments to Public Hospitals**

The Louisiana Medicaid program must repay some $240 million to the federal government for overpayments for uncompensated care costs (UCC) at nine public hospitals from 1996-2006, the Fifth Circuit held May 6.

Affirming a lower court ruling, which upheld a Department of Health and Human Services Departmental Appeals Board (Board) decision, the appeals court found the state’s removal and revision of the recoupment provision in its Medicaid plans did not change its obligation to return the federal share of Medicaid overpayments even if the state did not recover the amounts from the individual hospitals.

According to the opinion, Centers for Medicare & Medicaid Services (CMS) audits showed nine Louisiana public hospitals “received hundreds of millions of dollars in excess payments” above their UCC costs over the course of a decade.

The state argued that after 1997, its CMS-approved Medicaid plans did not require recoupment of overpaid UCC from the hospitals and reimbursement to the federal government. According to the state, the removal of a recoupment provision from the plans ended its obligation to seek recoupment.

But the Fifth Circuit disagreed, finding the Board did not act arbitrarily or capriciously in interpreting the state’s plans as “retrospective” in nature—i.e., requiring an “annual reconciliation of payments to actual costs incurred by the hospitals and a return of excess payments.”

“That Louisiana advocates its ability to ‘recoup’ additional funds from the federal government in case of UCC underpayments demonstrates how retrospective reconciliation works in its plans, and there is no textual basis in the plans for the State’s asymmetrical interpretation,” the appeals court said.

While the state removed the specific recoupment provision, the appeals court said this did not change the plans’ general methodology from that of a retrospective payment system.

Even assuming the removal of the provision meant the state no longer had to seek recoupment from the hospitals, it did not follow that the state was no longer obligated to return the federal share of any Medicaid overpayments, the appeals court concluded.

A federal court in the District of Columbia denied relief May 9 to home health care providers after the District of Columbia Medicaid program cut off payments to them citing pending fraud investigations against them.

While granting the provider plaintiffs a temporary restraining order (TRO) in April, the U.S. District Court for the District of Columbia found in its latest opinion that plaintiffs failed to demonstrate a property interest protected by due process and therefore denied them a preliminary injunction.

The court determined the Department of Health Care Finance (DHCF), which administers the DC Medicaid program, only temporarily suspended the providers' Medicaid payments pending its fraud investigation.

Citing various federal circuit court rulings, the court noted a temporary suspension of Medicaid payments—as opposed to terminating a provider from the program altogether—does not implicate due process or require a pre-suspension hearing.

In March 2014, DHCF decided to suspend Medicaid payments for certain home health care providers citing 42 C.F.R. § 455.23, which it said requires such action where a “credible allegation of fraud” exists and an investigation is pending. The decision affected 52% of home health providers, serving 79% of the city’s Medicaid recipients.

At the same time, DHCF informed providers they were legally obligated to continue rendering personal care aid (PCA) services to their Medicaid patients until those individuals were transferred to another provider.

Plaintiff home health providers sued in court, alleging among other things a violation of their due process rights and seeking money damages.

The court initially granted them a TRO based on evidence plaintiffs would suffer irreparable harm—the loss of their businesses. The court also found a likelihood of succeeding on their due process claim because the evidence at the time indicated DHCF terminated plaintiffs’ participation in Medicaid—a protected interest—and not just “temporarily” suspended payments.

But based on further evidence, the court refused to grant plaintiffs the preliminary injunction they sought. The court now determined plaintiffs were not likely to succeed on the merits given their Medicaid payments only were temporarily suspended pending the fraud investigation.

In particular, the court noted DHCF continued to pay plaintiffs for other Medicaid services, such as skilled nursing and case management services, belying arguments they were terminated from the program entirely.

“All Circuits that have addressed the issue have determined that a temporary suspension of Medicare or Medicaid payments does not implicate due process and that no pre-suspension hearing is required,” the court said.

The court also pointed to evidence refuting plaintiffs’ contention that they were required to render PCA services indefinitely without payment “and [that] raised serious questions about
whether they could have transferred their patients because there were an alleged insufficient number of non-suspended providers in the area.”

Finally, the court noted plaintiffs likely would not succeed on the merits because they failed to exhaust their administrative remedies and did not demonstrate futility.


**Medical Malpractice**

*Florida Supreme Court Strikes Medical Malpractice Damages Cap as Violating Equal Protection Under State Constitution*

The Florida Supreme Court struck down March 13 the state’s cap on wrongful death noneconomic damages in medical malpractice actions in a 5-2 plurality opinion.

The high court found the cap violates the Equal Protection Clause of the Florida Constitution because it improperly limits the right of recovery of certain claimants and bears no rational relationship to its stated purpose—addressing the alleged medical malpractice crisis in Florida.

The Eleventh Circuit in May 2011, after rejecting claims the cap violates the Takings and Equal Protection Clauses of the U.S. Constitution, certified several questions to the Florida Supreme Court to resolve issues of state law.

**Negligent Care**

Michelle McCall received prenatal care from the Family Practice Department of a U.S. Air Force clinic. During her final trimester, she was diagnosed with severe preeclampsia. The Family Practice medical providers immediately induced her labor and McCall delivered a healthy baby boy but experienced excessive blood loss during the delivery and died five days later.

McCall’s estate sued the United States under the Federal Tort Claims Act, alleging the negligent care administered by government-employed medical practitioners was the proximate cause of her death.

The district court issued judgment in favor of the estate and awarded noneconomic damages totaling $2 million—which the court reduced in compliance with Florida’s statutory cap. The estate then challenged the application and constitutionality of the damages cap.

**Cap Improperly Limits Rights of Certain Plaintiffs**

The Florida Supreme Court first addressed whether the cap violates the Equal Protection Clause of the Florida Constitution.

Under a rational basis test, the high court held the cap violates the state’s guarantee of equal protection “because it imposes unfair and illogical burdens on injured parties when an act of medical negligence gives rise to multiple claimants.”

Here, the damages suffered by McCall’s parents were determined by the district court to be $750,000 each, and McCall’s surviving son sustained damages determined to be $500,000. Applying the cap, the federal court then reduced the damages so each claimant would receive only half of his or her respective awards. Accordingly, if McCall had been survived only by her son, he would have recovered the full amount of his noneconomic damages of $500,000, the high court explained.
The cap limited the recovery of a surviving child (and surviving parents) simply because others also suffered losses, the high court noted.

“In such circumstances, medical malpractice claimants do not receive the same rights to full compensation because of arbitrarily diminished compensation for legally cognizable claims,” the high court said.

**No Rational Relationship to Stated Purpose**

Further, the high court found the statutory cap “does not bear a rational relationship to the stated purpose that the cap is purported to address, the alleged medical malpractice insurance crisis in Florida.”

After a lengthy review of the conclusions reached by the Florida Legislature as to the existence of a medical malpractice crisis, the high court dubbed the Legislature’s findings “dubious and questionable at the very best.” Even assuming the state was suffering from a medical malpractice crisis, the evidence did not “establish a rational relationship between a cap on noneconomic damages and alleviation of the purported crisis,” the high court said.

The high court lastly concluded the remaining certified questions need not be addressed.

**Concurring/Dissenting Opinions**

A separate concurrence disagreed with the plurality’s application of the rational basis test, but joined in the opinion’s conclusion that the arbitrary reduction of survivors’ noneconomic damages in wrongful death cases based on the number of survivors lacked a rational relationship to the goal of reducing medical malpractice premiums.

A dissent argued the cap did not violate Florida’s constitutional guarantee of equal protection.


On May 28, the Wyoming Supreme Court reversed the district court’s grant of summary judgment to a defendant hospital, holding a plaintiff’s medical malpractice claim was not time barred because the continuous treatment rule applied.

Plaintiff Ted Nobles was admitted to the intensive care unit (ICU) of Memorial Hospital of Laramie County (Memorial) on December 21, 2007 for acute respiratory failure. On February 19, 2008, Nobles was transferred to Memorial’s transitional care unit (TCU) for further treatment and finally discharged from Memorial on March 15, 2008.

On March 11, 2010, Nobles filed a notice of claim against Memorial with the state’s Medical Review Panel and presented his claim to Memorial alleging he sustained serious injury and damage to his right shoulder, arm, and brachial plexus while being treated at its ICU. Memorial waived review and the Panel authorized Nobles to file his suit against the hospital.

Nobles filed his complaint on June 11, 2010. Memorial filed a motion to dismiss or in the alternative, a motion for summary judgment, claiming Nobles did not timely file his complaint and therefore the action was barred by the statute of limitations for professional negligence under Wyo. Stat. Ann. § 1-3-107(a)(i), which requires a claim or action be filed within two years of the date of the alleged act, error, or omission. The trial court granted the motion.

Reversing, the high court held the “continuous treatment rule” as adopted in _Metzger v. Kalke_, 709 P.2d 414 (Wyo. 1985), applied in this case. According to the high court, the two-year statute of limitations under Section 1-3-107(a)(i) began when Nobles’ course of treatment for
the same or related illnesses or injuries stopped on March 15, 2008 as a result of being discharged from the hospital.

Memorial argued Nobles’ alleged injury occurred while he was being treated in the ICU prior to February 19, 2008 and this was the act that triggered the running of the statute of limitations. The court disagreed, holding the limitations period commenced after Nobles was discharged from Memorial’s ICU on March 15, not when he was transferred to the ICU from the TCU on February 19, as evidence indicated he continued to be treated for the same or related condition (i.e., acute respiratory failure) until his discharge from Memorial on March 15.

Memorial further argued if the continuous treatment rule applied, Nobles’ case qualified for the single act exception that would make the rule inapplicable if a single malpractice act could be pointed to as the source of Nobles’ damage or injury. The court declined to adopt the single act exception as it was difficult to apply, led to confusion rather than predictability, was not widely accepted by other jurisdictions, and was inconsistent with the court’s rulings in similar cases.


Texas Supreme Court Holds Nonsuit Tolls Period for Filing Expert Report

On June 21, the Texas Supreme Court held when a claimant nonsuits a claim before the statutory deadline to serve an expert report expires, as required by the Texas Medical Liability Act’s (TMLA), but then subsequently re-files the claim against the same defendant, the expert-report period is tolled between the date the nonsuit was taken and the date the new lawsuit was filed.

Plaintiffs Scott and Angela Lidji filed a healthcare liability claim against the CHCA Women’s Hospital (CHCA) on April 2, 2009, alleging their daughter suffered permanent neurological damage following her premature birth. On July 27, 2009, 116 days after filing their original petition, the Lidjis nonsuited their claim. Two years later on August 15, 2011, the Lidjis filed a new lawsuit against CHCA, the same day on which they also served an expert report on the hospital.

CHCA objected to the Lidjis’ expert report as untimely, contending the deadline to serve the report pursuant to the TMLA expired on July 31, 2009, 120 days after the Lidjis filed their original petition on April 2, 2009. CHCA also argued the TMLA contained no language tolling or abating the 120-day deadline in the event of a nonsuit.

The trial court disagreed and denied CHCA’s motion to dismiss. The appeals court affirmed, holding the Lidjis’ nonsuit filed before the expiration of the state’s 120-day period for expert reports stopped the running of the statutory period until the Lidjis re-filed their claim, at which point the Lidjis had whatever time remained from the 120-day period to serve CHCA with their expert report.

The Texas high court affirmed, pointing out the tolling of the expert report period can be proper under certain circumstances in spite of the TMLA’s silence on the matter, one of those being where the plaintiffs, as here, nonsuited their healthcare liability claim before the deadline to serve their report passed.

The high court further noted “various provisions of the TMLA’s expert-report requirement . . . demonstrate legislative intent that the expert report be provided within the context of pending litigation.” In other words, construing the TMLA to require claimants like the Lidjis to submit an expert report when there is no pending lawsuit would result in “a host of procedural complications that the statute does not envision and cannot adequately address,” the high court said.
Texas Supreme Court Finds State Medical Liability Act Applies to Employee’s Claim Against Health Care Provider

The Texas Supreme Court ruled August 23 that a psychiatric nurse’s negligence action against a behavioral health facility where he worked after he was injured while caring for a patient was a health care liability claim (HCLC) subject to the expert filing requirements of the Texas Medical Liability Act (TMLA).

In reversing the decisions below, the high court relied heavily on its 2012 decision in Texas W. Oaks Hosp., LP v. Williams, No. 10-0603 (Tex. June 29, 2012), which presented similar facts.

As in that case, the high court said 2003 amendments expanded TMLA’s application from “patients” of a health care provider to “claimants.” The high court found the nurse was a “claimant” because his claims of “improper security of a psychiatric patient and inadequate safety” were HCLCs under the TMLA.

Plaintiff Kenneth Palit was injured by a psychiatric patient while working at Mission Vista Behavioral Health Center, operated by Psychiatric Solutions, Inc., as a psychiatric nurse. Plaintiff sued Mission for negligence and sought damages for personal injuries.

After 120 days had elapsed, Mission moved to dismiss plaintiff’s lawsuit on the ground his claims constituted HCLCs under the TMLA and he failed to serve an expert report under the statutory time frame for doing so. Both the trial and appeals courts sided with plaintiff and denied the motion.

As amended in 2003, the TMLA expanded the breath of HCLCs to include actions against healthcare providers for negligence in the provision of “medical care, or health care, or safety or professional or administrative services directly related to healthcare.” Those amendments also replaced the term “patient” with “claimant” in the definition of an HCLC.

As in West Oaks, the high court found plaintiff’s claims alleged departures from accepted standards of “health care” and “safety.”

“[B]ecause Palit’s allegations implicate a standard of care that requires expert testimony to prove or refute it, his claim is an HCLC.” His failure to comply with the expert report requirement therefore required dismissal of the action, the high court held.


New Mexico Supreme Court Says Professional Medical Entities Are “Health Care Providers” for Purposes of Medical Malpractice Act

The New Mexico Supreme Court held September 5 that professional medical organizations are “health care providers” under the state’s Medical Malpractice Act (MMA).

According to the high court, the MMA’s definition of health care provider includes professional entities formed by physicians even if such groups are not specifically enumerated in the statute. Moreover, designating professional entities as health care providers is consistent with the purpose of the MMA.

To hold otherwise, the high court said, would lead to absurd results where a physician would be covered under the Act as an individual, but the business entity he formed would not be.
The case came to the high court as a consolidated action of three medical malpractice lawsuits that sought to hold both physicians and their professional business entities liable for negligence.

Plaintiffs argued the professional entities were vicariously liable for the physicians’ alleged negligence under the doctrine of respondeat superior. Defendant corporations argued they are health care providers under the Act and therefore the MMA’s expert witness requirements and damages caps applied.

The MMA defines a “health care provider” as “a person, corporation, organization, facility or institution licensed or certified by this state to provide health care or professional services as a doctor of medicine, hospital, outpatient health care facility, doctor or osteopathy, chiropractor, podiatrist, nurse anesthetist or physician’s assistant.”

The appeals court held the MMA literally excluded defendants because it specifically lists only individuals (i.e., doctors, chiropractors, etc.) and facilities (hospitals and outpatient health care facilities), but legislative intent and the underlying purpose of the statute overrode the literal language of the Act. The high court affirmed, albeit on different grounds.

In the high court’s view, the plain meaning of health care provider under the MMA included professional medical organizations as the definition specifically references “professional services,” which are provided by businesses, not individuals.

The high court also pointed out that plaintiffs’ interpretation of the Act would force individual medical professionals to choose between “having the protection of the corporate form and having the protection of the MMA.” Plaintiffs’ interpretation also would allow patients to “circumvent” the MMA by suing the physician-formed entity directly.

“The Legislature could not have intended to strip individual medical professionals of the MMA’s protections simply because they choose to operate as a business corporation, professional corporation, limited liability corporation, or any other legal form of business organization,” the high court reasoned.


**Ohio Supreme Court Finds Faculty Physician Immune from Liability Even Though Not Teaching Residents When Allegedly Negligent Care Was Rendered**

The faculty member of a state medical school was entitled to personal immunity from a negligence and wrongful death action even if the physician was not engaged in teaching at the time he provided care to the patient, the Ohio Supreme Court ruled October 17.

The fact the physician also was employed by the school’s nonprofit medical-practice plan did not defeat the immunity from liability provided under state law to public employees because part of his duties for the school included rendering clinical care to patients, even outside the presence of medical students or residents he was hired to teach.

Ohio law provides immunity to state employees unless the employee acts “manifestly outside the scope of employment, with malicious purpose, in bad faith, or in a wanton or reckless manner,” the high court explained in affirming the lower court decisions.

Dr. Syed G. Husain was part of the faculty of the Ohio State University College of Medicine in the Department of Surgery. As a condition of his faculty employment, Husain was required to participate in an affiliated nonprofit medical practice plan, Ohio State University Physicians, Inc.
(OSUP). Husain entered into a separate contract with OSUP so it could bill and collect for his services.

The Department of Surgery assigned Husain to staff its colorectal surgery clinic. In September 2009, Michael McNew consulted Husain at the clinic with various symptoms. Several days later he died. His estate and surviving spouse (plaintiffs) sued the medical school for negligence and wrongful death. They filed a separate action against Husain and OSUP in state trial court.

Although finding Husain was not engaged in teaching activities at the time he provided care to McNew, the trial court nonetheless held he was entitled to immunity as he was acting within the scope of his employment. The appeals court affirmed.

On appeal, plaintiffs argued Husain’s state employment duties were education related and therefore he was not entitled to immunity for care he provided to patients that did not involve teaching residents. Plaintiffs further contended Husain had two separate contracts—one with the medical school, which paid him a salary to teach and conduct research, and a second with OSUP, which governed his personal medical practice.

But the high court rejected these arguments and agreed with the lower courts that Husain was entitled to immunity.

The key issue, the high court said, was whether Husain was acting within the scope of his employment as a state employee, which is a fact-based inquiry.

In this case, the Department of Surgery, not OSUP, directed Husain to staff the colorectal surgery clinic where McNew was treated.

According to the high court,

Even if no medical student or resident observed the clinical services Husain rendered, and even though the university organized its medical practice plan as a private corporation, Husain’s clinical practice advanced the interests of the state because he staffed a faculty clinic and treated patients at the Ohio State University Medical Center, he contributed to its national ranking and reputation and he generated revenue that supported the academic mission of the university.


Georgia Supreme Court Holds Emergency Department Medical Director Not Liable for Patient’s Death Allegedly Caused by Failure to Implement Hospital Protocol

On November 25, the Georgia Supreme Court held the medical director of an emergency department was not liable for a patient’s death that plaintiff attributed to the alleged failure of staff to implement a chest pain protocol.

Plaintiff’s mother died in defendant-hospital’s emergency department. Plaintiff sued the emergency department’s medical director, Dr. Bobby Herrington, alleging her mother could have been saved if the treating physician and nurse had promptly and properly implemented a chest pain protocol that the hospital had adopted. The daughter alleged Herrington owed a duty to supervise the training of physicians and nurses with respect to the protocol but negligently failed to ensure they were adequately trained.

The trial court awarded summary judgment to Herrington but the appeals court reversed to the extent the claim against Herrington involved professional negligence. The appeals court reasoned that as medical director, Herrington assumed responsibility to supervise and train emergency
department staff; as a result, he owed a legal duty to patients to ensure physicians and nurses were adequately informed of and knowledgeable about the chest pain protocol.

The high court reversed the appeals court’s judgment, concluding the court’s reliance on Gray v. Vaughn, 217 Ga.App. 872 (1995), and the Restatement (Second) of Torts § 324A was misplaced. In Gray, the defendant-professional corporation undertook to not only supervise the nursing staff but also to direct the method and manner of care provided by the staff. In this case, Herrington had no responsibility or authority to control or direct the manner and method of care provided by the emergency department’s treating physicians and nurses.

The high court also held Section 324A(a) was inapplicable because “the mere failure to abate a hazardous condition—without making it worse—does not trigger” Section 324A(a), which applies only to the extent a defendant’s alleged negligence “exposes the injured person to a greater risk of harm than had existed previously.” In this case, the court found no evidence the risk to plaintiff’s mother was affirmatively escalated by Herrington’s alleged failure to adequately supervise the training of his emergency department staff.


Virginia High Court Rules Statutory Damages Cap Applies to Child Who Was Injured Before Birth

On January 10, the Virginia Supreme Court held an unborn child became a physician’s patient upon being born alive, that performance of an amniocentesis constituted “health care” as defined by the Virginia Medical Malpractice Act (Act), and that the statutory cap on damages applied to the claim for negligent performance of the amniocentesis.

Plaintiff was an infant who was born with damaged kidneys and cerebral palsy allegedly as a result of an unsuccessful amniocentesis performed by defendant-physician, Dr. David Roberts, the opinion said. Plaintiff, through her father and next friend, filed alternative common law and statutory medical malpractice claims against Roberts.

Plaintiff argued she could bring a common law claim because she did not have a physician-patient relationship with Roberts since at the time of the unsuccessful amniocentesis she was not a “natural person” as defined by the Act. Roberts contended because plaintiff was born alive, she became his patient at that time bringing her claim under the Act.

A jury returned a $7 million verdict in plaintiff’s favor against Roberts, who later filed a motion to reduce the jury verdict pursuant to Virginia’s statutory cap under the Act. The trial court held the cap applied because plaintiff became Roberts’ patient under the Act when she was born alive.

Relying on one of its own cases, Kalafut v. Gruver, 239 Va. 278 (1990), the high court explained that the statutory test was had death not occurred, could plaintiff have subsequently maintained a personal injury action?

In this case, plaintiff, upon being born alive, became a natural person under the Act and simultaneously became Roberts’ patient, which gave plaintiff her own claim against the physician. Relying on another one of its cases, Castle v. Lester, 272 Va. 591 (2006), the high court held Roberts’ negligence in performing the procedure caused plaintiff serious injuries and that both her mother and plaintiff were Roberts’ patients, each of whom were now entitled to a separate statutory damage cap under the Act.

Having determined plaintiff was Roberts’ patient, the high court found the term “health care” as defined in the Act was sufficient to encompass the amniocentesis and related medical procedures that Roberts provided or should have provided while plaintiff was in utero.
The high court rejected plaintiff’s broad interpretation of the Act, which would have otherwise exposed health care providers who treat pregnant women to unlimited liability, and therefore affirmed the trial court’s ruling that the state’s statutory cap on damages applied in this case.


**Washington Supreme Court Holds Minority Tolling Exemption Violates State Constitution**

On January 16, the Washington Supreme Court held the state’s minority tolling exemption found in Wash. Rev. Code § 4.16.190(2) violated the Washington State Constitution. In so holding, the high court found no reasonable ground for limiting a medical malpractice defendant’s liability to patients who were injured during minority and said the statute raised concerns underlying the state’s equal protection cases.

In May 2001, defendants (Dr. Steven Weighall and a magnetic resonance imaging (MRI) center) took MRIs of the then nine-year old plaintiff and found everything to be normal. Plaintiff, however, continued to suffer from headaches, nausea, dizziness, weakness, and double vision. In November 2009, plaintiff underwent another MRI where a radiologist found plaintiff’s brain tissue was protruding into his spinal cord. On January 13, 2011, the day before his 19 birthday, plaintiff filed a medical malpractice action against Weighall and the MRI center.

Weighall asserted plaintiff’s action was barred by the statute of limitations codified at Wash. Rev. Code § 4.16.350, which provides a medical malpractice lawsuit must be filed within three years of the act or omission that gave rise to the claim or one year after the patient discovered or reasonably should have discovered the injury was caused by the act or omission in question. Weighall further argued plaintiff’s claim was subject to the minority tolling exemption codified at Section 4.16.190(2), which eliminates tolling for minors in medical malpractice actions.

According to the trial court, plaintiff and his mother discovered Weighall’s alleged omission in November 2009 when plaintiff was still a minor. The trial court concluded the combined effect of Sections 4.16.350 and 4.16.190(2) placed plaintiff’s January 13, 2011 filing date about two months outside the statute of limitations and thereby dismissed the action.

Plaintiff appealed, arguing Section 4.16.190(2) violated article I, section 10 and article I, section 12 of the Washington State Constitution.

The high court said Section 4.16.190(2) conferred limited liability or immunity from suits pursued by certain plaintiffs and that where a cause of action derived from the common law, the ability to pursue that cause of action was a privilege of state citizenship that triggered an article I, section 12 reasonable ground analysis. In this case, the high court held Section 4.16.190(2) limited plaintiff’s ability to bring a medical malpractice claim as his injury occurred during childhood, which thereby granted immunity that triggered the reasonable ground analysis.

Applying this analysis, the high court concluded there was no reasonable ground for limiting the defendants’ liability to patients who were injured during minority. The high court found insufficient defendants’ arguments that Section 4.16.190(2) would reduce medical malpractice insurance premiums or limit stale medical malpractice claims.

Finally, the high court held Section 4.16.190(2) raised equal protection concerns because it conferred a benefit (i.e., immunity) on one group of citizens (defendants like Weighall), but had the potential of burdening a particularly vulnerable minority.
The high court therefore reversed the trial court’s summary judgment order dismissing plaintiff’s medical malpractice action even though it was filed approximately two months after the statute of limitations had passed.


Washington Supreme Court Sets Parameters for Corporate Defendant’s Ex Parte Contact with Employee, Nonparty Physicians in Patient Lawsuit

The Washington Supreme Court issued January 23 a ruling attempting to “balance” the values underlying the attorney-client privilege and the physician-patient privilege when it comes to ex parte communications between corporate defendants and their employee, nonparty physicians in patient negligence actions.


At the same time, the attorney-client privilege, codified in Wash. Rev. Code § 5.60.060(2)(a), extends to corporate clients under the Supreme Court decision in Upjohn Co. v. United States, 449 U.S. 383 (1981).

The consolidated case before the state high court posed the question of how to resolve these seemingly conflicting privileges in the case of negligence actions brought by patients against a corporate defendant.

“On the one hand, Upjohn would allow corporate counsel to have privileged (confidential and private) discussions with corporate employees, including a plaintiff’s nonparty treating physician, to investigate claims and prepare for litigation,” the high court observed.

“On the other hand, Loudon would bar confidential discussions between defense counsel and the plaintiff’s nonparty treating physicians about the subject of the litigation,” requiring instead the presence of opposing counsel, the high court added.

The issue arose in two separate cases that were consolidated on appeal. The first case involved plaintiff Marc Youngs’ lawsuit against defendant St. Joseph Hospital where he had surgery in 2008. He later sued the hospital for negligence, but did not name his treating physicians as defendants. The trial court in that case allowed the defendant hospital to have ex parte contact with employees who provided care to Youngs.

The second case was brought by Aolani Glover against Harborview Medical Center. The trial court in that case barred ex parte contract with any of Glover’s treating physicians.

The high court adopted a “modified version of the Upjohn test” to resolve the conflict with the Loudon.

Under this test, a corporate defendant’s counsel may have ex parte communications with a plaintiff’s nonparty treating physician who are employed by the defendant “only where the communication meets the general prerequisites of the attorney-client privilege, the communication is with a physician who has direct knowledge of the event or events triggering the litigation, and the communications concern the facts of the alleged negligent incident.”
The high court remanded the two cases to the trial courts for further proceedings to apply the decision to the specific facts at issue.


Florida Supreme Court Quashes Order Precluding Production of Adverse Incident Records in Malpractice Action

The Florida Supreme Court quashed January 30 the Third District Court of Appeal’s order precluding defendant Cedars Healthcare Group, Ltd. from producing records of adverse medical incidents related to a plaintiff’s medical malpractice wrongful death action.

Plaintiff Myriam Ampuero-Martinez, who was treated at a Cedars-operated facility, sought those records pursuant to article X, section 25 of the Florida Constitution (Amendment 7), which guarantees patients the 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.”

In its decision, the appeals court held the trial court—which overruled defendant’s objection to plaintiff’s pre-trial discovery request—failed to limit plaintiff’s request as required by Fla. Stat. § 381.028(7)(a).

The high court found, however, the appeals court’s reliance on the statute impermissibly conflicted with the high court’s decision in Waterman, Inc. v. Buster, 948 So.2d 478 (Fla. 2008), which declared Section 381.028(7)(a) invalid as it “unconstitutionally impinge[d] upon the rights granted pursuant to amendment 7 . . .”

The high court therefore quashed the appeals court’s decision and remanded for reconsideration pursuant to Buster.


Sixth Circuit Finds Injection of Medication Against Patient’s Wishes Can Be Basis of Medical Battery Claim

The injection of a medication that a patient had specifically refused was a medical procedure, as opposed to a therapeutic drug treatment, for the purposes of a medical battery claim, the Sixth Circuit held February 14.

Pauline Shuler died while being treated at defendant hospital. Plaintiffs, Shuler’s heirs, alleged she died from an allergic reaction to heparin injections despite her objections and refusal to receiving them and the doctors’ awareness of her allergy to the drug. Plaintiffs sued the hospital claiming negligence and medical battery.

The district court construed plaintiffs’ complaint as a medical malpractice suit and dismissed for failure to comply with the notice and heightened pleading requirement of the Tennessee Medical Malpractice Act (TMMA). But the Sixth Circuit reversed the district court’s dismissal of the medical battery portion of the complaint, holding plaintiffs plausibly alleged medical battery, which is not subject to the TMMA.

Defendants argued heparin injections were not “procedures” or “treatments” for the purposes of medical battery but were therapeutic drug treatments that could form the basis for medical malpractice, not medical battery. Defendant argued the injections were only “component parts”
of the deceased’s treatment process for which defendant did not need a patient’s specific consent to administer.


In Abeyta, the Tennessee court of appeals held the plaintiff could proceed on a medical battery theory premised on medical injections she specifically refused to take. The Sixth Circuit also pointed out that other state and federal courts have held that drug administration over the patient’s objections or despite the patient’s contrary instruction constituted medical battery.

In addition, the Sixth Circuit pointed out that application of the commonplace understanding of “procedure” as defined in the Oxford English Dictionary was appropriate “in conjunction with the types of contact that would support an ordinary battery claim under Tennessee law.”

The Sixth Circuit therefore held the injections that the deceased received despite her objections was a form of nonconsensual touching or physical contact that violated her “right to bodily integrity” and that proximately caused her death. This, according to the appeals court, provided a sufficient basis for the contact element of a medical battery claim.

Defendants next argued a patient’s general authorization for an operation or course of treatment included authorization for the component parts of that treatment. The Sixth Circuit disagreed, however, finding defendants’ argument left unanswered the question of how a patient could authorize a procedure she specifically refused?

Moreover, the court could not find, and defendants did not offer any, case law supporting the argument that a prior general grant of consent trumped a subsequent, explicit refusal to submit to a procedure or that a physician could perform a procedure on a patient who previously refused it and has not subsequently consented.


Medicare

U.S. Court in Florida Vacates 1979 Injunction Barring Disclosure of Physician Medicare Claims Data

The U.S. District Court for the Middle District of Florida vacated May 31 an injunction issued in 1979 that barred the Department of Health and Human Services (HHS) from disclosing certain Medicare claims data for physicians.

The court found a “significant change in the law” since the injunction was issued—namely an Eleventh Circuit decision that narrowly construed the scope of injunctive relief a court could award for a Privacy Act violation—made its continued prospective application “no longer equitable” pursuant to Fed. R. Civ. P. 60(b)(5).

1979 Injunction

The Florida Medical Association (FMA), and later the American Medical Association (AMA), initially sought to enjoin HHS’ predecessor from releasing further lists identifying physicians or groups of physicians who received a certain level of Medicare reimbursements. HHS made such a disclosure in 1977 and amended its regulations that same year to specifically allow such disclosures.
Among other things, plaintiffs invoked the court’s jurisdiction under the Freedom of Information Act (FOIA) and the Privacy Act. The court in 1979 granted a permanent injunction after finding the disclosure was covered by FOIA Exemption 6, which provides that FOIA “does not apply to matters that are . . . personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy,” and therefore violated the Privacy Act.


Change in Facts, Law

Jennifer Alley, owner of Real Time Medical Data, LLC, which uses Medicare claims data to assist hospitals and other clients with marketing and strategic planning efforts, filed a FOIA request in 2003 with HHS. The request sought data on all Medicare claims paid in 2002 for procedures performed in several states.

HHS provided Alley with some of the information she requested, but refused to release any Medicare Part B outpatient claims data to avoid a “clearly unwarranted invasion of personal privacy” under FOIA Exemption 6, and to avoid running afoul of the 1979 injunction. The district court ordered disclosure of the requested claims data, finding the injunction should be narrowly construed.

In a 2010 decision, the Eleventh Circuit reversed, finding the claims data at issue were covered by the 1979 injunction. The appeals court suggested those attempting to obtain the data could seek modification of the injunction from the issuing court, but could not do so collaterally. Alley v. Department of Health and Human Servs., No. 08-16914 (11th Cir. Dec. 18, 2009).

Before the Middle District of Florida, RTMD, which was allowed to intervene in the instant action, argued the 1979 injunction should be vacated pursuant to Rule 60 because of factual changes since the ruling, including a shift in the balance between physician privacy interests and the public interest in disclosure of Medicare reimbursement amounts. RTMD also noted reduced physician privacy interests in such data given the Affordable Care Act-created program permitting disclosures of Part B data to qualified entities to generate provider performance reports.

Another intervenor in the instant action, Dow Jones and Company, Inc., which publishes The Wall Street Journal, made similar arguments, noting Medicare claims data could be invaluable in identifying fraudulent conduct.

HHS argued, on the other hand, that prospective enforcement of the 1979 injunction was no longer equitable because of a change in the law since the injunction was issued, citing the Eleventh Circuit’s decision in Edison v. Department of Army, 672 F.2d 840 (11th Cir. 1982), which held “the Privacy Act does not authorize injunctive relief against a government agency to prevent it from disclosing information.”

The FMA and AMA both opposed modifying or vacating the injunction.

Privacy Act Prohibited Disclosure

The court first determined that the basis for the 1979 injunction was the judge’s determination that the information at issue fell within FOIA Exemption 6, which meant HHS was permitted, but not required, to withhold disclosure. After finding Exemption 6 did not require disclosure, the
judge then turned to a Privacy Act analysis and held disclosure was prohibited without prior written consent pursuant to that statute.

The court’s determination that the Privacy Act was the legal basis for the 1979 injunction was key because plaintiffs argued their complaint challenged a final agency action—i.e., HHS’ amendment to its regulations—under the Administrative Procedure Act (APA).

But the court found no suggestion in the 1979 injunction was based on an APA violation, or that the issuing judge even considered the HHS regulation.

In the court’s view, the 1979 injunction was based solely on the determination that the Privacy Act authorized such relief, a conclusion clearly at odds with the Eleventh Circuit’s subsequent interpretation in Edison.

**Reverse FOIA Claim**

Plaintiffs argued because the proposed disclosure would violate the Privacy Act, it was “not in accordance with the law” and therefore invalid under the APA. They noted courts have held the government can be enjoined from making a disclosure pursuant to a “reverse FOIA action” under the APA.

The problem with this argument, the court said, was the injunction barred “any” and “all” present and future disclosures. The reverse FOIA cases cited by plaintiffs enjoined disclosures of specific information at issue in the particular action.

The APA is not a vehicle for enjoining possible future agency actions, the court observed. “Vacatur of the injunction permits the type of case by case review envisioned by the APA in the future,” the court said.

**No Immediate Data Release Foreseen**

The court also did not foresee that vacating the injunction would trigger an immediate release of identifiable Medicare claims data. The court noted a policy HHS issued in 1980 that individually identifiable Medicare reimbursement data should not be released based on Exemption 6 of FOIA.

If HHS agreed to disclose the data pursuant to a FOIA request, plaintiffs could at that point bring a reverse FOIA action for review of the agency’s decision under the APA, the court reasoned.


**D.C. Circuit Sides with HHS in Challenge to DSH Adjustment Involving Medicare-Exhausted Dual Eligibles**

The D.C. Circuit upheld June 11 the exclusion of certain Medicare-exhausted dual eligible patient days from a hospital’s Medicaid fraction for purposes of determining its disproportionate share hospital (DSH) adjustment in its 1997 cost year.

In so holding, the D.C. Circuit reversed a lower court decision finding the Department of Health and Human Services Secretary’s decision was unlawful because it retroactively applied a 2004 final rule requiring such days be included in the Medicare, rather than Medicaid, fraction of the DSH calculation.

The appeals court found the policy underlying the Secretary’s exclusion of the days at issue was first announced in a 2000 adjudication, not in the 2004 rulemaking, and therefore was not based

The appeals court also upheld the Secretary’s interpretation of the DSH calculation as a permissible construction of the Medicare statute and found the hospital failed to show any detrimental reliance.

A hospital’s DSH adjustment is calculated based on the sum of the Medicare and Medicaid fractions. At issue in this case was the Medicaid fraction, which is based on the number of patient days for individuals “eligible for” Medicaid, but not “entitled to” Medicare Part A.

Catholic Health Initiatives-Iowa, Corp., which owns and operates Mercy Medical Center-Des Moines, argued the Secretary improperly excluded from the hospital’s Medicaid fraction patient days for dual-eligible individuals—those eligible for Medicare and Medicaid—who had exhausted their Part A benefit for the 1997 cost year.

The appeals court noted, at least in some cases, including dual-eligible exhausted days in the Medicaid fraction would increase a hospital’s disproportionate payment percentage, and, in turn, its DSH payment adjustment.

Catholic Health argued the Secretary’s current interpretation of what should be included in the Medicaid fraction, as set forth in an October 2004 final rule, was at odds with the agency’s prior position. HHS contended, however, the final rule was a “clarification” of its long-standing position that Medicare-exhausted days should be excluded from the Medicaid fraction.

The U.S. District Court for the District of Columbia agreed with Catholic Health and granted summary judgment in its favor. Catholic Health Initiatives – Iowa, Corp. v. Sebelius, No. 10-cv-411 (RCL) (D.D.C. Jan. 30, 2012). The court did not address whether the Secretary’s interpretation was a permissible reading of the statute, but determined the decision in this case amounted to an unlawful retroactive application of the 2004 rulemaking.

Reversing, the appeals court first concluded the statute was ambiguous and the Secretary’s interpretation was a permissible construction entitled to deference.

On the issue of retroactivity, the appeals court said “while the 2004 rulemaking was phrased as a matter of revised statutory interpretation, it is clear that the regulation—at least as it bears on the issue in this case—simply reiterated the prior rule of decision first announced in the Edgewater adjudication.”

The D.C. Circuit continued: “And, of course, it is black-letter administrative law that adjudications are inherently retroactive.”

Although the Secretary’s decision apparently relied on the 2004 rulemaking, the actual policy of excluding dual-eligible exhausted days from the Medicaid fraction was announced four years earlier in the Edgewater decision, the appeals court observed.

In a footnote, the appeals court noted the 2004 rulemaking did change the fact that Medicare-exhausted dual eligible days would be included in the Medicare fraction, but that was not at issue here.

The only remaining question, the appeals court said, was whether applying Edgewater retroactively to the hospital in this case was improper because it “sustinut[es] . . . new law for old law that was reasonably clear” and relied on by the affected party. Here, the hospital failed to show any detrimental reliance on the alleged prior policy, the appeals court said.
“So even assuming the Edgewater rule was ‘retroactively’ applied to the 1997 cost-reporting period, it would not constitute the sort of unfair retroactivity that may render an agency decision arbitrary and capricious,” the appeals court concluded.


**Fifth Circuit Says Statutory Mergers Must Be Bona Fide Sale for Medicare Loss Payments**

The Fifth Circuit agreed July 12 with a lower court’s decision that a statutory merger must constitute a bona fide sale in order to be eligible for depreciation adjustments under 42 C.F.R. § 413.134(l).

Following the merger of Hermann Hospital (Hermann) with Memorial Hospital (Memorial), creating Memorial Herman Hospital System (MHHS), the Administrator of the Centers of Medicare & Medicaid Services denied MHHS’ request for a loss payment of nearly $22 million, pursuant to Section 413.134(l), holding the merger was not a bona fide sale as required by statute. The district court agreed with the Administrator’s conclusion and dismissed MHHS’ case on summary judgment.

According to the Fifth Circuit, every other federal circuit (D.C., Ninth, Tenth, and Third) to consider the issue has concluded statutory mergers must meet the bona fide sale requirement to qualify for a Medicare loss payment.

Depreciation adjustments are authorized by the Social Security Act, which entitles Medicare providers to reimbursement for the “reasonable costs” of furnishing Medicare services, including “an appropriate allowance for depreciation on building and equipment used in the provision of patient care.” 42 C.F.R. § 413.134(a).

In October 2000, the Department of Health and Human Services Secretary issued guidance for determining whether a statutory merger is eligible for a depreciable loss payment. See _Clarification of the Application of the Regulations at 42 C.F.R. § 413.134(l) to Mergers and Consolidations Involving Non-Profit Providers, Program Memorandum A-00-76 (Oct. 19, 2000) (PM A-00-76)._ PM A-00-76 explains that mergers and consolidations must involve one of the events described in 42 C.F.R. § 413.134(f), typically a bona fide sale, which requires reasonable consideration based on a comparison of the sales price with the fair market value of the assets acquired. See _Provider Reimbursement Manual § 104.24._

The Fifth Circuit rejected MHHS’ argument that the bona fide sale requirement does not apply to mergers because PM-A-00-76 created “new law” without meeting the notice and comment requirements of the Administrative Procedure Act (APA). Citing to other circuit court decisions, all of which have affirmed the Secretary’s interpretation of the applicable Medicare regulations, the Fifth Circuit agreed PM-A-00-76 does not add a bona fide sales requirement. Instead, the requirement “is established by the plain language of 42 C.F.R. § 413.134(l).” PM-A-00-76 specifically states that it “does not include any new policies regarding mergers,” which indicates the Secretary always maintained the bona fide sale requirement applied to mergers.

As several circuits have recognized, applying the bona fide sale requirement in this context also is consistent with the general Medicare principle that providers should be compensated only for actual payments to keep costs low, the appeals court added.

Next, the Fifth Circuit rejected MHHS’ argument that the Secretary’s definition of “bona fide sale” as requiring a comparison of sales price and fair market value of the assets to determine
“reasonable consideration” departed from the previous definition requiring only “valuable consideration.” Again citing other circuit court decisions, the appeals court found requiring “reasonable consideration” for a bona fide sale is consistent with the Medicare Act and applicable regulations.

Finally, the appeals court concluded the merger at issue did not constitute a bona fide sale. Here, Memorial assumed about $373 million in liabilities, which was greatly offset by the total book value of the assets acquired totaling approximately $755.5 million. The Administrator properly concluded Hermann sold these assets at a discount and essentially charged nothing for its depreciable assets, the appeals court said.

As a result, the Fifth Circuit affirmed the lower court’s decision, finding the Secretary properly denied MHHS a depreciation adjustment under Section 413.134(l).


D.C. Circuit Finds Secretary May Delegate to Medicare Contractor “High Level of Payment Error” Determination

The D.C. Circuit held July 23 that the Department of Health and Human Services Secretary may delegate to an outside contractor the statutory authority under 42 U.S.C. § 1395ddd(f)(3) to determine whether a healthcare provider billing for Medicare services exhibited a “sustained or high level of payment error.”

Affirming a lower court decision, the appeals court found the Secretary’s interpretation of the statute was reasonable and entitled to deference.

Medicare contractor Cahaba Safeguard Administrators (CSA) found 58% of the claims for home healthcare services submitted by Gentiva Healthcare Corporation (Gentiva) over a year-and-a-half had been at least partially denied. As a result, CSA determined Gentiva’s claims exhibited a “sustained or high level of payment error.” CSA went on to sample 30 claims, determining 87% were overpaid. CSA then extrapolated the 87% error rate over the universe of claims resulting in an estimated Medicare overpayment of more than $4.2 million.

The overpayment was reduced to $2.1 million after Gentiva successfully argued that ten of the identified claims were coded correctly. Gentiva did not prevail, however, on its argument before an Administrative Law Judge that the extrapolation methodology CSA used was invalid.

On appeal to the Medicare Appeals Council, Gentiva argued Section 1395ddd(f)(3) did not permit CSA—or any other outside contractor—to make the “sustained or high level of payment error” determination that is a prerequisite for using statistical extrapolation to calculate an overpayment. But the Medicare Appeals Council disagreed, citing the Secretary’s “broad authority” to delegate Medicare functions “directly, or by contract” under 42 U.S.C. § 1395kk(a).

The U.S. District Court for the District of Columbia granted summary judgment to the Secretary, holding Section 1395ddd(f)(3) did not unambiguously foreclose delegation of the “sustained or high level of payment error” determination and the Secretary’s interpretation, which was entitled to Chevron deference, was reasonable.

While conceding that Gentiva “may have the better reading of § 1395ddd(f)(3),” the D.C. Circuit affirmed the ruling below, agreeing with the district court that the statute was ambiguous and Chevron deference applied.

Gentiva argued Section 1395ddd(f)(3) permits a Medicare contractor to use extrapolation but only after the Secretary makes the initial determination that extrapolation is warranted. But the
appeals court noted no dispute that the payment error determination was a Medicare “function” within the scope of the Secretary’s broad delegation authority under Section 1395kk(a), which Section 1395ddd(f)(3) did not unambiguously override.

The appeals court also was not persuaded by Gentiva’s contention that the result should be different because the high payment error determination is not subject to judicial review. The determination is only a screening mechanism for triggering extrapolation, the appeals court noted. Providers may still challenge the final overpayment, as well as the underlying extrapolation methodology, at both the agency level and in court.

Finally, the D.C. Circuit also upheld the district court’s conclusion that Section 1395ddd(f)(3) precluded judicial review of the high payment error determination, even where the Secretary did not make the determination herself.


_U.S. Court in DC Says “Hold Harmless” Provision Did Not Apply to Hospitals Challenging DSH Adjustment_

On July 15, the U.S. District Court for the District of Columbia held the Department of Health and Human Services Secretary properly excluded several hospitals’ state-only patient days from their Medicare disproportionate share hospital (DSH) hospital adjustment for fiscal year (FY) 1996.

The appeals court agreed with the Secretary that the state-only patient days for the Kansas Medicaid program, known as MediKan days, should not be included in the hospitals’ Medicaid fraction used to calculate their DSH adjustment, and that the agency’s “hold harmless” policy did not apply unless the days at issue had been erroneously included in the calculation for FYs prior to January 1, 2000.

Plaintiffs are three hospitals who argued certain state-only “MediKan” days (i.e., that were funded entirely by the state and not eligible for federal matching under Medicaid) should have been included in their DSH adjustment for FY 1996 pursuant to the “hold harmless” provision of Program Memorandum No. A-99-62 (Dec. 1999) (Program Memorandum).

The Medicare DSH adjustment, which is intended to provide additional reimbursement to hospitals treating a significantly disproportionate number of low-income patients, is determined in part based on the number of Medicaid-eligible patients a hospital treats. Under HCFA Ruling 97-2 (Feb. 27, 1997), only Medicaid-eligible patient days (i.e. federal-state plan beneficiary patient days) may be included in a hospital’s Medicaid fraction. State-only plan beneficiary days should be excluded.

Because some state Medicaid programs, however, failed to distinguish between state-only and federal-state patient days, the Secretary issued the Program Memorandum, which included a “hold harmless” provision that instructed fiscal intermediaries (FIs) not to reopen hospital cost reports to disallow DSH reimbursement for state-only days and to allow hospitals to include such days in their Medicaid Fraction for cost years prior to January 1, 2000 if they had done so in the past.

Kansas was one of the states that failed to distinguish between state-only and federal-state patient Medicaid days. As a result, the hospitals’ FI mistakenly included MediKan-eligible patient days in their Medicaid fractions. The FI did not include, however, all of plaintiffs’ MediKan-eligible patient days. The parties distinguished between primary MediKan days, where MediKan reimbursed a hospital for services, and secondary MediKan days, where an insurer other than MediKan was the primary payer. In this case, the FI included only the primary MediKan days when calculating plaintiffs’ Medicaid fractions.
Plaintiffs conceded that under the Medicare statute and HCFA Ruling 97-2, MediKan-eligible patient days, regardless of whether they are primary or secondary, cannot be counted in their Medicaid fractions. Nevertheless, plaintiffs appealed the FI’s decision, arguing because the FI erroneously included primary MediKan days in plaintiffs’ Medicaid fractions, the FI also should have included the secondary MediKan days pursuant the Program Memorandum’s hold harmless provision.

The Secretary concluded the FI properly excluded the contested secondary MediKan days from plaintiffs’ Medicaid fractions because under the Program Memorandum’s Past Payment Prong, they failed to demonstrate the secondary MediKan days were included in their past Medicaid fractions. According to the Program Memorandum, the Past Payment Prong allowed FIs to continue allowing erroneously included days in a provider’s Medicaid fraction “only if” those days had been erroneously included in the provider’s Medicaid fractions “in the past.”

Affirming, the court first noted plaintiffs conceded the MediKan days, regardless of whether they are primary or secondary, could not be included in their Medicaid fractions absent the hold harmless provision.

The court rejected plaintiffs’ argument that the hold harmless provision essentially amounted to a concession by the Secretary that MediKan beneficiaries are Medicaid-eligible for purposes of the DSH calculation. Instead, the court viewed the hold harmless provision as the Secretary’s “measured attempt to remedy a breakdown in the system,” and well within the Secretary’s discretion in administering the Medicare program.

The court also disagreed with plaintiffs’ contention that because the FIs included primary MediKan days in their past Medicaid fractions, they had to do the same for the secondary MediKan days pursuant to the hold harmless provision. Plaintiffs failed to demonstrate they had been paid for secondary MediKan days in the past; thus, the Secretary properly concluded they did not qualify for hold harmless relief under the Program Memorandum. The hold harmless provision was intended in part as relief for hospitals that, through no fault of their own, relied on the erroneous DSH payments in their budgeting process. Because plaintiffs never received Medicare reimbursement based on secondary MediKan days, there was no such reliance, the court said.


**U.S. Court in DC Upholds Disallowance of “Bad Debt” Reimbursement Where Outside Collection Efforts Pending**

On July 16, the U.S. District Court for the District of Columbia held a hospital could not write off as bad debt and expect reimbursement on unpaid Medicare coinsurance and deductibles when collection efforts by an outside collection agency were not yet completed.

Lakeland Regional Health System (Lakeland) initially made internal efforts to collect coinsurance and deductibles from Medicare beneficiaries who failed to pay during the 2005 fiscal year (FY). When those efforts failed to yield payment, Lakeland wrote off the debts as uncollectible and referred them to an outside collection agency.

While those collection efforts were pending, Lakeland submitted its FY 2005 cost report to its fiscal intermediary, National Government Services (NGS), including the bad debt write offs. NGS disallowed payment for the debts that Lakeland sent to the collection agency as they had not yet been returned as uncollectible.
Lakeland appealed to the Provider Reimbursement Review Board (PRRB), which concluded NGS’ decision was erroneous. The Centers for Medicare & Medicaid Services Administrator reversed the PRRB’s decision.

Lakeland appealed, arguing the Secretary’s position constituted a change in policy in violation of the Bad Debt Moratorium under 42 U.S.C. § 1395f or in the alternative, the Secretary’s decision was “arbitrary, capricious, and inconsistent with the governing statute and regulations.” The court granted summary judgment to the Secretary.

The court found the Secretary’s policy always has been that accounts pending at collection agencies cannot be written off as bad debts until collection activity has terminated. The court pointed to the interpretive guidance issued by the Secretary in 42 C.F.R. § 413.89(e), which plainly states a debt is not reimbursable unless it is “actually uncollectable when claimed as worthless” and “sound business judgment established that there was no likelihood of recovery at any time in the future.” According to the court, the agency’s pre- and post- Bad Debt Moratorium interpretive guidance and audit guidelines reflected the Secretary’s policy, which expressly states bad debts may be claimed “only after the collection agency completes its collection effort.”

Lastly, the court held the Secretary’s decision was not arbitrary, capricious and inconsistent with governing law. Instead, the decision was consistent with 42 C.F.R. § 413.89(e), the agency’s interpretive guidelines, and administrative practice.


**Eleventh Circuit Rejects Government’s MSP Action as Untimely**

The Eleventh Circuit affirmed July 26 the dismissal of the federal government’s action against the parties to a toxic tort settlement under the Medicare Secondary Payer Act (MSP) as time-barred.

In so holding, the appeals court found regardless of whether the three-year statute of limitations—applicable to tort actions—or six-year statute of limitations—applicable to contract claims—applied, the government’s MSP action was untimely because it accrued when the majority of the settlement funds were transferred to the plaintiffs, not when the settlement was finalized, as the government contended.

In 1996, “thousands of individuals” initiated personal injury actions against the producers of polychlorinated biphenyls (PCBs)—toxic pollutants linked to cancer and birth defects—that operated a chemical plant in Anniston, AL. The parties entered into a $300 million settlement agreement in September 9, 2003.

On October 29, 2003, the PCB producers paid $275 million to the PCP plaintiffs’ lawyers. Under the terms of the settlements, the PCP plaintiffs’ lawyers had 90 days to obtain liability releases from 97% of the PCB plaintiffs, otherwise the PCB producers had the option to void the settlement. On December 2, 2003, the PCB plaintiffs’ lawyers certified that 97% of the PCB plaintiffs had signed the releases.

The federal government filed its lawsuit under the MSP Act against the PCB producers, their insurers, and the PCB plaintiffs’ lawyers on December 1, 2009, one day short of six years from the day the PCB plaintiffs’ lawyers filed the 97% certification, but more than six years after the PCB producers paid the $275 million settlement.

The government alleged Medicare paid for medical treatment needed by beneficiaries who were injured by PCBs and under the MSP Act, the PCB producers and their insurers were responsible primary plans responsible for those medical expenses conditionally paid by Medicare. The
government alleged the PCP plaintiffs’ lawyers also were liable under the Act because they accepted payment from the primary plans.

The PCB producers, insurers, and the PCB plaintiffs’ lawyers (collectively, defendants) moved to dismiss, arguing the government’s lawsuit was untimely. The district court agreed, and the government appealed.

Applying a six-year statute of limitations period, the Eleventh Circuit said the issue came down to when the government’s claim accrued—when the bulk of the settlement was paid to the PCP plaintiffs’ lawyers or when the settlement was finalized with the 97% of releases.

Under the MSP Act, a “primary plan’s responsibility for . . . payment may be demonstrated by a judgment, a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is a determination or admission of liability) . . . or by other means.”

Defendants argued the “payment conditioned upon . . . release” occurred when they transferred the $275 million on October 29, 2003. The government contended, however, that the language of the statute requires a “final, enforceable settlement agreement.” Because the PCB producers could void the settlement until 97% of the PCB plaintiffs released their claims, a final release did not occur until December 2, 2003, according to the government.

The appeals court found the statute was ambiguous and therefore it should defer to an implementing regulation, 42 C.F.R. § 411.22(b), which defined “other means” as including a “settlement” or “contractual obligation.” According to the appeals court, given this definition, the “government’s construction would render the statutory payment-conditioned-upon-release language meaningless, for the ‘other means’ language (as interpreted in the regulation) would incorporate it wholesale.”

Thus, the appeals court interpreted the statutory language to include a payment that is conditioned upon a release in the future, even though the settlement is not fully concluded.

The appeals court discounted the government’s argument that this interpretation would require the filing of premature lawsuits. Another regulation, 42 C.F.R. § 411.24(b), allowed the government to initiate recovery “as soon as it learns that payment has been made or could be made. . . .”

According to the Eleventh Circuit, the “government need not wait to file suit until a payment for medical bills has been made by a responsible entity; it is sufficient for the government to learn that payment ‘could be made’ by a responsible entity.”

*United States v. Stricker,* No. 11-14745 (11th Cir. July 26, 2013).

**U.S. Court in Michigan Tosses Suit Alleging Medicare Discriminates in Providing Mental Health Coverage**

The U.S. District Court for the Eastern District of Michigan dismissed August 2 a pro se plaintiff’s claims that Medicare unlawfully discriminates against individuals with mental health illnesses. In dismissing the action, the court found the plaintiff failed to exhaust administrative remedies as required by the Medicare Act.

Plaintiff Gina Moller sued the Centers for Medicare & Medicaid Services (CMS) alleging unlawful discrimination against those with mental health disorders in violation of the Equal Protection Clause by requiring them to pay a greater percentage of the cost of mental health services than what is required for non-mental health services.
According to plaintiff, Medicare covers 80% of the cost of most health-related expenses (leaving patients responsible for a 20% copayment) but only covers 60% of the cost of mental health services (leaving patients with a 40% copayment).

CMS moved to dismiss, arguing plaintiff failed to exhaust administrative remedies. The court agreed.

Under the Medicare Act, claims must be pursued all the way to the end of an administrative review process before a court is able to exercise its jurisdiction, the opinion noted.

According to the court, plaintiff’s argument regarding exhaustion “appears to be that she attempted to obtain administrative review by writing letters to various ‘de facto Administrative Law Judges,’ including the Attorney General, the Social Security Administration, and the Department of Health and Human Services Office for Civil Rights, but that none of those offices took any action regarding her claim.”

However, the court explained, Medicare has developed a specific process for appeals, and plaintiff’s “failure to follow that process does not allow her to ignore it entirely.”

“Plaintiff has neither exhausted the administrative remedies available to her, nor shown why the exhaustion requirement should be waived in this case,” the court found in dismissing the action.


U.S. Court in Illinois Upholds Bed Count Determination for IME Adjustment, but Reverses Exclusion of Research Time

On August 15, the U.S. District Court for the Northern District of Illinois held the Department of Health and Human Services Secretary properly included beds as available and as not for observational purposes in calculating a hospital’s indirect graduate medical education (IME) adjustment. The court also found, however, the Secretary improperly excluded research time from the hospital’s IME resident count for the fiscal years at issue.

Defendant Rush University Medical Center (Rush) is a tertiary care hospital and academic medical center that participates in Medicare. Rush filed administrative appeals of its 1993, 1994, and 1996 Notice of Program Reimbursements before the Provider Reimbursement Review Board (PRRB) contesting whether its fiscal intermediary accurately determined the hospital’s bed count and correctly excluded research rotations of residents participating in approved medical education programs when calculating its IME adjustment. The PRRB ruled in Rush’s favor on the bed count issue, but against the hospital on the resident research issue.

The Centers for Medicare & Medicaid Services (CMS) Administrator found (1) Rush failed to provide adequate documentation to support its position that it could not place beds that were taken out of service back into service in a timely manner; (2) Rush failed to show its bed total should be lowered for the number of beds used for observational purposes; and (3) research time of residents who were not associated with patient care was properly excluded from the IME adjustment.

The court granted in part and denied in part both parties’ motions for summary judgment.

Regarding the disputed number of accountable beds for FY 1993, Rush argued the Secretary erred in failing to exclude as unavailable, beds that were not listed in the August 1992 room and board index. Citing 50 Fed. Reg. at 35683, the court noted bed availability for Medicare reimbursement purposes is based on the immediacy by which a bed can be put into use to house
an inpatient and that the omission of those beds from a master room and board index did not translate into unavailability.

The court also pointed out that per the Medicare Provider Reimbursement Manual, providers, like Rush, have the burden of excluding beds as unavailable in the IME adjustment. According to the court, Rush did not meet that burden.

The number of disputed accountable beds for FY 1994 involved beds located in an area of the hospital that underwent construction from the beginning of FY 1993 into FY 1994. When the floor reopened in September 1993, Rush initially placed 28 beds in service and then added 12 more over the course of FY 1994. The CMS Administrator considered all 40 beds to be available, but Rush argued only the beds in actual service should have been counted.

The court affirmed the Administrator’s determination that although Rush initially placed only 28 beds into service, it could have added the other 12 at any time, thereby making them available for purposes of the IME adjustment. The court again noted the deciding factor of a bed’s availability is not whether it actually is in service, but whether the bed could be placed in service in a short period of time. According to the court, evidence supported finding the 40 beds were available for the entire year as Rush eventually placed all of them into service during FY 1994.

The court also upheld the Administrator’s findings that Rush failed to provide evidence substantiating its position that the 72-hour window in returning a bed to service was determinative, and what evidence Rush did provide was contradictory as some evidence demonstrated the hospital could return a bed to service the same day.

As for the accountable beds in FY 1996, Rush argued vacating a floor in anticipation of construction, including emptying it of everything needed for patient care, redeploying its nurses, and not including it on room and board indices, rendered the beds unavailable for purposes of the IME adjustment. The court disagreed, upholding the decision to include these beds as available because Rush vacated the floor five months before construction began and failed to show the beds at issues could not be placed back into service before construction commenced.

Rush also argued the Secretary improperly included observation beds in the calculation of its IME adjustment bed count. The court found Rush failed to meet its burden of establishing which of its beds were observation beds because it did not provide adequate documentation that they had been billed to Medicare as such.

Turning to the issue of whether the Secretary properly excluded from the IME adjustment time spent by residents conducting research that was unrelated to patient care, the court held the Seventh Circuit’s ruling in University of Chicago Med. Ctr. v. Sebelius, 618 F.3d at 739 (7th Cir. 2010), was controlling. In University of Chicago Medical Center, the Seventh Circuit held the Secretary should have included pure research time when calculating the hospital’s IME adjustment based on the language of the Affordable Care Act (ACA).

After the Seventh Circuit decided University of Chicago, the Secretary issued a final rule stating time spent by residents conducting pure research was not included as a compensable non-patient care activity. The court held, however, that it was bound by the Seventh Circuit’s interpretation even though it was inconsistent with the Secretary’s later-issued promulgation. The court therefore held the Secretary improperly excluded research time from the IME adjustment for FYs 1993, 1994, and 1996.

Ninth Circuit Reverses Ruling That HHS’ MSP Collection Practices Contrary to Statute

The Ninth Circuit reversed September 4 a federal district court in Arizona ruling in favor of a group of Medicare beneficiaries who challenged the Department of Health and Human Services Secretary’s authority under the Medicare Secondary Payer (MSP) provisions to demand immediate reimbursement from them before pending appeals and waiver requests were decided.

The appeals court found none of the named beneficiaries in the class action challenged the Secretary’s policy of demanding “upfront” reimbursement through the administrative process and therefore the court lacked subject matter jurisdiction pursuant to 42 U.S.C. 405(g).

The appeals court also overturned the lower court’s decision that the Secretary could not preclude plaintiffs’ attorneys from disbursing undisputed portions of settlement proceeds to their beneficiary clients. While the attorney who challenged the policy had no available administrative remedies, and thus was excused from the exhaustion requirement, the appeals court held on the merits that the Secretary’s interpretation of an ambiguity in the MSP statute was reasonable.

The appeals court therefore vacated the injunctions granted by the U.S. District Court for the District of Arizona and remanded for consideration of the beneficiaries’ due process claim, which the court had not addressed.

Upfront Reimbursement

The Medicare statute provides other insurance covering health care for Medicare beneficiaries is the primary payer. When a liability insurer does not pay “promptly,” i.e. within 120 days, Medicare makes a “conditional” payment for care and may seek reimbursement from a “primary plan [or] an entity that receives payment from a primary plan” within 60 days of determining a primary plan’s responsibility or interest starts to accrue.

Medicare beneficiaries Patricia Haro and John McNutt alleged the Secretary’s policy of demanding immediate reimbursement, within 60 days, in advance of resolving any appeal or request for a hardship waiver of the reimbursement claim sought by Medicare was contrary to the MSP statute and violated their due process rights.

Haro’s attorney, John G. Balentine, also challenged the Secretary’s requirement that attorneys withhold distribution of disputed insurance proceeds from their clients, under threat of monetary penalties, including being personally liable for the reimbursement claim.

Both Haro and McNutt were injured in automobile accidents. Medicare paid conditionally for their medical care and then sought reimbursement from them when they received insurance proceeds.

Plaintiffs disputed the amounts of the reimbursement determinations, but received demand notices from Medicare before their appeals were resolved.

The district court granted summary judgment in plaintiffs’ favor and enjoined the Secretary from enforcing the policies. While finding the Secretary’s interpretation was entitled to Chevron deference, the court held the policies, for both beneficiaries and attorneys, were unreasonable. Haro v. Sebelius, No. CV-09-134 TUC DCB (D. Ariz. May 9, 2011).
Jurisdiction Lacking

Reversing the ruling below, the appeals court found subject matter jurisdiction over the beneficiary plaintiffs’ challenge was lacking because they failed to exhaust their administrative remedies.

Although the named plaintiffs disputed the reimbursement amounts sought by Medicare at the administrative level, they did not object to the Secretary’s interpretation of the MSP. The appeals court said the purpose of the administrative channeling requirement—i.e., to give the agency a chance to “apply, interpret, or revise” its policies and regulations—would be undermined if plaintiffs could wait “to raise claims in federal court that were not raised before the agency.”

The appeals court remanded to the district court for consideration of plaintiffs’ due process claim.

Secretary’s Interpretation Reasonable

The appeals court did consider the merits of Balentine’s claims. As he brought his action as an attorney for Medicare beneficiaries, he had no other avenue for seeking administrative review of his policy challenge, the appeals court noted.

Because applying the channeling requirement would mean no review at all, his claim fell into the narrow exception to the exhaustion requirement, the appeals court concluded.

But the appeals court went on to reject his challenge after finding the Secretary’s interpretation of the MSP reimbursement provision was reasonable under Chevron deference.

The appeals court saw no statutory basis to distinguish between “entities” that receive payment from a primary plan (in this case Balentine) and end-point recipients (i.e., his beneficiary clients). In fact, 2003 amendments to the MSP provision indicated Congress intended a more expansive construction of “entity that has received payment from a primary plan” than previous court interpretations.

Finally, the appeals court found the Secretary’s interpretation was consistent with the purpose of the MSP provisions—namely, reducing Medicare costs by ensuring proceeds are available for reimbursement.

The appeals court did not address whether the Secretary would have a right of action against attorneys who already disbursed settlement proceeds, because this issue was not ripe for review.

Haro v. Sebelius, No. 11-16606 (9th Cir. Sept. 4, 2013).

U.S. Court in D.C. Rejects Hospitals’ Bid for Medicare Reimbursement of Offsite Resident Training

On September 4, the U.S. District Court for the District of Columbia upheld the Department of Health and Human Services Secretary’s denial of Medicare reimbursements for costs associated with offsite resident training due to plaintiff hospitals’ failure to meet the requirements that they incur “all or substantially all” of the training program’s costs and have a written agreement in place with the nonhospital site.

In so holding, the court deferred to the Secretary’s interpretation of the “all or substantially all” requirement as precluding cost-splitting by hospitals as “reasonable and consistent” with the plain language of the applicable statute. The court also found reasonable the Secretary’s interpretation of the “written agreement” requirement.
Plaintiffs are nonprofit acute care hospitals that have affiliation agreements with the Michigan State University Kalamazoo Center for Medical Studies (KCMS) to rotate medical residents through KCMS’ nonhospital clinic facility. The affiliation agreements state that the hospitals “share joint and equal responsibility for providing [KCMS] with sufficient financing to carry out [the KCMS] programs as negotiated on a yearly basis.”

In 2008, plaintiffs’ fiscal intermediary issued a Notice of Program Reimbursement disallowing Medicare reimbursement for costs plaintiffs incurred for resident rotations completed at KCMS clinics. The intermediary claimed plaintiffs did not satisfy the statutory “all or substantially all” requirement within the Nonhospital Site Statutes under 42 U.S.C. §§ 1395ww(d)(5)(B)(iv) and 1395ww(h)(4)(E) as plaintiffs split the training program’s costs. The intermediary also found plaintiffs failed to meet the written agreement requirement under 42 C.F.R. § 413.86(f)(4)(ii).

Plaintiffs successfully challenged the intermediary’s disallowance before the Provider Reimbursement Review Board (PRRB), but the Centers for Medicare & Medicaid Services Administrator reversed the PRRB’s decision. The district court upheld the Secretary’s interpretation of the applicable statutory and regulatory requirements for reimbursement of offsite resident training and therefore denied plaintiffs’ motion for summary judgment and granted defendant’s motion for summary judgment.

The court said the Secretary’s “single hospital” interpretation, as clarified in 72 Fed.Reg. 26870, 26969 (May 11, 2007), to disallow cost sharing between two or more hospitals of a joint residency training program at the same nonhospital site was reasonable and consistent with the “all or substantially all” requirement in the Nonhospital Site Statutes.

The court also agreed with the Secretary’s interpretation of the written agreement requirement, which required plaintiffs and KCMS to indicate that the hospital would incur the cost of the resident’s salary and fringe benefits while in training at the nonhospital site and that plaintiffs would provide reasonable compensation to the nonhospital site for supervisory training activities.

The court found the affiliation agreements did not comply with the written agreement requirement as their use of the phrase “sufficient financing” was ambiguous; they did not obligate plaintiffs to pay for all or substantially all of the KCMS’ training programs; and they failed to sufficiently detail the compensation scheme for supervisory teaching activities and the amounts plaintiffs would actually pay for those activities.

Moreover, the court said KCMS’ bylaws did not meet the written agreement requirement because they were not an agreement between a hospital and nonhospital site; they did not commit plaintiffs to incur all or substantially all of the training program’s costs; and KCMS received funding from private patients and grants that plaintiffs were unable to confirm if supervisory physician costs, resident salaries, and other nonhospital training costs were paid from those funds.


**U.S. Court in New Jersey Dismisses Ambulance Company’s Mandamus Claims Against Medicare Program Safeguard Contractor**

The U.S. District Court for the District of New Jersey dismissed September 3 an ambulance company’s claims against a Medicare Program SafeGuard Contractor (PSC), finding the company failed to exhaust administrative remedies.

Plaintiff Nationwide Ambulance Services renders non-emergency ambulance services to dialysis patients. Defendant SafeGuard is a designated PSC specifically contracted to review and investigate claims with a focus on preventing fraudulent or improper claims. SafeGuard serves as
an intermediary between a service provider, such as Nationwide, and a Medicare Administrative Contractor, such as Highmark Medicare Services.

Nationwide had been receiving reimbursement payments regularly from Highmark under the Medicare program. On January 13, 2011, the Centers for Medicare & Medicaid Services notified Nationwide that “the PSC for New York and New Jersey” would be conducting a “pre-payment process . . . to ensure that all payments made by the Medicare program are appropriate and consistent with Medicare policy” (pre-payment audit).

As of September 20, 2011, 950 claims had been reviewed by SafeGuard as part of the pre-payment audit, 875 of which have been denied (92.1%) by Highmark based on SafeGuard’s recommendation.

Nationwide filed a flurry of complaints against SafeGuard Services, among other things asserting state law tort claims against it for insisting on reviewing documentation in addition to physician certifications in determining the medical necessity of Nationwide’s ambulance services during the prepayment review. Safeguard moved to dismiss for lack of subject matter jurisdiction.

The court first noted that for a writ of mandamus to issue, three conditions must be satisfied: (1) the party seeking issuance of the writ must have no other adequate means to attain the relief he desires; (2) the petitioner must satisfy the burden of showing that his right to issuance of the writ is clear and indisputable; and (3) the writ must be appropriate under the circumstances.

The court said the Medicare Act provides “a clear alternative avenue for relief.” Because plaintiff failed to exhaust its administrative remedies, the court found it lacked subject matter jurisdiction.

The court said plaintiff also failed to identify a clear, nondiscretionary duty of the Secretary. The court agreed with defendants that the plain language of 42 C.F.R. § 410.40(d) “does not support the existence of a clear, nondiscretionary duty of the Secretary to make medical necessity determinations based solely upon a physician’s certification and without reviewing any medical documentation.”


**U.S. Court in Connecticut Rejects Beneficiaries’ Challenge to “Observation Status”**

A federal district court in Connecticut granted summary judgment to the Department of Health and Human Services Secretary in a dispute brought by a putative class of Medicare beneficiaries arguing the classification of their hospital stays as “observation status” violated the Medicare Act, the Administrative Procedure Act (APA), and their due process rights.

The Second Circuit’s decision in *Estate of Landers v. Leavitt*, 545 F.3d 98 (2d Cir.), which upheld the Secretary’s decision to tie the distinction between inpatients and outpatients to whether a beneficiary was formally admitted to the hospital, foreclosed most of plaintiffs’ arguments.

The court also rejected plaintiffs’ other claims that were not foreclosed by *Landers*, including that they failed to receive APA-required notices and that the “observation status” classification violated constitutional due process.

Plaintiffs are 14 Medicare beneficiaries who each spent several nights in the hospital, but who were not formally admitted and therefore were denied Part A coverage. According to the opinion,
plaintiffs received many of the same services they would have received had they been admitted as inpatients.

The inpatient/outpatient designation has financial repercussions for beneficiaries on several fronts, the court explained. For example, under Medicare Part A, a beneficiary admitted as an inpatient pays a one-time deductible for the first 60 days in the hospital, but under Part B, which pays for outpatient services, a beneficiary owes a co-payment for every individual hospital service.

The inpatient/outpatient distinction has even greater significance in terms of skilled nursing facility (SNF) services—which Medicare covers only “after transfer from a hospital in which [the individual] was an inpatient for not less than 3 consecutive days before his discharge,” the court explained. “Thousands of dollars may turn on whether a beneficiary received inpatient or outpatient hospital services.”

In the Medicare Benefit Policy Manual, the Secretary defined “inpatient,” which is not spelled out by the Medicare statute, as “a person who has been admitted to a hospital . . . . Generally a patient is considered an inpatient if formally admitted as inpatient . . . .” Instead of admitting a beneficiary as an inpatient, the hospital can place him on “observation status,” which entails monitoring a patient to determine whether a formal admission is in order. Services provided to beneficiaries with “observation status” are treated as outpatient services payable under Part B.

Plaintiffs alleged, among other things, the Secretary’s “use” of observation status violates the Medicare statute by depriving them of Part A coverage; violates the notice and comment requirements of the APA; violates the Freedom of Information Act (FOIA) because “observation status” has not been published in the Federal Register; and violates the Medicare statute and the Due Process Clause of the Fifth Amendment by not requiring beneficiaries receive written notification of the placement on observation status, the consequences of that status, and their right to challenge it.

After finding plaintiffs qualified for judicial waiver of the exhaustion requirement, the court turned to the merits and rejected each of plaintiffs’ claims.

First, the court noted the Landers decision foreclosed the majority of plaintiffs’ arguments.

Plaintiffs argued they received essentially the same services on “outpatient status” as they would have as inpatients, and therefore denying them Part A coverage “elevates form over substance.” But the Second Circuit specifically rejected that argument in Landers and upheld the Secretary’s decision to tie Part A coverage to formal hospital admission rather than the nature of the services provided, the court said.

The court also was bound by the Landers court determination that the policy manual provision was an “interpretative” rule and therefore exempt from notice-and-comment rulemaking under the APA and the Medicare statute.

The court dispensed with the alleged FOIA violation by noting the concept of observation services and the decision to classify them as outpatient services were published in the Federal Register. Moreover, there was no indication that plaintiffs’ health care providers would have changed their decisions whether to formally admit them as inpatients had the statements about “observation status” been published more prominently and clearly.

As to their due process claim, the court held plaintiffs failed to establish a property right in formal hospital admission, inpatient status, and Part A benefits. “Ultimately the decision to admit is up to the physician based on his or her medical judgment,” the court observed.

**U.S. Court in D.C. Upholds Exclusion of Dual-Eligible Exhausted Days from Medicaid Fraction of DSH Calculation**

On October 8, the U.S. District Court for the District of Columbia upheld the Department of Health and Human Services Secretary’s interpretation that dual-eligible exhausted benefit days and Medicare secondary payer (MSP) days must be excluded from the Medicaid fraction of the disproportionate share hospital (DSH) adjustment because a patient’s entitlement to Part A benefits turned on whether the patient met the statutory criteria for Medicare benefits, regardless of whether Medicare paid for the days at issue.

Plaintiff Allina Health System owns and operates five hospitals that participate in Medicare. In calculating the applicable DSH adjustments for fiscal years 1993-2003, Allina’s fiscal intermediary determined dual-eligible exhausted benefit days and MSP days should be excluded from the Medicaid fraction. The intermediary concluded such patient days did not fall into the category of individuals who were “not entitled to benefits under [Medicare] Part A.”

Allina appealed to the Provider Reimbursement Review Board (PRRB), which reversed the intermediary’s determination. The Centers for Medicare and Medicaid Services (CMS) reversed the PRRB’s decision and upheld the intermediary’s original determination, concluding the contested days should be excluded from the Medicaid fraction of the DSH adjustment formula. The court denied Allina’s motion for summary judgment and granted the Secretary’s cross-motion for summary judgment.

According to the court, the parties’ dispute was based on whether patients falling within these categories of dual-eligible exhausted days and MSP days were “entitled to benefits under Part A” as used in the Medicaid fraction of the disproportionate patient percentage (DPP).

The court found either party’s interpretation of “entitled to benefits under Part A” in the Medicaid fraction numerator of the DSH adjustment formula seemed permissible. In other words, “[t]he statutory language does not unambiguously compel either side’s interpretation.” The court therefore looked at “whether the agency’s [interpretation] is based on a permissible construction of the statute,” as required under the Supreme Court’s two-part Chevron test (*Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

The court held the Secretary’s interpretation was based on a permissible reading of the Medicare statute and was not arbitrary or capricious. Allina argued the Secretary’s interpretation was unreasonable because it conflicted with her construction of the same language in 42 U.S.C. § 1395ww(d)(5)(G)(iv) regarding Medicare-dependent, small rural hospitals. The court waived the argument as Allina never raised it during any of the administrative proceedings, whether before the PRRB or the CMS Administrator.

The court also refused to consider Allina’s argument that even if the Secretary properly excluded the contested days from the Medicaid fraction, the Secretary should have at least counted those days in the Medicare fraction. The court held Allina could not “so substantially repackage its theory at this late stage in the game,” as Allina’s consistently sought-after relief before the PRRB, CMS, and this court was “much narrower: a determination that the contested days be included in the numerator of the Medicaid fraction.”

Allina next contended the Secretary’s interpretation was unreasonable because she improperly equated the terms “eligible” and “entitled” as used in the Medicaid fraction. Allina relied on several appellate decisions that concluded the two terms have different meanings in the DSH adjustment formula. The court was not persuaded because none of the cases Allina relied on “directly dealt with the precise issue before this Court—i.e., the phrase ‘entitled to benefits under..."
Part A.” Instead, the decisions on which Allina relied all dealt with interpreting the requirement that patients be eligible for Medicaid.

Lastly, Allina argued the Secretary’s interpretation amounted to impermissible retroactive rulemaking. The court disagreed. Referencing Edgewater Med. Ctr., HCFA Adm’r Dec., 2000 WL 1146601, the court pointed out the Secretary’s “policy of excluding dual-eligible exhausted days from the Medicaid fraction was announced four years earlier in Edgewater, and the [2004] rulemaking was simply a reiteration of this position.”


U.S. Court in DC Rejects Hospital’s Bid to Revive Previously Litigated Challenge to Medicare Rule for SNF Reimbursement

On October 17, the U.S. District Court for the District of Columbia held issue preclusion barred a hospital’s challenge to Medicare reimbursement rules for hospital-based skilled nursing facilities (SNFs). The court held once a party has had its day in court with every incentive to litigate its case fully, a compelling showing of unfairness is necessary to avoid the application of issue preclusion to any subsequent suit between the same parties addressing the same legal issues.

Plaintiff Canonsburg General Hospital (Canonsburg) owns and operates a hospital-based SNF. Plaintiff participated in the Medicare program and was reimbursed on a reasonable cost basis, subject to reasonable cost limits (RCLs) promulgated by the Centers for Medicare & Medicaid Services (CMS). Plaintiff’s SNF was exempted from RCLs as a new provider for fiscal years ending on June 30, 1984, 1985, and 1986. For every year thereafter, including through fiscal year 1996, plaintiff exceeded the hospital-based SNF RCL and sought RCL exceptions for each of those years.

In 1994, the Department of Health and Human Services (HHS) added a new section to the Provider Reimbursement Manual (PRM), Section 2534.5, which states that when “determining reasonable cost, the provider’s per diem costs in excess of the cost limit are . . . compared to per diem costs of a peer group of similarly classified providers.” For hospital-based SNFs, the qualifying amount for reimbursement under an exception is measured from 112% of the SNFs peer group mean per diem cost, not its peer group RCL. This prevents hospital-based SNFs from being reimbursed for costs incurred when providing atypical services that were in excess of the RCL but below the 112% peer group mean per diem threshold.

Following the application of PRM § 2534.5 to cost reports that plaintiff filed for the five fiscal years ending June 30, 1987 through June 30, 1993, plaintiff sued in the U.S. District Court for the Western District of Pennsylvania (Canonsburg I), arguing PRM § 2534.5 improperly interpreted 42 U.S.C. § 1395yy(c) and 42 C.F.R. § 413.30(f) (the cost limit statute and regulation); PRM § 2534.5 was a substantive rule that was not passed according to the Administrative Procedure Act’s (APA’s) notice and comment requirements; and the exception methodology outlined in PRM § 2534.5 was “arbitrary, capricious and an abuse of discretion.”

The Canonsburg I court held the HHS Secretary’s interpretation of the regulation and statute was reasonable because the cost limits in the Medicare statute are phrased in permissive, not mandatory, language; the PRM rules are widely held to be “interpretive rules” and therefore exempt from notice and comment rulemaking; PRM § 2534.5 on its face did not “effect new substantive reimbursement standards inconsistent with prior regulations”; and the regulation did not discriminate between free-standing and hospital-based SNFs because “once [hospital-based SNFs are] discounted for their unreasonable costs as determined by Congress . . . [both types of SNFs are] treated relatively the same.”
In September 1998, several years before the court decided *Canonsburg I*, plaintiff again filed a cost report with its Medicare fiscal intermediary claiming certain costs incurred by its SNF were atypical for fiscal year 1996. The intermediary granted an atypical services exception but calculated the exception amount according to PRM § 2534.5. Plaintiff appealed to the Provider Reimbursement Review Board (PRRB).

In 2009, the PRRB found the intermediary should have reimbursed plaintiff’s costs in excess of the RCL and that PRM § 2534.5 was invalid on substantive and procedural grounds. The CMS Administrator reversed the PRRB’s decision and found all hospital-based SNF costs between the RCL and the 112% threshold were unreasonable costs.

Plaintiff timely filed this suit challenging the CMS Administrator’s decision, “raising what are effectively the identical arguments to those raised” when plaintiff sued in Pennsylvania district court. The court granted the Secretary’s motion for summary judgment, thereby estopping plaintiff from raising again the issues resolved in *Canonsburg I*.

The court argued plaintiff’s claims were precluded by the decision in *Canonsburg I*. Plaintiff raised four arguments against issue preclusion, but the court found all of them unpersuasive.

Plaintiff first argued applying issue preclusion to its claim would be unfair because “the legal context has changed significantly in the last 10 years since 2001.” The court disagreed as plaintiff failed to show a significant change or shift in controlling law.

Plaintiff next contended that because defendant did not raise the collateral estoppel issue in the administrative proceedings, it waived the affirmative defense. The court rejected plaintiff’s argument that to invoke issue preclusion arising from a prior judicial decision, an agency must satisfy “dual requirements that the defense be asserted first at the administrative level and, subsequently, in court.” In this case, the court found defendant consistently raised the collateral estoppel defense throughout court proceedings. The focus was on the preclusive effect of a judicial decision made by a court, not an agency.

Plaintiff also argued because defendant did not use issue preclusion based on *Canonsburg I* to dispose of the case during administrative proceedings, the court was barred from considering this defense as it was “beyond the proper scope of review.” Plaintiff relied on *SEC v. Chenery*, 332 U.S. 194 (1947) which held that courts “judge the propriety of [agency] action solely by the grounds invoked by the agency” when dealing with a determination that an administrative agency alone is authorized to make. In this case, the court found *Chenery* to be inapplicable because the issue under review did not involve a determination that the agency alone was authorized to make.

Lastly, plaintiff argued the policy considerations underlying the collateral estoppel doctrine would be undercut by its application in this case. The court said reviewing the same legal issue between identical parties was the type of “duplicative expenditure of judicial resources” that preclusion was intended to bar, regardless of administrative resources already spent.

The court also rejected plaintiff’s contention that defendant’s choice to settle with other plaintiffs in unrelated cases resulted in providers having to repeatedly sue on the same issues. The court pointed out that defendant’s choice to settle with others who had similar legal issues had no bearing on whether issue preclusion in this particular case created a fundamental unfairness for Canonsburg General Hospital.
Finally, the court concluded plaintiff offered no rationale as to why this chance at being heard on the merits again would be any different than the chance provided to any other precluded party. The court concluded plaintiff’s policy arguments were insufficient to show that application of issue preclusion would be fundamentally unfair in this case.


**U.S. Court in DC Reconsiders Ruling, Finds Out-Of-Network Hospital Could Not Sue MCO as Third-Party Beneficiary**

An out-of-network hospital could not sue a Medicaid managed care organization (MCO) for alleged nonpayment of emergency services provided to five of its members as an intended third-party beneficiary of a contract between the District of Columbia and the MCO, the U.S. District Court for the District of Columbia held October 21 in a reversal of a previous decision.

In a June 2012 ruling, the court held Prince George’s Hospital Center had no private right of action against Advantage Health Plan, Inc., an MCO under contract with the District of Columbia to provide medical insurance to its Medicaid-eligible residents, under the Medicaid statute, which requires MCOs to provide coverage for emergency services “without regard to prior authorization or the emergency care provider’s contractual relationship with the organization or manager . . . .” 42 U.S.C. § 1396u-2(b)(2)(A)(I). _See_ _Prince George’s Hosp. Ctr. v. Advantage Health Plan, Inc._, No. 03-2392 (RWR) (D.D.C. June 6, 2012).

Applying the four-prong test set forth in _Cort v. Ash_, 422 U.S. 66 (1975), the court found the hospital failed to establish Congress intended to create a private remedy under the Medicaid statute for reimbursement of emergency services. The court also held the hospital could not sue under the common law of subrogation for nonpayment of emergency medical services.

But the court did find the hospital had a claim as an intended third-party beneficiary of the contract between the District and Advantage, which specified the MCO was required to reimburse providers for emergency services regardless of whether they were rendered in-network or out-of-network.

In its latest opinion, which granted Advantage’s motion for reconsideration, the court concluded a third-party beneficiary claim was not an option either in light of two recent cases: the Supreme Court decision in _Astra USA, Inc. v. Santa Clara County_, 131 S. Ct. 1342 (2011), and _Medevac MidAtlantic, LLC v. Keystone Mercy Health Plan_, 817 F. Supp. 2d 515 (E.D. Pa. 2011).

In _Astra_, the Court held a county that operated several 340B entities could not sue a drug manufacturer for alleged overcharges stemming from a violation of the program requirements and a contract with the Department of Health and Human Services.

The Court found the Public Health Services Act provisions related to the 340B program did not create a private right of action and the contracts between HHS and drug companies that incorporated those statutory requirements did not evidence any intent by the parties to benefit the 340B entities apart from the statutory requirements. Thus, the Court rejected the county’s argument that the contract at issue gave rise to a third-party beneficiary claim, noting to hold otherwise would circumvent Congress’ intent not to allow private enforcement of the statute.

In _Medevac_, the Eastern District of Pennsylvania also rejected an emergency services provider’s attempt to sue an MCO under a third-party beneficiary theory to recover alleged nonpayments, finding contractual provisions at issue were intended to ensure compliance with existing statutory or regulatory requirements, and not to benefit a non-party.
Applying these cases here, the court concluded the hospital’s third-party beneficiary claim had to be dismissed.

As in *Astra*, the relevant contract provisions merely incorporated the Medicaid statutory requirements and therefore “the inclusion of such term in the managed care contracts is not indicative of any intent on the part of the signatories to benefit [the hospital] beyond the requirements of the Medicaid statute,” the court said. According to the court, to hold otherwise would “frustrate the intent of Congress in enacting the Medicaid statute,” which did not include a private right of action to enforce the provision at issue.

Also as was the case in *Astra*, the court noted, Congress provided an extra-judicial mechanism for resolving provider reimbursement disputes through MCOs’ statutorily mandated grievance procedures, not through the courts.

Finally, the court said the managed care provisions of the Medicaid statute include “extensive sanctions for non-compliance” that are themselves designed to incentivize compliance with contractual requirements and further shows Congress intended for the states, not providers, to enforce them.


**U.S. Court in Connecticut Blocks United’s Move to Shed Physicians in Medicare Advantage Network**

A federal court in Connecticut granted a preliminary injunction preventing United Healthcare, the largest private Medicare insurer in the state, from terminating some 2,200 physicians from its Medicare Advantage (MA) program.

In agreeing to maintain the status quo, the U.S. District Court for the District of Connecticut found the members of the two medical associations that asked the court to intervene demonstrated irreparable harm to their physician members in the form of the potential disruption of physician-patient relationships, loss of good will and reputational harm, and “a resulting loss of ability to compete in the market for provision of Medicare services.”

The court also concluded the two associations—Fairfield County Medical Association and Hartford County Medical Association—demonstrated a likelihood of success on the merits of their contract-based claims.

“United’s argument that it has a unilateral right to terminate participating physicians from participation in the Medicare Advantage plan by ‘amendment’ of that plan is not supported by the language of the contract or the parties’ experience under it,” the court said.

The court enjoined United from terminating any of the affected physicians from its MA network, from notifying its MA customers that certain physician members would be terminated from the network as of February 1, 2014, and “removing or failing to advertise/market” the physicians in United’s 2014 directories for the MA network.

In October, United issued letters to more than 2,000 physicians in Connecticut notifying them of their removal from its MA network as of February 1, 2014, characterizing the move as an “amendment” to their provider contractors.

The associations filed the instant action alleging United denied the terminated physicians substantive and procedural due process rights under the Medicare Act and breached the provider contracts.
According to the associations, United’s termination notices were not “amendments” of the agreements but terminations of the provider contracts, which triggered the contracts’ termination clause. Under the contracts, United has broad discretion to amend its physician agreements with 90-days’ notice, but requires a more extended timeline for terminations without cause.

In further developments, the court denied December 8 United’s motion to stay the injunction pending appeal. United filed December 9 a notice of its appeal to the Second Circuit.

In denying the motion to stay, the court pointed out its order did not preclude United from following the procedures for termination without cause set forth in the contract, which allow termination of providers on the anniversary dates of the contracts.

Regarding its finding that physician members could suffer reputational harm in the absence of an injunction, the court distinguished between “amend[ing] physicians out of its network” early and allowing a contract with a physician to expire. “The former implies that one did something wrong, the latter does not,” the court observed.

The court also found no support for United’s assertion that the terminations are “expressly permitted by . . . [Centers for Medicare & Medicaid Services] regulations.”

Other arguments United advanced that the court rejected included that the associations lacked standing to sue, no federal cause of action permitted the associations or their physician members to challenge United’s changes to its MA network, failure to exhaust administrative appeal remedies or submit their disputes to arbitration per contract requirements, and Medicare preemption of the associations’ claims.

Second Circuit Modifies Injunction, Sets 30-Day Deadline for Physicians to Challenge Removal from United’s MA Network

The Second Circuit upheld February 7 a preliminary injunction preventing United Healthcare, the largest private Medicare insurer in the state of Connecticut, from terminating some 2,200 physicians from its Medicare Advantage (MA) program, but said the injunction would expire after 30 days.

During that period, physicians could initiate arbitration proceedings challenging their removal from the network and seek emergency or injunctive relief from an arbitrator, according to the summary order.

Rejecting United’s appeal of the preliminary injunction, the Second Circuit panel confirmed the U.S. District Court for the District of Connecticut had federal subject matter jurisdiction over the case and plaintiffs Fairfield County Medical Association and Hartford County Medical Association had associational standing.

In agreeing to maintain the status quo, the district court in its December 5, 2013 decision found the two medical associations demonstrated irreparable harm to their physician members in the form of the potential disruption of physician-patient relationships, loss of good will and reputational harm, and “a resulting loss of ability to compete in the market for provision of Medicare services.” Fairfield County Med. Ass’n v. United Healthcare of New Eng., No. 3:13-cv-1621 (SRU) (D. Conn. Dec. 5, 2013).
The district court enjoined United from terminating any of the affected physicians from its MA network “until a ruling on the merits of the [plaintiffs’] claims or a further order of this court.”

In October, United issued letters to more than 2,000 physicians in Connecticut notifying them of their removal from its MA network as of February 1, 2014, characterizing the move as an “amendment” to their provider contracts.

The associations filed the instant action alleging United denied the terminated physicians substantive and procedural due process rights under the Medicare Act and breached the provider contracts.

According to the associations, United’s termination notices were not “amendments” of the agreements but terminations of the provider contracts, which triggered the contracts’ termination clause. Under the contracts, United has broad discretion to amend its physician agreements with 90-days’ notice, but requires a more extended timeline for terminations without cause.


**U.S. Court in DC Upholds Methodology for Outlier Payments to Hospitals**

The U.S. District Court for the District of Columbia granted January 6 summary judgment in favor of the Department of Health and Human Services (HHS) in a lawsuit challenging the methodology for setting fixed-loss thresholds for Medicare outlier payments.

Medicare typically compensates hospitals at a fixed rate based on the average operating costs of hospital services. Because this may undercompensate hospitals for certain patients, Medicare makes additional “outlier payments” for patients who are unusually expensive to treat.

Outlier payments are based on the amount by which the cost of care exceeds an outlier threshold. The outlier threshold is determined by adding the prospective payment rate to a “fixed-loss threshold,” which is calculated using historical charge data, an inflation factor, charge-to-cost ratios, and other factors. A higher charge inflation factor or charge-to-cost ratio results in a higher fixed-loss threshold, causing lower outlier payments. The fixed-loss threshold is set each year as part of an annual Inpatient Prospective Payment System (IPPS) rulemaking.

Plaintiffs are various hospitals that alleged the IPPS rules for federal fiscal years (FFYs) 2004, 2005, and 2006 were arbitrary and capricious. Plaintiffs claimed HHS’ use of historical data in determining charge inflation and cost-to-charge ratios unreasonably failed to consider the effects of the Outlier Correction Rule, causing underpayments to participating hospitals.

The Outlier Correction Rule was promulgated in 2003 to prevent “turbo-charging” by which some hospitals greatly increased their outlier payments. Plaintiffs argued this caused predictable decreases in charge inflation and charge-to-cost ratios that HHS failed to take into account, resulting in overinflated projections and thus an excessively high loss threshold.

Regarding the charge inflation factor, Plaintiffs pointed to the Outlier Correction Interim Final Rule (IFR), in which a proposed mid-year loss threshold reduction excluded data from 123 of the worst turbo-charging hospitals. Plaintiffs argued that failure to exclude these hospitals from the subsequent FFY 2004 IPPS represented an abandonment “without explanation,” and was therefore arbitrary and capricious.

The court rejected this argument, noting neither the Proposed Outlier Correction Rule nor the Final Outlier Correction Rule had used this methodology (because the proposed mid-year reduction was not adopted by these rules). The court ruled HHS was under no obligation to
explain why a particular methodology considered in drafting an interim rule was not formally adopted.

Plaintiffs also argued even if HHS was not required to explain why it did not adopt the IFR’s methodology, the exclusion of the 123 hospitals was a “reasonably obvious alternative” that the agency was required to address. HHS responded that there was nothing obvious about the number 123, and that consideration in a previous rule that involved now-outdated data that was not ultimately adopted did not make the alternative so obvious that it needed to be addressed.

The court agreed with HHS, adding that while exclusion of the “turbo-charging” data may have been a reasonable option, it was not unreasonable to have decided otherwise, given that exclusion may have resulted in an excessively low fixed-loss threshold.

Finally, plaintiffs argued HHS failed to account for industry response to regulatory action. However, the court found no evidence that at the time of the rulemaking there was more recent data that could have been used to account for changes in hospital behavior. The court also dismissed claims regarding FFYs 2005 and 2006 on the additional grounds there was no evidence from the public comments that the charge inflation factor was before HHS during the 2005 or 2006 IPPS.

Turning to the cost-to-charge ratio determinations, the court identified three separate arguments. First, that although HHS attempted to calculate the cost-to-charge ratio more accurately by using the “latest tentatively settled cost reports” rather than “latest settled cost reports,” the report was still outdated; second, that HHS (in FFY 2004 only) failed to account for the Outlier Correction Rule’s termination of the practice of defaulting some hospitals’ cost-to-charge ratio to the state average; and third, that HHS had not accounted for the post-payment reconciliation mechanism.

Regarding the reports, court initially ruled that although the reports for FFY 2004 were “approximated,” HHS adequately explained its method for doing so. The court further noted plaintiffs offered no specific method or data that HHS could have used as an alternative. Finally, the court held the use of historic data rather than projections was within the agency’s discretion.

Moving on to the practice of defaulting to statewide averages, the court found that although HHS did not directly address the elimination, it did account for the more general policy change. The court also deferred to HHS’ expertise in determining not to attempt to model hospital behavior.

Finally, examining the reconciliation claim, the court held the agency’s explanation that it could not project specifically which, or how many, hospitals would be subject to reconciliation was adequate.

Having concluded HHS acted reasonably in determining the fixed-loss thresholds, the court granted HHS’ motion for summary judgment and denied the plaintiff’s.


U.S. Court in Maine Rejects Hospital’s Challenge to Agency Interpretation of Sole Community Hospital Regulation

The U.S. District Court for the District of Maine on January 6 affirmed the ruling of a magistrate judge granting the government’s motion for judgment on the administrative record in a suit over the “sole community hospital” designation for Medicare reimbursement.
Under applicable regulations, in addition to other criteria, a hospital may be defined as a “sole community hospital” when “no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital’s service area are admitted to other like hospitals located with a 35 mile radius of the hospital.”

The Department of Health and Human Services (HHS) determined plaintiff Maine Coast Memorial Hospital did not qualify for the sole community hospital designation, which entitles hospitals to enhanced Medicare reimbursement rates, under the regulations.

The parties agreed "like hospitals" within a 35-mile radius of plaintiff admitted 459 Medicare beneficiaries who resided in Maine Coast’s service area during the fiscal year in question. Plaintiff argued, however, the number used in the determination of “residents who become hospital inpatients” should have been 2,173—the total admissions to all hospitals within a 35-mile radius, whereas HHS interpreted the regulation to only count admissions to “like hospitals”—for a total of 1,643 in this case. Under plaintiff’s approach, Maine Coast would be designated as a sole community hospital.

While acknowledging plaintiff’s interpretation of the regulation was one plausible reading, the court found the language was ambiguous and, in the context of the regulatory framework, HHS’ construction was reasonable.

The court also noted support for the agency’s interpretation in the primary purpose of the statutory sole community hospital designation to determine whether patients in a specific area predominately rely on a specific “section (d)” rural hospital.

The court also rejected plaintiff’s argument that the requirement to submit patient origin data from all other hospitals within 35 miles was an indication that the regulation should be read to include all hospitals within the 35-mile radius, stating that bureaucracies often require data not directly related to the issue.

Finally, the court was persuaded by the agency’s past practices and regulations of including only admissions to “like hospitals” in the determination. As a result, the court concluded the agency’s reading was not plainly erroneous, arbitrary and capricious, or an abuse of discretion.


**U.S. Court in Arkansas Affirms Medicare Non-Coverage of Certain Audiological Diagnostic Tests**

The U.S. District Court for the Eastern District of Arkansas affirmed January 10 the final decision of the Secretary of the Department of Health and Human Services that certain audiological diagnostic tests were not reasonable and necessary and therefore would not be covered by Medicare.

In January 2008, a prepayment auditor denied coverage of over 150 claims filed by plaintiff Doctors Testing Center (DTC) for audiological diagnostic testing. After several levels of appeals, DTC sought review by an administrative law judge (ALJ).

On June 30, 2009, the ALJ issued a decision partially in favor of DTC. On August 25, 2010, a Medicare Administrative Contractor (MAC) vacated and remanded the ALJ’s unfavorable decision on claims of 91 beneficiaries. On remand, the ALJ issued a decision finding claims for 68 beneficiaries met Medicare coverage requirements but that other claims did not. On October 5, 2011, the MAC issued a final decision reversing in part the ALJ’s decision. Specifically, the MAC found the ALJ erred in finding claims for the 68 Medicare beneficiaries qualified for Medicare coverage. DTC sought review of the MAC’s decision.
DTC alleged the MAC exceeded its authority by making its own findings of fact and reviewing the ALJ's decision de novo, instead of reviewing the ALJ's decision for errors of law only. But the court disagreed, finding the statute cited by DTC applied only to the MAC's determination of whether to review an ALJ decision, not to the MAC's standard of review once that determination was made. Accordingly, the court found it was within the MAC's authority to review the ALJ's decision de novo and to reverse that decision as to all issues properly before it.

DTC next argued the MAC erred in finding "a physician's signature is required prior to rendering diagnostic testing and that failure to obtain a signature on the 'front end' results in any services rendered as not being 'reasonable and necessary,'" among other findings. The court rejected this argument as well, holding the MAC's findings were not a "plainly erroneous or inconsistent" interpretation of the Medicare statute.

Next the court determined substantial evidence supported the MAC's ruling that the diagnostic testing was not ordered by a treating physician, as there was no evidence of the doctors' intent, or knowledge, that certain tests were going to be performed. Instead, the court found substantial evidence that DTC technicians, not physicians, ordered the diagnostic tests.

Lastly, the court refused DTC's request to remand the case to the ALJ for further proceedings to determine whether it was liable for the non-covered services. "[R]emand to the ALJ is not necessary because the MAC properly addressed the limited liability issue and substantial evidence supports its determination that DTC II knew or should have known that a treating physician must order diagnostic tests," the court said.


**D.C. Circuit Rejects Rural, Sole Community Hospitals’ Challenge to Downward Rate Adjustment**

The D.C. Circuit affirmed January 24 a lower court decision denying relief to rural and sole community hospitals that challenged the Department of Health and Human Services (HHS) Secretary's downward adjustment to the "hospital specific rate" used to calculate their Medicare reimbursement.

The appeals court found the relevant statutory provisions at issue were ambiguous, and the Secretary's interpretation was not unreasonable. The D.C. Circuit therefore declined to disturb the rate adjustment.

Under Medicare, most hospitals are reimbursed a “federal rate,” which is determined by multiplying a standardized base amount derived from national data and multiplying it by a weight associated with a diagnosis-related group (DRG).

For hospitals in rural or otherwise underserved communities, however, reimbursement is based on a "hospital-specific rate," which is calculated by multiplying the hospital's historic operating costs, or hospital specific-base, by a DRG weight. These hospitals have the option of being paid at the higher of the federal rate or the hospital-specific rate.

Congress directed the Secretary to “adjust the classifications and weighting factors” associated with the DRGs to reflect various changes, but the agency demurred because it was unsure how to address the effects of such adjustments, according to the opinion.

In response, Congress enacted 42 U.S.C. § 1395ww(d)(3)(A)(vi), stating the Secretary “may adjust the average standardized amounts” in subsequent years “to eliminate the effect of such coding or classification changes.”
As a result, in 2007, the Secretary announced changes to the DRGs. “To combat the possibility of overpayments under the new system, the secretary adjusted the standardized amount downward by 1.2% and 1.8% for fiscal years 2008 and 2009, respectively.” Congress later intervened and halved the amount of the adjustment.

Concerned about the disruptive effects of only adjusting downward the standardized amounts, the Secretary opted to “split[] the difference between ‘federal rate’ and ‘hospital-specific rate’ hospitals.”

Rural and sole community hospitals (plaintiffs) objected, arguing Congress indicated the Secretary could only adjust the standardized amounts, not the hospital-specific rates that served as the basis for their reimbursement.

The district court disagreed, however, and upheld the Secretary’s determination.

Affirming on appeal, the D.C. Circuit agreed under a *Chevron* analysis plaintiffs’ challenge should be denied.

The appeals court found the statutory scheme ambiguous, noting Section 1395ww(d)(3)(A)(vi) did not say the Secretary “only” could adjust downward the standardized amounts and, at the same time, pointing to the Secretary’s broad grant of authority under 42 U.S.C. § 1395ww(d)(5)(I)(i) to “provide by regulation for such other exceptions and adjustments to . . . payment amounts.”

“The only certainty that we can discern from the statutory scheme is that it is unclear,” the appeals court said in turning to the second step of its *Chevron* analysis.

The D.C. Circuit found the Secretary’s decision to include the payment rate for rural and sole community hospitals in the downward adjustment stemming from the changes to the diagnosis coding system was a reasonable exercise of her authority under Section 1395ww(d)(5)(I)(i).


**U.S. Court in Michigan Rejects Hospital’s Bid to Reopen Cost Report Based on ACA GME Change**

The U.S. District Court for the Eastern District of Michigan granted January 30 summary judgment in favor of the Department of Health and Human Services (HHS) in a dispute over whether changes to Medicare graduate medical education (GME) reimbursement requirements under the Affordable Care Act (ACA) required the reopening of a hospital’s cost report when it had an appeal pending at the time the law was enacted.

Applying *Chevron* analysis, the court determined the ACA provisions did not speak directly to the issue and that HHS’ interpretation applying the changes prospectively only was a reasonable construction of the statute.

Before the ACA, hospitals were eligible for GME reimbursement only if they incurred “all or substantially all” of the costs of a medical residency program. HHS regulations also impose a written agreement requirement for hospitals seeking GME reimbursement for residents spending time in nonhospital settings.

The ACA amended, however, the GME reimbursement rules. In particular, Section 5504(a) of the ACA states that effective for cost reporting periods beginning on or after July 1, 2010, if more than one hospital incurs costs associated with GME, they may count a proportional share of the time the resident spends training. Section 5504(c) specifies that the amendments “shall not be
applied in a manner that requires the reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the [ACA’s] enactment.”

HHS issued regulations interpreting the new ACA standards as not requiring it to reopen cost reports and apply the new proportional GME criteria for periods before July 2010 solely because a hospital had an appeal pending at the time of the ACA’s enactment. 75 Fed. Reg. 71800 (Nov. 24, 2010).

Plaintiff Covenant Medical Center partially funds the operation of Synergy Medical Education Alliance, a residency program that provides residents for a clinic and area hospitals. Covenant previously challenged HHS’ refusal to reimburse GME costs associated with Synergy from fiscal years (FYs) 1999-2001.

In that case (Covenant I), the Sixth Circuit ruled HHS properly concluded Covenant failed to meet the written agreement requirement and therefore was not entitled to the disputed reimbursement for that time period.

In the instant case, Covenant similarly appealed HHS’ refusal to reimburse for GME costs of more than $3.6 million from FYs 2002-2006. Covenant’s appeals for those fiscal years were pending at the time the ACA was enacted and it therefore argued Section 5504 required the reopening of its cost reports for those FYs.

The Provider Reimbursement Review Board granted expedited judicial review, and Covenant filed the instant lawsuit in which both parties moved for summary judgment.

As a threshold matter, the court rejected HHS’ argument that the suit was barred by collaterally estoppel because of the decision in Covenant I. The court found Covenant I did not turn on the applicability of the new provisions and that if Covenant’s claim that § 5504(c) applied retroactively was correct, it did not need to have a written agreement to be entitled to reimbursement.

The court ruled, however, that Covenant’s claims nonetheless were without merit.

Applying Chevron, the court first addressed whether Congress clearly intended that “every cost report be reopened for which there was a jurisdictionally proper appeal at the time of the ACA’s enactment.” Answering this question in the negative, the court noting the only certainty from the statutory language was that Congress “established that under no circumstances would a final cost report be reopened unless there was a pending appeal.”

Turning to the second Chevron prong, the court held HHS’ construction of the statute as applying prospectively only—i.e., for cost reporting periods beginning on or after July 1, 2010—was reasonable.

Covenant claimed Section 5504(c) would be superfluous under HHS’ interpretation, because there would be no reason to reopen past reports regardless of their appeal status. The court noted Covenant’s reading would instead make Section 5504(a) meaningless by applying it to cost reports from 2002-2006 when the statute explicitly stated the new standards should only apply to cost reporting periods on or after July 1, 2010.

Covenant next argued that a prior case, Henry Ford Health Systems v. Department of Health and Human Services, 654 F.3d 660 (6th Cir. 2011), construed a similar provision to apply retroactively. However, the court found the decision in Henry Ford relied on an explicit authorization to apply the statute retroactively.
Finally, Covenant argued HHS’ interpretation conflicted with its own interpretation of another regulation. The court rejected this argument as well, holding that HHS had interpreted both provisions to apply only prospectively.


**Third Circuit Says No Review of High-Error Rate Trigger for Extrapolation**

The Third Circuit affirmed February 12 a district court ruling granting summary judgment in favor of the Department of Health and Human Services (HHS) Secretary in a provider’s overpayment dispute. The appeals court held it did not have jurisdiction to review the determination that a provider had a sustained or high payment error rate to trigger extrapolation by a Medicare auditor.

The appeals court also found substantial evidence supporting HHS’ decision that the provider was liable for more than $641,000 in Medicare overpayments.

Plaintiff John Balko and Associates, Inc. (Balko) provides medical services to nursing home residents, including podiatry, audiology, and optometry. In 2008, SafeGuard Services, a Medicare contractor, audited Balko after noting it was the highest-paid provider of services to nursing home services in Pennsylvania. SafeGuard concluded Balko was providing certain services that were ineligible for Medicare reimbursement.

Using statistical sampling, Safeguard found a 99.85% error rate in the claims it reviewed. HHS considered this figure a high error rate and directed Safeguard to establish the total overpayment using extrapolation, which the contractor determined to be $857,109.07.

Subsequent administrative appeals found some of the services in the audit had been properly billed, reducing the error rate to 77% and the repayment to 641,437. The Medicare Appeals Council (MAC) ultimately rejected Balko’s contention that the statistical sampling and extrapolation were invalid.

Balko sought relief in federal district court. The court granted, however, summary judgment in favor of the HHS Secretary, finding it lacked jurisdiction under 42 U.S.C. § 1395ddd(f)(3) to review the determination of a high error rate.

Section 1395ddd(f)(3) allows the use of extrapolation to determine a total overpayment amount only after a finding of a sustained or high level of payment error or that the provider was informed of the error and failed to correct it. This provision also states, however, that “[t]here shall be no administrative or judicial review . . . of determinations by the Secretary of sustained or high levels of payment errors.”

Balko argued SafeGuard impermissibly used the same sample to determine the existence of a high error rate and the overpayment amount through extrapolation, because it meant SafeGuard had not found a high error rate prior to conducting the audit. But the appeals court found the plain language of Section 1395ddd(f)(3) precluded any review of the high-error rate determination.

The appeals court rejected Balko’s contention that it sought to challenge the procedure rather than the merits of the decision, holding the statute made no such distinction.

Balko also claimed the MAC’s decision upholding the overpayment was not based on sufficient evidence on two grounds.
First, Balko contended the MAC improperly overturned the credibility findings of the Administrative Law Judge (ALJ) (who ruled in Balko’s favor). The appeals court disagreed, noting the MAC’s review of an ALJ’s findings is conducted *de novo* and therefore the MAC was not obligated to defer to the outcome of prior decisions.

Second, Balko maintained the MAC ruling was flawed because it did not cite specific evidence to support the ruling that the extrapolation procedure was valid. The appeals court rejected this argument as well, finding the MAC’s conclusion was well supported, and that Balko bore the burden of showing the sample was invalid.


**Sixth Circuit Agrees Medicare Not Obligated to Cover Infusion Pump Under National Coverage Determination**

The Sixth Circuit affirmed February 27 in an unpublished opinion the decision of the Department of Health and Human Services (HHS) Secretary not to cover an implantable infusion pump where its use is contraindicated under a Medicare national coverage determination.

Plaintiff Mary Woodfill suffers from spinal degenerative disease and has lived with “chronic low back pain” for years. In the mid-1990s, her doctors implanted a spinal cord stimulator, which provided some relief. Woodfill’s doctors recommended an implantable infusion pump, which would deliver pain medication directly to the spinal cord and thus offer the prospect of additional relief.

But Woodfill’s health insurance provider through the Medicare Advantage program, Humana, denied her request to cover the costs of the pump and the procedure for inserting it. Woodfill appealed the decision—first to Humana for reconsideration, then to an outside reviewer and then to HHS. An administrative law judge (ALJ) upheld the denial of benefits and the Medicare Appeals Council adopted the ALJ’s decision.

The district court later upheld the agency’s determination, holding substantial evidence supported the decision. Woodfill appealed.

The appeals court first noted the HHS Secretary issued a national coverage determination with respect to infusion pumps that permits Medicare coverage for an “implantable infusion pump” when, among other things, it is “used to administer opioid drugs . . . for treatment of severe chronic intractable pain.”

The coverage determination adds, however, that the pump “is contraindicated” for patients with “other implanted programmable devices since crosstalk between the devices may inadvertently change the prescription.”

“Crosstalk” means unprompted communications between devices, such as a signal from a spinal cord stimulator that changes the pain medication dosage setting on an implantable infusion pump, the opinion explained.

According to the appeals court, “[i]n view of the Secretary’s unchallenged interpretation of the regulation, she permissibly denied coverage for Woodfill’s pump.”

Woodfill’s principal argument—that the risk of crosstalk did not apply to her case—“speaks to the wisdom of the determination’s categorical bar, not to its existence,” the appeals court found.
The appeals court held the Secretary did not abuse her discretion in applying the categorical bar here.


**Tenth Circuit Affirms CMPs Imposed on SNF, Transfers Challenges to Other Noncompliance Remedies to District Court**

A skilled nursing facility (SNF) could bring its challenges to civil monetary penalties (CMPs) imposed for noncompliance with Medicare conditions of participation directly in federal appeals court, the Tenth Circuit held February 14. The SNF’s challenges to other noncompliance remedies, however, including termination of its provider agreement, must be heard first in federal district court, the appeals court found.

After deciding the jurisdictional issues, the Sixth Circuit affirmed the CMPs and transferred to the U.S. District Court for the District of New Mexico the challenges to the remaining remedies imposed by the Centers for Medicare & Medicaid Services (CMS).

Sunshine Haven Nursing Operations LLC (Sunshine) operates a 67-bed nursing home in Lordsburg, NM. The state survey agency (SA) conducted a series of visits between November 2008 and April 2009 during which it concluded Sunshine was not in substantial compliance with Medicare conditions of participation.

As a result of the SA’s reports, CMS issued a denial of payment for new admissions; terminated Sunshine’s Medicare provider agreement; imposed four per-instance CMPs totaling $14,000; and withdrew approval of the facility’s nurse aide training and competency evaluation program for two years.

An Administrative Law Judge and the Department of Health and Human Services Departmental Appeals Board upheld the findings. Sunshine petitioned for review in the Tenth Circuit.

Both the government and Sunshine argued the Tenth Circuit had jurisdiction to review the case in its entirety, but the appeals court disagreed.

According to the appeals court, 42 U.S.C. § 1320a-7a(e), the CMP provision, by its plain language allows a circuit court to conduct initial judicial review of CMPs. In fact, the statute provides that once such a challenge is filed, the circuit court’s jurisdiction is exclusive and subject only to Supreme Court review.

“Congress has specified that challenges to CMPs, not challenges to other noncompliance remedies, may go directly to a circuit court under 42 U.S.C. § 1320a-7a(e),” the appeals court said. “The district court has initial jurisdiction under § 1395cc(h)(1)(A) over Sunshine’s challenges to the secretary’s non-CMP determinations of noncompliance, and we will have jurisdiction to review its decision if appeal is taken.”

The Tenth Circuit went on to find that substantial evidence supported the findings of noncompliance underlying the CMPs.

D.C. Circuit Upholds Vacatur of DSH Rule That Included M+C Days in Medicare Fraction

The D.C. Circuit upheld April 1 a federal district court decision vacating a Department of Health and Human Services (HHS) final rule requiring the inclusion of certain patient days attributable to individuals enrolled in Medicare+Choice (M+C, now called Medicare Advantage) in the Medicare/Supplemental Security Income (SSI) fraction of the disproportionate share hospital (DSH) calculation.

The appeals court agreed with the U.S. District Court for the District of Columbia finding that the 2004 final rule, which announced the Secretary’s interpretation of the Medicare DSH fraction as including M+C days, as later codified in 2007 at 42 C.F.R. § 412.106(b)(2), violated the Administrative Procedure Act (APA).

According to the appeals court, HHS failed to provide adequate notice and opportunity to comment under the APA because the final rule was not a “logical outgrowth” of the 2003 notice of proposed rulemaking (NPRM), which took the exact opposite position than the 2004 final rule. The appeals court reversed, however, the district court’s decision in so far as it directed the HHS Secretary to recalculate the hospital challengers’ reimbursement using the alternate methodology. “The question whether the Secretary could reach the same result through adjudication was not before the district court,” the appeals court said. The district court therefore should not have directed the Secretary how to calculate the hospital’s reimbursements on remand.

Prior Decisions

The instant action—which involves 27 hospitals that challenged the inclusion of Part C days in the Medicare/SSI fraction for fiscal year 2007—had been stayed pending the D.C. Circuit’s decision in Northeast Hosp. Corp. v. Sebelius, No. 10-5163 (D.C. Cir. Sept. 13, 2011).

The D.C. Circuit in Northeast determined the Secretary’s interpretation of whether M+C beneficiaries are still “entitled to benefits under [Medicare] Part A” and, therefore, should not be counted in the Medicaid fraction of the DSH calculation, was not foreclosed by the statute.

The appeals court concluded, however, “the Secretary’s decision to apply her present interpretation of the DSH statute to fiscal years 1999-2002 violates the rule against retroactive rulemaking.”


Inadequate Notice

The D.C. Circuit agreed the fact that the 2004 final rule adopted “the exact opposite interpretation of the statute” than the 2003 NPRM was problematic, particularly because the Secretary had a prior practice of excluding Part C days from the Medicare fraction.

The appeals court found it significant that the 2003 NPRM estimated no major financial impact for hospitals with the proposed changes. If the 2003 NPRM was intended to signal the possibility that the agency would adopt the methodology established under the 2004 final rule, “the
potential estimated financial impact should have been stated in the hundreds of millions of dollars,” the appeals court observed.

The practical result, the D.C. Circuit said, was that hospitals were not given adequate notice to comment on what was otherwise a significant departure from longstanding practice for calculating their DSH payments.

The appeals court therefore upheld vacatur of the 2004 rule.


U.S. Court in D.C. Rejects Challenge to Wage Index Calculation That Included Multi-Campus Hospitals

The U.S. District Court for the District of Columbia granted summary judgment to the Department of Health and Human Services (HHS) Secretary in a lawsuit challenging the inclusion of multi-campus hospitals outside of a given geographic area in the plaintiff hospitals' “wage index” calculation.

The court found the applicable statutory language did not direct the Secretary to implement a particular method for calculating the wage index; and the method that was adopted for the time period at issue was reasonable.

The 41 plaintiff hospitals that brought the lawsuit alleged the Secretary improperly included two hospitals located outside their geographic area—the Boston-Quincy Core-Based Statistical Area (CBSA)—when calculating the wage index for that CBSA for fiscal years (FYs) 2006 and 2007, resulting in lower Medicare payments.

The issue arose because HHS adopted in FY 2006 a policy to include all the wage costs of multi-facility hospital groups in the CBSA where the facility with the principal provider number was located. In this case, the policy resulted in the wage costs of two larger hospitals, which were part of a multi-facility group, being included in the Boston-Quincy CBSA even though they were located in a different CBSA.

HHS changed the policy beginning in FY 2008, when it decided to allocate each hospital group member’s costs to the CBSA where its campus is located.

Plaintiffs argued the calculation of their wage index for FYs 2006 and 2007 violated the clear terms of the statute and was arbitrary and capricious.

Applying Chevron, the court agreed with the Secretary that the statute did not spell out how to construct the wage index—and, in particular, how the wage costs of multi-campus hospital groups should be treated.

Plaintiffs contended the Secretary’s interpretation was arbitrary and capricious because HHS paid the two hospitals the wage index applicable to the CBSA where they were located, but nonetheless included their wage costs in the Boston-Quincy CBSA.

But the court found how the agency treated the hospitals for payment purposes did not dictate how it treated them for purposes of calculating the wage index.

The court also was not persuaded that the Secretary’s 2008 policy change made the initial policy unreasonable.
Finally, the court noted the agency applied the 2006 policy consistently across all multi-campus hospitals located in multiple CBSAs.


Third Circuit Upholds Exclusion of State’s General Assistance Days in Medicare DSH Calculation

The Third Circuit held April 2 the Department of Health and Human Services (HHS) Secretary had a rational basis for counting hospital inpatient days provided under a Section 1115 waiver in the Medicare disproportionate share hospital (DSH) adjustment while at the same time excluding a state’s general medical assistance (GA) program days.

The appeals court decision reversed a federal district court’s April 2013 ruling in favor of two Pennsylvania hospitals—Nazareth Hospital and St. Agnes Medical Center—that challenged their fiscal year (FY) 2000 DSH adjustment. The appeals court decision reversed a federal district court’s April 2013 ruling in favor of two Pennsylvania hospitals—Nazareth Hospital and St. Agnes Medical Center—that challenged their fiscal year (FY) 2000 DSH adjustment.

The U.S. District Court for the Eastern District of Pennsylvania found HHS violated the Administrative Procedure Act (APA) and constitutional equal protection by distinguishing between Section 1115 Medicaid demonstration projects and GA programs for purposes of the Medicare DSH adjustment. The court ordered HHS to recalculate the hospitals’ Medicare DSH adjustments for FY 2002 and remit the difference with interest. Nazareth Hosp. v. Sebelius, No. 10-3513 (E.D. Pa. Apr. 8, 2013).

But the Third Circuit disagreed with the lower court, finding the Secretary “set forth multiple rational bases upon which to distinguish patient days covered under Pennsylvania’s GA program, from days covered under a Section 1115 waiver project.”

The hospitals brought the lawsuit after the Secretary issued a final rule in August 2000, which “clarified” that Section 1115 waiver patient days could be included in Medicare DSH calculations, while GA patient stays remained excluded. Before HHS issued the regulation, the appeals court noted, intermediaries in some states, including Pennsylvania, counted GA patient days in hospitals’ Medicare DSH adjustments.

The Deficit Reduction Act of 2005 (DRA) subsequently “ratified” the Medicare DSH rule, allowing the Secretary to include inpatient days of patients who receive benefits under an “approved demonstration project” but who were ineligible otherwise for Medicaid. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II)

Plaintiffs argued the regulation implementing the DSH statute unfairly disadvantaged hospitals treating low-income patients under a Centers for Medicare & Medicaid Services-approved state plan as opposed to a Section 1115 waiver. According to plaintiffs, this disparate treatment violated the APA and the Equal Protection Clause.

At the outset, the appeals court noted the Secretary had statutory authority to distinguish between Section 1115 waivers and GA programs for DSH purposes. The amendments to the DSH provision enacted by the DRA merely “clarified” an ambiguity in the law and explicitly “ratified” the Secretary’s position, the appeals court said.

The appeals court next concluded the Secretary articulated several rational bases for distinguishing between the two, which were more than enough to uphold the DSH rule.

A Section 1115 waiver is reviewed differently—to determine whether the demonstration promotes the objectives of Medicaid—than a state plan amendment—to review compliance for how a state distributes Medicaid DSH payments. The Secretary also has greater control and
oversight over Section 1115 demonstration projects, including determining the precise scope of the project. The same is not true, however, for a state GA program.

The fact that Section 1115 waiver projects and GA programs may serve the same or similar low-income populations is irrelevant, the Third Circuit added.

Finally, the appeals court found HHS properly considered and responded to comments during the rulemaking process.


U.S. Court in D.C. Says No GME Reimbursement for Hospital Without Written Affiliation Agreement

The Department of Health and Human Services Secretary properly denied a hospital Medicare graduate medical education (GME) reimbursement for lack of a written affiliation agreement, a federal district court in the District of Columbia held March 31.

In 1997, Alegent Health—Immanuel Medical Center (Alegent), a nonprofit general acute care hospital in Omaha, NE, agreed to be the primary training site for Creighton University’s psychiatric residency training program.

Before that time, Alegent did not participate in a medical residency training program and therefore had a cap of zero full time equivalent (FTE) medical residents, which is used to determine Medicare direct and indirect GME reimbursement.

The Secretary issued a final rule in 1998 requiring a written affiliation agreement to apply FTE caps on an aggregate basis. On June 30, 1998, Alegent entered into an academic affiliation agreement with St. Joseph Regional Healthcare System, LLC (St. Joseph), which previously served as Creighton’s training site.

Alegent’s fiscal intermediary initially determined the agreement satisfied the requirements for establishing an affiliated group for purposes of applying FTE caps on an aggregate basis. During a subsequent audit, however, the intermediary found the agreement was insufficient and disallowed all GME payments claimed by Alegent for fiscal years (FYs) ending June 30, 2000 through June 30, 2003.

The Provider Reimbursement Review Board (PRRB) reversed as to FYs ending June 30, 2000 and June 30, 2001, finding the affiliation agreement satisfied applicable requirements for creating an affiliated group for those FYs. After that, however, the PRRB found the agreement lapsed without renewal in 2001 and therefore Alegent and St. Joseph could not aggregate the FTE caps for FYs 2002 and 2003. The Centers for Medicare & Medicaid Services Administrator declined to review the PRRB’s decision, and Alegent filed the instant lawsuit.

Alegent argued the requirement for a written affiliation agreement violated the Paperwork Reduction Act (PRA), the Medicare Act, and the Administrative Procedure Act (APA). Alegent also argued the Secretary should be estopped from denying GME reimbursement for FYs 2002 and 2003 because the hospital reasonably relied, to its detriment, on the intermediary’s prior determinations that such reimbursement was proper.

The U.S. District Court for the District of Columbia granted summary judgment to the Secretary, rejecting each of these arguments.
The court noted the PRA does not provide a private right of action to challenge a regulatory requirement, but rather only “may be raised as a defense to an agency action.”

The court similarly rejected the hospital’s contention that the written agreement requirement violated the Medicare Act. The Balanced Budget Act of 1997 explicitly granted the Secretary authority to define an affiliated group for Medicare reimbursement purposes, but did not specifically require a written affiliation agreement.

Given this ambiguity, the court applied *Chevron* deference and found the Secretary’s interpretation a “permissible” construction of the statute. In fact, the court commented, “any interpretation that did not require a written affiliation agreement—given the complex nature of the reimbursement scheme and the thousands of hospitals participating in it—[appeared to be] unreasonable.”

Alegent also argued the written affiliation agreement prior to 2002 violated the APA. But the court disagreed, noting the Secretary issued the 1998 final rule requiring written affiliation agreements “following a period of notice and comment rulemaking.”

Finally, the court rejected Alegent’s equitable estoppel claim, noting the hospital could not show reasonable reliance as a matter of law.


**Ninth Circuit Upholds Reduction in Hospital’s Medicare Update for Missing Quality Data Submission Deadline**

The Ninth Circuit upheld April 8 a 2% reduction in a hospital’s Medicare Annual Payment Update for fiscal year 2009 for failing to submit its quarterly quality data on time. The appeals court found the hospital was not entitled to equitable relief, even though the data were late by less than a day due to its vendor’s error, and the delinquent submission could not be excused under the contractual doctrine of substantial performance.

Plaintiff PAMC, Ltd., a general acute care hospital, missed the deadline for submitting its second quarter quality data as required under the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. The submission was half a day late due to an error by its vendor, Thomson Reuters. As a result, the Centers for Medicare & Medicaid Services (CMS) reduced PAMC’s annual percentage increase by 2%.

The Provider Reimbursement Review Board (PRRB) upheld CMS’ decision. The Secretary declined review, and plaintiff sought relief in federal district court, arguing the PRRB erred when it failed to grant PAMC equitable relief and when it determined plaintiff had not substantially complied with the RHQDAPU program requirements. The district court ruled CMS and the PRRB lacked authority under the Medicare statute and regulations to award equitable relief when a provider missed the applicable deadline “through its own fault or that of its vendor.”

On appeal, plaintiff argued CMS acted arbitrarily and capriciously by refusing to excuse the late submission. Plaintiff also contended the PRRB should have applied equitable principles to ameliorate the consequences of its delinquent submission. Plaintiff pointed to 71 Fed. Reg. 47870, 48041 (Aug. 18, 2006), which states the agency will not hold a hospital responsible for errors committed by CMS or its contractors, to show CMS, and by extension the PRRB, had such equitable authority. The Ninth Circuit disagreed, pointing out that in this case, plaintiff committed the error, not CMS.

Plaintiff also contended the PRRB should have used the contract doctrine of substantial performance to excuse the hospital’s failure to submit its data on time.
Even assuming the doctrine could apply in the Medicare context, the appeals court noted CMS gives providers almost five months each quarter to submit accurate data and the “vast majority of hospital submit accurate data in a timely manner before the quarterly submission deadline.” The appeals court pointed out that while CMS’ rules may seem harsh, the importance of timely submissions is reflected in the precision of the deadline itself (by 11:59 p.m. CST) and the care the agency takes in alerting hospitals numerous times as the deadline approaches.

_PAMC v. Sebelius_, No. 12-56652 (9th Cir. Apr. 8, 2014).

### D.C. Circuit Upholds Denial of Depreciation Reimbursement from Medicare Following Merger

The D.C Circuit affirmed April 11 a lower court decision holding a hospital was not entitled to Medicare reimbursement for depreciation following its merger with another hospital because the transaction at issue was not a bona fide sale.

While the hospital argued the Department of Health and Human Services (HHS) Secretary used the wrong valuation approach in evaluating the deal, the court noted even under the method most favorable to the plaintiff hospital, the difference between the fair market value and the consideration exchanged was still $17 million—“and nothing in the briefing or administrative record suggests that a bona fide sale could be found in the face of such a discrepancy.”

Catholic Healthcare West (CHW), a nonprofit Catholic hospital system, was the surviving entity after a merger between Marian Medical Center and the hospitals previously constituting CHW. Following the merger, CHW filed a claim for a loss of roughly $8.1 million on the disposal of depreciable assets.

CHW lost on its claim before the Provider Reimbursement Review Board and ultimately the Centers for Medicare & Medicaid Services Administrator, which found the merger was not a “bona fide sale” between “unrelated parties.” According to the agency, Marian’s true worth was much more than the consideration paid. It reached this conclusion using a “cost” valuation approach—i.e., Marian’s transfer of $67 million in depreciable assets in exchange for $32.7 million in liabilities (a disparity of $34 million).

The U.S. District Court for the District of Columbia agreed the transaction was not a bona fide sale and affirmed the Secretary’s final decision disallowing CHW’s claim. _Catholic Healthcare West v. Sebelius_, Civ. A. 11-459(GK) (D.D.C. Jan. 29, 2013).

CHW argued the Secretary arbitrarily picked the “cost” valuation approach as opposed the “income” or “market value” methods on the basis of Program Memorandum (PM) A-00-76, which the Secretary issued in 2000 to clarify the application of 42 C.F.R. § 413.134(1) to nonprofit providers.

In the end, the D.C. Circuit said it did not have to resolve whether the PM provided an adequate basis for excluding the other valuation approaches, mainly because the Secretary’s finding of a “gross disparity” between value and implicit price was inescapable under any standard.

Under the approach most favorable to CHW, the income method, the appeals court tallied the disparity at $17 million.

“[E]ven by the most conservative estimate of Marian’s value, CHW paid only about 66 cents on the dollar in this transaction,” the appeals court said.
The appeals court therefore sustained the Secretary’s determination that the merger was not a bona fide sale.


**Physicians**

**U.S. Court In Indiana Refuses to Dismiss Physician’s Racial Discrimination Claims Against Hospital**

The U.S. District Court for the Southern District of Indiana refused June 28 to dismiss a physician’s 42 U.S.C. § 1981, emotional distress, and defamation claims against the hospital where he had privileges after the hospital took adverse actions against him. According to the court, the Palestinian physician sufficiently alleged his accusers had the requisite scienter to overcome immunity under the Health Care Quality Improvement Act (HCQIA).

Plaintiff, Dr. Talal S. Hamdan, is a citizen of the United States who is of Palestinian descent. Hamdan applied for and was granted privileges to practice coronary, endovascular, and other interventional procedures at Indiana University Hospital North, Inc. and Clarian Health North, LLC (hospital).

After Hamdan began working in the Cath Lab, several hospital employees began making racial and ethnic slurs, comments, and innuendoes directed at Hamdan based on his Palestinian race, ethnicity, and descent, the opinion said.

On March 5, 2010, two Cath Lab employees filed charges of misconduct against Hamdan and the hospital subjected Hamdan to a "Focused Professional Practice Evaluation" (FPPE) as provided in its bylaws. However, the FPPE the hospital instituted did not adhere to the governing standards or the bylaws, the court noted.

On April 14, 2011, the Hospital’s Medical Executive Committee (MEC) issued a first Adverse Action against Hamdan based on several of the complaints and allegations. On July 18, 2011, the MEC issued a second Adverse Action against Hamdan, and he requested an appeals hearing with respect to both Adverse Action letters.

The MEC eventually recommended against taking any disciplinary action and that the investigation be closed. Hamdan sued the hospital alleging: (1) violation of Section 1981; (2) intentional or reckless infliction of severe emotional harm; and (3) defamation. The hospital moved to dismiss.

The hospital contended Hamdan could not state a claim under Section 1981 because, as a matter of law, there was no contract between the parties. However, the court noted that hospital bylaws may constitute a contract between the hospital and its staff.

“Whether the Hospital Bylaws in this case did so--particularly in light of language providing that the Bylaws are not a contract--is a question of fact that cannot be decided on a motion to dismiss,” the court held, noting that “[a]t this time, it is enough that Dr. Hamdan has sufficiently alleged a plausible contractual relationship.”

The court also refused to dismiss Hamdan's defamation claim on the basis of immunity under the HCQIA. According to the court, the HCQIA provides immunity from suit for providing information to a professional review body "unless such information is false and the person providing it knew that such information was false." 42 U.S.C. § 11111(a)(2). Similar Indiana statutes also include a scienter requirement, the court noted.
“Here, Dr. Hamdan has alleged sufficient facts to render it plausible that his alleged tormenters had the requisite scienter. Accordingly, Dr. Hamdan’s defamation claim is not subject to dismissal on this basis,” the court held.


**U.S. Court in Nevada Holds Physician Members of Public Hospital’s MEC Entitled to Absolute Immunity**

Members of a county hospital’s physician credentialing committee who directly participated in the unlawful suspension of another physician’s staff privileges are entitled to absolute immunity from his claim under 42 U.S.C. § 1983, a federal district court in Nevada held June 21.

Plaintiff Dr. Richard Chudacoff, who specializes in obstetrics/gynecology, had medical privileges at the University Medical Center of Southern Nevada (UMC).

Shortly after being granted staff privileges, plaintiff received a letter from the chief of staff that the medical executive committee (MEC) had suspended his privileges. According to plaintiff, before the letter he had no knowledge the MEC was considering any adverse action against him.

UMC subsequently filed a report with the National Practitioner Databank stating plaintiff’s privileges were suspended indefinitely for substandard or inadequate care and/or skill level.

A fair hearing committee disagreed with the suspension but recommended peer review of plaintiff’s practice, as well as several other measures. Further administrative proceedings followed and the suspension eventually was lifted, but a formal letter of reprimand was issued.

While these proceedings were ongoing, plaintiff sued UMC and the individual members of the MEC. The district court granted summary judgment to all defendants on plaintiff’s claims under Section 1983, finding the physician defendants were not state actors and the municipal defendants did not have a policy or practice of due process violations to support a finding of liability.

Reversing on appeal, the Ninth Circuit found the voting members of the MEC were state actors for purposes of Section 1983. The appeals noted plaintiff sued defendant MEC members not in their capacity as private physicians but based on their actions taken within the course and scope of their duties as governing members of the medical staff of a public hospital as mandated by state law.

The appeals court affirmed, however, summary judgment in favor of the entity defendants, finding no evidence the suspension of plaintiff’s privileges flowed from any institutional policy. *Chudacoff v. University Med. Ctr. of S. Nev.*, Nos. 09-17558 and 09-17652 (9th Cir. Jun. 9, 2011).

On remand, the U.S. District Court for the District of Nevada said given the Ninth Circuit’s finding, the court now had to consider whether the physician defendants were entitled to absolute immunity from liability under Section 1983.

After considering the six factors outlined in *Butz v. Economou*, 438 U.S. 478 (1978), the court held defendant physicians were entitled to absolute immunity.

The court said the following factors weighed in favor of immunity: (1) the “strong need” to ensure performance of functions (i.e. disciplinary measures against physicians who present a potential safety threat) without harassment; (2) the procedural safeguards included in the
bylaws; (3) the bylaws provided for an adversarial process for summary suspensions and routine administrative actions; and (4) the correctability of errors on appeal.

The court noted one factor—insulation from political influence—weighed against granting immunity, citing the “risk of ‘self interest economic regulation’ because the members of the MEC are practicing in the same medical community as Plaintiff.” In the court’s view this factor was not dispositive, given the public interest in protecting the peer review process and the appeal rights that were available to plaintiff.

An additional factor—precedent—did not favor or disfavor absolute immunity since it was unclear whether the MEC relied on precedent.

“Taken as a whole, the Butz factors favor granting absolute immunity in this case,” the court concluded.

The court refused to grant at this time, however, the medical and dental staff’s and UMC’s motions for summary judgment on plaintiff’s breach of the implied covenant of good faith and fair dealing claim.


**Louisiana Supreme Court Finds Hospital Not Entitled to HCQIA Immunity, but Reduces Physician’s Damages Award**

The Louisiana Supreme Court held June 28 that a hospital was not entitled to immunity under the Health Care Quality Immunity Act (HCQIA) because it failed to comply with the statute’s requirements in the course of its peer review proceedings against a physician.

The high court also upheld a jury’s finding that the hospital’s actions breached its contract with the physician under the hospital bylaws. The high court found, however, the damages awarded to the physician ($2.8 million) for lost income could not stand because he voluntarily decided not to reapply for privileges.

Plaintiff Dr. Tommiee M. Granger is a cardiac surgeon who held medical staff privileges at Christus St. Frances Cabrini Hospital (Cabrini). Granger’s privileges were summarily suspended on December 19, 2002 for 21 days while an investigation was conducted into allegations he left a patient with post-surgical complications. His privileges were restored on January 10, 2003, but a letter of reprimand was placed in his record stating that the summary suspension was appropriate.

Granger asked for the removal of the letter or for hearing on the summary suspension, but the request was denied. The investigation of Granger continued after the summary suspension was lifted, with the Medical Executive Committee (MEC) ultimately recommending, and the Board’s Executive Committee (BEC) agreeing, that he be placed on six-month probation and be required to self-refer for anger management evaluation or face the automatic revocation of his medical staff membership and privileges. Granger did not self-refer and his privileges were revoked on July 30, 2003.

While the peer review investigation was ongoing, Granger sued Cabrini in federal district court, asserting, among other things, breach of contract and negligent misrepresentation.

The trial court found Cabrini was immune from liability for monetary damages under HCQIA with respect to the December 19 summary suspension, but declined to find HCQIA immunity for Granger’s remaining claims. A jury ultimately awarded Granger $3.9 million in damages, which the appeals court reduced to roughly $3 million.
The high court held Cabrini’s peer review proceedings violated HCQIA by failing to provide Granger a post-suspension hearing. While HCQIA, 42 U.S.C. § 11112(c)(2), allows for the immediate suspension or restriction of privileges where a failure to do so presents an “imminent danger,” that provision also requires “subsequent notice and hearing or other adequate procedures.” In this case, Granger asked for a post-suspension hearing, but the hospital refused to give him one.

Cabrini argued it was entitled to HCQIA immunity because no adverse action was taken against Granger following the post-suspension peer review. Even assuming no adverse action was taken, the high court pointed out that the jury concluded Cabrini failed to comply with the other HCQIA immunity requirements—i.e., that the peer review was taken in the reasonable belief that the action was in the furtherance of quality healthcare and warranted by the facts known.

The high court noted that under HCQIA only the notice and hearing procedures are excepted when no adverse action has been taken; an entity still must comply with the remaining requirements.

The high court also rejected Cabrini’s contention that its post-suspension proceedings amounted to professional review activity, not a professional review action. “[W]e conclude that professional review action is professional review activity that is concerned with the ‘competence or professional conduct’ of a physician that ‘affects (or may affect) adversely’ the physician’s clinical privileges, or membership in a professional society.”

Here, both the MEC and BEC concluded Granger’s clinical privileges should be automatically revoked unless he participated in anger management treatment, recommendations that were later ratified by the Board. In the high court’s view, at the latest, Granger was adversely affected when the MEC made its initial recommendation, triggering his due process protections under Section 11112, including the right to adequate notice and hearing procedures.

The high court also found Cabrini was not entitled to immunity under Louisiana’s peer review statute.

Next, the high court concluded the hospital’s failure to comply with its bylaws in its peer review of Granger could constitute a basis for his breach of contract claim under state law. The high court also found no error in the jury’s conclusion that Cabrini breached its contractual obligations under the bylaws and the finding in favor of Granger on his negligent misrepresentation claim.

The high court vacated, however, the $2.9 million award to Granger for past loss of income because he made the decision not to apply for reappointment after his medical staff membership and clinical privileges expired on July 31, 2003. Although the Board agreed to an automatic revocation of his privileges on July 30, 2003, Granger was not aware of that decision until after he allowed his medical staff membership to lapse, the high court said. According to the high court, Granger could have, but failed to, apply for reappointment at that time.


Fourth Circuit Finds Hospital Entitled to HCQIA Immunity

On July 5, the Fourth Circuit held a hospital and its Board of Governors (Board) were immune under the Health Care Quality Improvement Act (HCQIA) from monetary damages. The appeals court found the plaintiff physician failed to show the peer review proceedings did not meet the requirements for immunity under 42 U.S.C. § 11112(a).

The Aiken Regional Medical Center (ARMC) terminated plaintiff Dr. Margo Hein-Muniz’s clinical privileges following a peer review proceeding. Plaintiff sued the hospital alleging various causes

The Fourth Circuit affirmed, finding a reasonable jury, after viewing all of the facts in a light most favorable to plaintiff, could not have concluded plaintiff had shown by a preponderance of the evidence that the Board’s actions fell outside the scope of HCQIA Section 11112(a).

The appeals court concluded there was enough evidence against plaintiff for the Board to believe it was furthering the quality of healthcare by terminating her privileges; no reasonable jury could find the Board failed to make reasonable efforts to obtain the pertinent facts; a reasonable jury would find the Board’s decision was fair as the Board provided the doctor with “extensive opportunity in a lengthy hearing to explain her misrepresentation”; and a reasonable jury would find the Board acted in the reasonable belief that “the facts known to it” warranted the its actions.


**North Dakota Supreme Court Rejects Surgeon’s Defamation, Antitrust Claims Against Clinics**

On July 22, the North Dakota Supreme Court affirmed a district court’s grant of summary judgment to defendant medical clinics due to the plaintiff physician’s failure to show how their responses to a credentialing questionnaire for his potential employer constituted civil libel.

The high court held the clinics’ responses did not use innuendo, insinuation, or sarcasm to convey an untrue and defamatory meaning; the words as used in the context of the credentialing questionnaire were not reasonably susceptible of a defamatory meaning; and defendants did not act in concert when responding to the questionnaire.

Plaintiff John Schmitt is a surgeon, formerly employed from 2002-2004 by defendants Dakota Clinic and from 2005-2007 by MeritCare Health System (MeritCare). When Schmitt’s employment with MeritCare ended in July 2007, he contracted with a physician placement agency to provide temporary physician services. St. Joseph’s Hospital offered him a job subject to credentialing requirements.

Dakota Clinic responded to St. Joseph’s credentialing questionnaire with a “do not recommend.” Schmitt initially refused to sign MeritCare’s release but later signed it after learning St. Joseph’s rescinded its job offer. MeritCare responded to St. Joseph’s questionnaire with a “would recommend with reservation.” MeritCare stated in the questionnaire that Schmitt had disciplinary actions due to insensitivity and irritability with others but it did not restrict or limit his privileges. Schmitt sued MeritCare and Dakota Clinic for defamation, tortious interference with a prospective business advantage, and violation of state antitrust law.

Regarding the defamation claim, Schmitt contended MeritCare’s responses to St. Joseph’s questionnaire, while “technically true,” constituted defamation by implication because MeritCare used “innuendo, insinuation, or sarcasm to convey an untrue and defamatory meaning.” The high court disagreed, stating MeritCare’s responses, when construed in the context of the entire credentialing document, were not “reasonably and fairly susceptible of a defamatory meaning” and that the “natural and ordinary meaning” of MeritCare’s words in this context could not be construed as insinuation, innuendo, or sarcasm.

Schmitt also argued MeritCare’s failure to timely respond to the questionnaire constituted an implied defamatory assertion. The high court again disagreed as Schmitt offered only conclusory
assertions that MeritCare’s alleged delay was interpreted as a false assertion of his medical competence, which was insufficient to raise an issue of material fact.

As to his tortious interference with a prospective business advantage claim, the high court held to the extent his argument on this issue relied on his defamation claim, the district court did not err in dismissing it.

The doctor also argued defendants’ “independent wrongful conduct” was supplied by the “force of numbers” or “economic boycott” exception to the tort of civil conspiracy, which requires concerted action or an agreement of two or more parties in concert to commit an unlawful act or commit an unlawful act by unlawful means. In this case, the court found Schmitt failed to provide any evidence to support an inference that Dakota Clinic and MeritCare acted in concert regarding their responses to St. Joseph’s credentialing questionnaire.

Lastly, Dr. Schmitt argued MeritCare and Dakota Clinic’s actions constituted the use of monopoly powers to preclude him from obtaining medical staffing privileges. The high court agreed with the district court’s finding that Schmitt failed to provide any facts on which a jury could reasonably conclude defendants engaged in a contract, combination, or conspiracy for antitrust purposes.


U.S. Court in Texas Dismisses Physician’s HCQIA, State Law Claims Against Hospital Finding No Federal Question Jurisdiction

The U.S. District Court for the Western District of Texas dismissed a physician’s state law and Health Care Quality Improvement Act (HCQIA) claims against the hospital where he practiced for lack of subject matter jurisdiction.

After finding the HCQIA does not confer a private right of action, the court said plaintiff’s state law claims do not raise federal questions and therefore belong in state court.

Plaintiff Harold V. Gaskill III M.D. is a surgeon who has privileges at defendant North Central Baptist Hospital. After several alleged incidents involving the quality of care received by Gaskill’s patients, he was suspended by the hospital on December 7, 2011. The suspension was eventually lifted on June 3, 2013.

Plaintiff sued the hospital claiming it violated the HCQIA and alleging state law claims for breach of contract, defamation, business disparagement, and intentional infliction of emotional distress.

The court noted the text of the HCQIA does not expressly create a private cause of action. The court therefore looked to plaintiff’s state law claims as a basis for jurisdiction, noting a court has jurisdiction over federal question cases where the cause of action is created by federal law or when a state law cause of action raises a “contested and substantial federal question.”

“Other federal district courts that have considered this issue have found that the applicability of HCQIA immunity to state law claims is not a ‘substantial’ issue of federal law,” the court said. See Shah v. Palmetto Health Alliance, 2006 WL 3230755 (D.S.C. Nov. 6, 2006).

The only purported federal issue here comes from plaintiff’s allegation that that the defendants are not eligible for HCQIA immunity, the court said. But it is “well-settled that anticipating a federally created defense to a state law claim does not confer federal question jurisdiction,” the court noted. Plaintiffs asserting jurisdiction on this basis must plead federal issues other than those related to an anticipated defense in their complaint, but plaintiff failed to do so here, the court held.
The court rejected plaintiff’s argument that his claim for bad faith peer review necessarily requires overcoming the HCQIA’s presumption of immunity for physicians. “If the Court accepts the argument that this is sufficient to confer jurisdiction, the practical effect would be to provide almost every aggrieved physician access to the federal courts,” the opinion said.

While the court “recognizes that the federal issue may be ‘substantial’ to the parties in this litigation, [6] that alone does not make it a ‘substantial’ issue of federal law,” the court commented. In addition, the court said, plaintiffs have failed to articulate what federal interest would be served by resolving these cases in federal court.

_Gaskill v. VHS San Antonio Partners LLC, No. 5:13-cv-00665-XR (W.D. Tex. Sept. 6, 2013)._  

**U.S. Court in Nebraska Refuses to Dismiss Physician’s Defamation Suit Against Hospital**

The U.S. District Court for the District of Nebraska refused October 22 to grant a hospital summary judgment in a defamation suit brought by a physician after the hospital made a report to the National Practitioner’s Data Bank (NPDB).

According to the court, the truth of the report—which the physician was able to later have removed—is a question for a jury.

Plaintiff David Steinberg is a physician specializing in psychiatry. He was placed at Good Samaritan Hospital’s facility as a "locum tenens" physician and was awarded temporary privileges to provide psychiatric services to Hospital patients from December 1, 2008, through January 19, 2009.

On the evening of January 10, 2009, a psychiatric patient struck Steinberg. Hospital staff who observed the incident perceived that Steinberg responded inappropriately to the attack. The Hospital revoked Steinberg’s privileges effective January 10, 2009 and offered him a hearing, which he did not accept.

The Hospital subsequently filed a notice with the NPDB. Steinberg petitioned for its removal and an administrative determination was made that the report was not mandatory pursuant to the regulations governing such filings, because Steinberg's privileges at the Hospital would have expired before 30 days elapsed from the time his privileges were revoked.

Plaintiff later sued the Hospital for defamation and the Hospital moved for summary judgment.

The court first decided that Nebraska law should apply to the dispute. In so holding, the court rejected the Hospital’s argument that New Jersey law should apply because Steinberg is a New Jersey resident. Instead, the court found all relevant conduct took place in Nebraska where the Hospital is located.

The Hospital next argued that it cannot be held liable for defamation because the information reported to the NPDB was true. The court said that because the statements reported to the NPDB were statements of fact, their truth is a question for a jury.

The Hospital also argued that the Nebraska law governing defamation is unconstitutional under the First Amendment. The law provides that truth is a complete defense to defamation except where there is “actual malice.”

But the court found it need not reach this issue because the Hospital said it intends to file another motion for summary judgment raising issues of qualified immunity under federal law, making resolution of this issue premature.
The Virginia Supreme Court held October 31 that a trauma surgeon’s statements that an anesthesiologist effectively “euthanized” a patient and did not try hard enough to save him were actionable in a defamation action.

The high court agreed with the lower court that the statement about euthanizing the patient was entitled to a qualified privilege. But the high court also found the lower court erred in limiting the ways to overcome the privilege to a showing of “personal spite or ill will.”

Dr. Robert Smith, a trauma surgeon employed by Carilion Medical Center, and Dr. Bradley Cashion, an anesthesiologist employed by an anesthesiology group that provides services to the hospital, provided care to a critically injured patient. The patient died during surgery.

After the patient’s death, Smith criticized Cashion in the operating room, saying the patient “could have made it with better resuscitation”; “this was a very poor effort”; “You didn’t really try”; “you gave up on him”; and “you determined from the beginning that he wasn’t going to make it and purposefully didn’t resuscitate him.”

In the hallway outside the operating room, Smith also remarked “you just euthanized my patient.”

Cashion sued Smith and Carilion (defendants) for defamation and defamation per se. Defendants argued Smith’s statements were non-actionable expressions of opinion or rhetorical hyperbole. They also asserted qualified privilege applied to the statements, and Cashion failed to allege common law malice to overcome the privilege.

The trial court first found the non-euthanasia statements were non-actionable expressions of opinion that could not support Cashion’s defamation claims. While finding the euthanasia statement was not rhetorical hyperbole, the court concluded a qualified privilege applied and there was no evidence of malice to overcome the privilege. The court granted summary judgment to defendants.

The Virginia Supreme Court’s majority opinion affirmed in part and reversed in part.

The high court agreed that the statements “this was very poor effort,” “you didn’t really try,” and “you gave up on him” were non-actionable expressions of opinion.

The high court also found, however, that the statements that the patient “could have made it with better resuscitation” and “you determined from the beginning that he wasn’t going to make it and purposefully didn’t resuscitate” him insinuated that the quality of the care Cashion provided was lacking.

“Whether the quality of Dr. Cashion’s treatment caused or even contributed to the patient’s death is an allegation of fact capable of being proven true or false, such as through expert opinion testimony,” the high court said in concluding the lower court erred in ruling the two statements were non-actionable.

The high court majority agreed with the lower court that the euthanasia statements were not rhetorical hyperbole, but were privileged as a matter of law because they related to the quality of care provided to a patient.
But the high court parted ways with the decision below that Cashion failed to prove the privilege was lost or abused. The high court noted the question of whether a defendant has lost or abused the privilege is a question of fact for the jury.

“Because the circuit court limited the elements capable of defeating a qualified privilege to the showing of personal spite or ill will, independent of the occasion on which it was made, it erred by deciding as a matter of law that Dr. Smith did not lose or abuse the privilege,” the high court said in remanding for further consistent proceedings.


**Ninth Circuit Affirms Injunction Allowing Physician Access to Medical Center After Revocation of Privileges**

The Ninth Circuit affirmed February 24 a partial preliminary injunction allowing a physician to continue to practice at the defendant medical center after his privileges were revoked. According to the appeals court, the lower court correctly found the physician would suffer irreparable harm if the injunction was not issued and the order was narrowly tailored to avoid the specific harm.

Plaintiff radiation oncologists had their privileges to perform certain medical procedures at the Queen’s Medical Center revoked when the Medical Center decided to move to an employment-based model, permitting only employees to use its radiation oncology facilities.

The district court granted a partial preliminary injunction to plaintiff John Lederer, M.D. to perform certain procedures at the Medical Center’s facilities, and the Medical Center appealed.

The appeals court found federal jurisdiction based on plaintiffs’ Fourteenth Amendment claim against the Medical Center. “Although it is uncertain whether the Medical Center qualifies as a state actor for purposes of this claim, the question is not ‘so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy,’” the appeals court said.

The appeals court next found the district court did not abuse its discretion in granting the partial preliminary injunction.

To qualify for injunctive relief, plaintiffs must show they are “likely to succeed on the merits, that [they are] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest.” _Winter v. Natural Res. Def. Council, Inc._, 555 U.S. 7, 20 (2008).

In determining the district court did not err in finding plaintiffs were likely to succeed on their due process claim, the appeals court explained that in _Silver v. Castle Mem’l Hosp._, 497 P.2d 564 (Haw. 1972), the Hawaii Supreme Court said a private hospital’s decision to refuse to extend staff privileges to a licensed doctor without proper procedural due process could violate the Hawaii Constitution if that hospital were “quasi-public.”

Noting that Hawaii appropriated the Medical Center $1.5 million to operate an organ transplant center, the appeals court found it likely plaintiffs would succeed on their claim that the Medical Center qualifies as “quasi-public” based on the government funding as well as the hospital’s historical ties to the state.

Moreover, the district court pointed to evidence the Medical Center based its decision to revoke plaintiffs’ privileges, at least in part, on “concerns about the PRO physicians’ competence or qualifications.” The revocation of privileges on the basis of “professional competence or conduct”
triggers due process rights under the Medical Center’s bylaws, and plaintiffs are likely to succeed on their claim for denial of due process, the appeals court said.

The appeals court also agreed Lederer was likely to suffer irreparable harm as to two groups of patients who would not be able to receive certain needed procedures under Lederer’s care unless he continued to exercise privileges at the Medical Center.

Finally, the appeals court found the district court did not abuse its discretion by determining the balance of equities and the public interest favor a preliminary injunction because cancer patients would be denied access to Lederer’s level of expertise for certain procedures if the Medical Center were not preliminarily enjoined.


California Supreme Court Says Physician Whistleblower Suit Not Subject to “Peer Review” Exhaustion

The California Supreme Court ruled February 20 that a physician who allegedly reported substandard patient care may bring a statutory whistleblower retaliation action against a hospital without first obtaining mandamus relief setting aside the hospital’s unfavorable peer review decision.

According to the high court, the legislature enacted the whistleblower statute at issue, Cal. Health and Safety Code § 1278.5, without expressly or impliedly conditioning the right to bring a civil action under the law on a successful mandamus challenge to a hospital’s decision to restrict or terminate the whistleblower’s medical staff privileges.

“Indeed, the statute includes terms indicating the Legislature’s understanding and expectation that a medical staff member’s whistleblower suit might begin and go forward while the hospital’s proceedings against the physician were still pending,” the high court said.

To hold otherwise, the high court continued, could undermine the purpose behind the statutory provision to afford a physician whistleblower an avenue for bringing suit. The mandamus court, based on its limited review, could find sufficient evidence to uphold the hospital’s decision and thereby “entirely and permanently foreclose the physician’s statutory right to litigate, in court, his or her distinct claim that whistleblower retaliation was a reason for the exclusionary effort.”

The high court acknowledged the need to balance the whistleblower law with the important purpose served by hospital peer review proceedings in safeguarding patient care, but emphasized its decision was limited to the narrow question before it.

“Future litigants may argue that proper attention to these various concerns should affect the trial timing, the issues, and the available remedies in an individual physician’s whistleblower suit under section 1278.5,” but those issues are not before the court, the opinion noted.

Privileges Terminated

Plaintiff Mark T. Fahlen, a kidney specialist, was employed by Gould Medical Group in Modesto, CA. An area hospital operated by defendant Sutter Central Valley Hospital granted him staff privileges in 2004.

Between 2004 and 2008, plaintiff had clashes with hospital nurses and on several occasions reported to nursing supervisors or the hospital’s administration that the nurses were insubordinate and had provided substandard care.
In May 2008, the hospital’s chief operating officer contacted Gould’s medical director about plaintiff. Gould ended up terminating plaintiff’s at-will employment contract, triggering the cancellation of his medical malpractice insurance.

The hospital’s Medical Executive Committee (MEC) then recommended against renewing his privileges. A Judicial Review Committee (JRC) reversed the MEC’s decision, finding the evidence failed to show plaintiff was professionally incompetent or had endangered patient care. The hospital Board, however, reversed the JRC and agreed with the MEC that plaintiff’s privileges should be terminated.

Plaintiff did not petition in court for writ of mandamus to set the decision aside but instead sued Sutter and others alleging, among other things, that his termination stemmed from his complaints about substandard nursing care in violation of the health care whistleblower statute, Section 1278.5.

Defendants argued plaintiff could not assert his retaliation claim without first successfully challenging the hospital’s adverse peer review decision by a petition for mandamus. The trial court rejected this argument, as did the appeals court.

No Judicial Exhaustion

The high court agreed with the lower courts that judicial exhaustion was not required for a Section 1278.5 whistleblower retaliation action.

The high court noted the statute itself gave no indication that a protected individual had to exhaust other remedies before proceeding on his whistleblower retaliation claim.

The high court seemed particularly concerned that the significant hurdle to successfully challenge a hospital peer review action could effectively prevent a physician plaintiff from bringing a whistleblower action under Section 1278.5, which only requires proof by a preponderance of the evidence of a forbidden retaliatory motive for the decision.

The legislative history of the whistleblower provision supported this conclusion, the high court added. Noting the California Hospital Association attempted, but was unsuccessful, in having the statute amended to include an exhaustion requirement.

The high court declined to consider defendants’ argument that the Health Care Quality Improvement Act (HCQIA) preempted Section 1278.5 to the extent the state law allowed a physician to sidestep a direct challenge to the hospital’s peer review decision. According to the high court, this argument was not raised below and therefore beyond the appropriate scope of review.

At the same time, the high court noted “nothing in HCQIA’s terms absolutely forecloses a state tort suit alleging that a peer review decision constitutes improper retaliation against a whistleblower.”


Connecticut Supreme Court Holds Data Bank Records Not Subject to Public Disclosure

On March 25, the Connecticut Supreme Court held that under federal law, records received by a state agency in 2009 from both the National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HDB) were not subject to public disclosure under the state’s Freedom of Information Act.
In November 2009, the Greenwich Time newspaper requested from Connecticut’s Commissioner of Public Health all records that were reviewed by a consultant regarding a case where a physician allegedly inseminated a patient undergoing intrauterine insemination treatment with his own sperm instead of her husband’s sperm. A part of the records being requested by the newspaper included a NPDB report.

The department complied with the request but failed to provide the NPDB report. The newspaper filed a complaint with the Freedom of Information Commission (commission), which concluded federal regulations barred disclosure of records received from the HDB but other regulations pertaining to the NPDB did not bar disclosure of those records.

The department and newspaper both appealed to the trial court, which affirmed the commission’s decision. The trial court concluded the department was required to disclose records it received from the NPDB under the decision in Dir. of Health Affairs Policy Planning v. Freedom of Information Comm’n, 293 Conn. 164 (2009), but different regulatory language addressing HDB records not considered in Health Affairs precluded disclosure of those records.

Both the department and newspaper appealed to the state supreme court. The high court reversed in part, holding records from both the NPDB and HDB were not subject to disclosure, adding that the state agency could disclose publicly any information in its own files under the state’s freedom of information act.

The high court looked at the statutory and regulatory scheme in effect when the newspaper requested disclosure of records in November 2009.

With respect to the use of information in both the NPDB (which was created by the Health Care Quality Improvement Act of 1986 (1986 federal act)), and the HDB (created by the Health Insurance Portability and Accountability Act of 1996 (1996 federal act)), the implementing regulations for both federal acts stated information reported to the NPDB and HDB is confidential, “shall not be disclosed” outside the federal agency, and anyone receiving the information “either directly or from another party must use it solely with respect to the purpose for which it was provided.”

However, the implementing regulation for information reported to the HDB also added that “nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable State or Federal law.”

The high court concluded there was a “clear textual difference” between the implementing regulations for the 1986 federal act and the 1996 federal act and determined it must “engraft” HDB’s language into the NPDB regulation to construe both regulations consistently.

The high court pointed out that doing so was consistent with Congress’ and the federal agencies’ intent because: preventing public disclosure is consistent with the requirement that bars an entity from using the data banks’ information for any purpose other than the one for which the data bank records were provided; language in the statute addressing disclosure of NPDB records appears to refer to information reported from the party’s own files; the construction of the language regarding disclosure of NPDB records is consistent with what the NPDB has been articulating since 2001; and that such construction would avoid the “anomaly” of allowing public disclosure from a state whose law bars public disclosure of that information.

The high court also noted any remaining ambiguity was “dispelled by the recent amendments to the governing scheme.”
The Affordable Care Act required the merger of the two data banks, and implementing regulations effective May 6, 2013 indicate the merged NPDB reports "may not be disclosed" but that parties are not precluded from disclosing their "own files used to create such reports" where authorized under federal or state law.

The high court viewed the new regulation as a "clarification" of existing law pertaining to the NPDB, rather than a change in the NPD disclosure rules.


**U.S. Court in California Rejects Physician’s Discrimination Claim Against Hospital**

On March 13, the U.S. District Court for the Northern District of California held that plaintiff physician whose surgical privileges were temporarily suspended by defendant hospital failed to sufficiently allege facts to support his 42 U.S.C. § 1981 racial discrimination claim and his 42 U.S.C. § 1983 denial of due process claim.

Plaintiff J. Augusto Bastidas is a Columbian physician who was appointed to Good Samaritan Hospital’s medical staff in September 2004 after the original offer of appointment had been withdrawn. According to the opinion, on September 23, 2009, plaintiff performed a "Whipple surgery" on one of his cancer patients but mistakenly removed the patient’s kidney and damaged an artery. The patient suffered multiple organ failure and died three days following surgery.

Defendant Dr. Steven Schwartz convened a committee the day after surgery that determined a limited suspension of plaintiff’s surgical privileges was appropriate and necessary. Approximately one week later, the hospital’s medical executive committee (MEC) affirmed and expanded plaintiff’s suspension. A month later, plaintiff requested a hearing and as required by state law, the MEC reviewed plaintiff’s actions and concluded his care of the deceased cancer patient fell below the applicable standard of care. A year later, the hospital’s judicial review committee (JRC) found both the initial and expanded suspension of plaintiff’s privileges were warranted and reasonable. The hospital’s Board of Trustees affirmed the JRC’s ruling in December 2012.

Plaintiff filed suit in September 2013 against the hospital, its parent company HCA, Dr. Schwartz, and Dr. Bruce Wilbur, followed by a second amended complaint three months later alleging defendants engaged in racial discrimination in violation of 42 U.S.C. § 1981 and denial of due process in violation of 42 U.S.C. § 1983.

The hospital moved to dismiss plaintiff’s complaint for failure to adequately allege defendants intentionally discriminated against him on the basis of race and because the hospital is not a “state actor” as required under Section 1983. HCA joined the hospital’s arguments and further contended that, as a parent company, it was not responsible for its subsidiaries’ alleged actions.

The court granted the hospital and HCA’s motion to dismiss plaintiff’s Section 1981 claim with leave to amend. The court held a statement allegedly made by a Dr. Carl Bertelsen on at least two occasions about plaintiff being "blackballed" if he “got outside the box” failed to allege any facts that would reasonably support a racially discriminatory interpretation of this “facially neutral statement” as the phrasing indicated plaintiff’s actions--not his Columbian birth--might put him “outside the box.”

The court also held plaintiff failed to establish that Bertelsen was plaintiff’s employer or supervisor who had the power to interfere with plaintiff’s contract regarding privileges. The court rejected plaintiff’s argument that other minority physicians at the hospital received disparate
treatment from their white colleague as Section 1981 requires that plaintiff allege his injuries flowed from a racially motivated breach of his own contractual relationship, not of someone else’s.

The court granted defendants’ motion to dismiss plaintiff’s Section 1983 due process claim with prejudice, rejecting the argument that the statutorily mandated peer review proceedings in which defendants must operate transformed the defendants into state actors.

Citing Ninth Circuit case Pinhas v. Summit Health, Ltd., 894 F.2d 1024 (9th Cir. 1989), the court in the instant case held defendant’s status as a private, not public, hospital did not transform defendant hospital into a state actor by virtue of its compliance with the state’s statutory scheme regarding physicians’ peer review process. The court therefore concluded plaintiff failed to meet his burden of establishing defendants’ actions were fairly attributable to the state.

Lastly, the court granted HCA’s separate motion to dismiss with leave to amend. The court held plaintiff failed to allege sufficient facts that would allow the court to conclude HCA was directly or even indirectly liable for plaintiff’s privileges being suspended. The court pointed out that even if HCA was directly involved in the hospital’s decision to suspend plaintiff’s privileges, “a parent corporation may be directly involved in the activities of its subsidiaries without incurring liability so long as that involvement is ‘consistent with the parent’s investor status’.”


Tenth Circuit Says Physician Liable Under HCQIA for Attorney’s Fees

The Tenth Circuit found April 21 that a physician who unsuccessfully challenged his suspension from the hospital where he formerly held privileges was responsible for the hospital’s attorney’s fees under the Health Care Quality Improvement Act of 1986 (HCQIA).

After Dr. George Cohlmia, a cardiovascular and thoracic surgeon, performed two surgeries that resulted in the death of one of the patients and the permanent disfigurement of the other, St. John Medical Center suspended his staff privileges, according to the opinion.

Cohlmia sued St. John and others asserting multiple claims. After discovery was completed, the district court granted summary judgment for St. John on three claims: (1) violations of the Sherman Act and the Clayton Act; (2) violations of the Oklahoma Antitrust Reform Act; and (3) tortious interference with contract and interference with prospective economic advantage.

The Tenth Circuit affirmed on the basis the HCQIA shielded St. John from all claims for damages. St John subsequently sought attorney’s fees under HCQIA. The district court awarded $732,668 to St. John on the grounds that, under HCQIA, Cohlmia’s claims and conduct during litigation were frivolous and in bad faith.

On appeal, Cohlmia contended the appeals court should not consider the strength or weakness of his entire suit as part of the inquiry into the award of attorney’s fees. Instead, Cohlmia argued the statute requires the court to award attorney’s fees not if his underlying legal claims were frivolous but only if his challenge to HCQIA immunity was frivolous.

But the appeals court found “Cohlmia’s interpretation would allow underlying claims aimed at the peer review process . . . to be reframed as antitrust or business tort claims simply to evade § 11113’s fee shifting provision.”

According to the court, the HCQIA statute allows a prevailing party to recover fees in a case to which HCQIA applies. Accordingly, the attorney fee provision applies here—“especially in a case like this one, which is fundamentally about the consequences of the professional review process.”
The appeals court went on to find the district court did not abuse its discretion in concluding Cohlmia’s claims and conduct during litigation were frivolous and unreasonable and accordingly affirmed the lower court’s grant of attorney’s fees to St. John.

_Cohlmia v. Cardiovascular Surgical Specialists Corp.,_ No. 12-5188 (10th Cir. Apr. 21, 2014).

**U.S. Court in Oregon Allows Physician Discovery of His and Other Physicians' Peer Review Documents**

The U.S. District Court for the District of Oregon allowed a physician discovery of peer review materials in his suit alleging the hospital where he held clinical privileges treated him differently due to racial animosity.

Finding no federal peer review privilege, the court allowed the physician access to the materials, but agreed with the hospital that discovery should be staggered.

Plaintiffs Dr. Warren G. Roberts, an African-American neurological surgeon, and Aspen Spine and Neurosurgery Center, sued Legacy Meridian Park Hospital and others (defendants) alleging Roberts was subjected to restriction of his clinical privileges because of racial animosity and for anticompetitive reasons.

Plaintiffs moved to compel discovery of medical peer review information and all defendants opposed the motion. Defendant Meridian Park moved for a protective order to protect the disclosure of certain information.

Looking first at plaintiffs’ motion to compel, the court noted the Ninth Circuit does not recognize a federal peer review privilege and has expressly declined to create one. See _Agster v. Maricopa Cnty.,_ 422 F.3d 836 (9th Cir. 2005). Defendants urged the court to recognize such a privilege, relying on several district court cases outside of the Ninth Circuit that have recognized a federal medical peer review privilege. But the court declined to do so.

Defendants next argued even if no federal peer review privilege exists, plaintiffs contractually agreed to be bound by Oregon’s medical peer review privilege statute based on Roberts’ contractual agreement to be bound by the Meridian Park Medical Staff Bylaws.

The court found it did not need to reach the issue of whether the Bylaws are binding on plaintiffs because a statutory exception to Oregon’s medical peer review privilege applied in this case. The exception states:

Subsection (3) of this section shall not apply to proceedings in which a health care practitioner contests the denial, restriction or termination of clinical privileges by a health care facility or the denial, restriction or termination of membership in a professional society or any other health care group. However, any data disclosed in those proceedings shall not be admissible in any other judicial, administrative, arbitration or mediation proceeding.

Here, because Roberts “is contesting, or challenging, the ‘restriction’ of his clinical privileges,” the statutory exception applied, the court found.

The court turned next to Meridian Park’s motion for a protective order asking the requested discovery be staggered and reviewed by the court in camera. The court agreed that “some staggering of the discovery of peer review information is appropriate.”

“Because Plaintiffs allege that Dr. Roberts was treated differently from similarly situated physicians based on his race, the first round of discovery shall include the peer review information for Dr. Roberts and the other neurological surgeons with clinical privileges at
The court specified, though, that if “at some future time, Plaintiffs seek to discover peer review information of other non-party or non-neurosurgeon physicians, Plaintiffs will need to make a specific showing of (1) why that discovery would be reasonably likely to lead to relevant evidence, and (2) how much it will cost to review and redact confidential personal information from these documents.”

The court lastly declined to order an in camera review of the first round of peer review discovery.


U.S. Court in South Dakota Dismisses Physician’s Intentional Interference with Business Relationship Claim

The U.S. District Court for the District of South Dakota dismissed April 22 a physician’s claim for intentional interference with a business relationship against an insurance carrier conducting an external review of her surgical records, finding the physician failed to show any intentional acts.

Plaintiff Dr. Linda Miller worked as an independent contractor at Huron Regional Medical Center (HRMC). HRMC’s executive committee conducted a review of 100% of Miller’s patient charts under which it sent the medical records of one of Miller’s surgical patients out for an independent external peer review.

HRMC contacted ProAssurance, its professional liability insurance carrier, for help in conducting the external review. While ProAssurance was conducting the external review, Miller was asked by HRMC’s executive committee to request her privileges be reduced.

Shortly after Miller requested a reduction in her privileges, HRMC informed Miller the event needed to be reported to the National Practitioner Data Bank (NPDB) because there was an external review taking place when she requested her reduction in privileges. Later HRMC’s executive committee terminated Miller’s OB-GYN privileges, which also was reported to the NPDB.

HRMC’s Chief Executive Officer subsequently met with Miller and told her if she did not voluntarily resign she would be terminated. Miller resigned and then sued HRMC, ProAssurance, and others.

ProAssurance moved to dismiss Miller’s claim for tortious interference with a business relationship or expectancy, arguing Miller failed to show an intentional and unjustified act of interference on the part of ProAssurance.

Miller contended two of ProAssurance's acts constitute intentional and unjustified acts of interference. First, according to Miller, the amount of time it took for ProAssurance to complete the review equated to a breach of ProAssurance’s “duty to facilitate the external review in a reasonable and prudent manner.”

Second, Miller argued ProAssurance’s “refusal to provide the report of the physician conducting the external review constitutes breach of ProAssurance’s duty to facilitate the external review in a reasonable and prudent manner.”

The court disagreed, finding Miller alleged no facts to show ProAssurance intended to interfere with Miller’s employment or business relationships. "Miller’s own language, i.e., ‘ProAssurance’s
breach of its duty to facilitate the external review in a reasonable and prudent manner,' sounds in negligence," the court said.

But a claim for interference with business relationships and expectations requires more than mere negligence, there must be intentional acts, the court held.


**Ninth Circuit Refuses to Hear Challenge to Ongoing Physician Disciplinary Proceedings**

The district court correctly concluded it should not rule in a physician’s challenge to ongoing investigative proceedings of the state Board of Osteopathic Medicine and Surgery (Board), the Ninth Circuit held in an unpublished opinion May 16.

Dale E. Alsager, DO, PhD, a professional licensed Osteopathic physician and surgeon in the state of Washington, claimed the Board’s investigation of a patient complaint was unconstitutional because it required him to provide information to the Board or risk penalties for noncompliance.

The district court found abstention was required under *Younger v. Harris*, 401 U.S. 37 (1971), which held federal courts will not enjoin pending state prosecutions except under extraordinary circumstances where the danger of irreparable loss is both great and immediate. Alsager appealed.

The appeals court affirmed, finding all four *Younger* requirements were satisfied.

First, the Board’s proceedings are an ongoing state proceeding for purposes of *Younger*, the appeals court found. Under state law, compliance with the Board’s requests for information is compulsory and the investigation is the first part of a multi-step disciplinary process, the court noted.

Second, the Board’s disciplinary proceedings against Alsager implicated important state interests, namely regulating physician conduct and licensing.

Further, the disciplinary proceedings afforded Alsager an adequate opportunity to raise his constitutional claims, the appeals court found.

Alsager argued the Board’s process was insufficient to protect his constitutional interests because it required him to provide information to the Board (which he contended would violate his constitutional rights) or risk penalties for noncompliance.

“But the Supreme Court has held that judicial review of state agency decisions provides a sufficient opportunity to raise federal claims, even when the state agency may not consider those claims in the first instance,” the appeals court said. *See Ohio Civil Rights Comm’n v. Dayton Christian Schools, Inc.*, 477 U.S. 619, 629 (1986).

Moreover, Alsager could seek a stay of any adverse Board decision pending appeal, which would allow him to litigate his constitutional claims before the Board’s decision took effect, the appeals court noted.

Finally, the appeals court held Alsager’s suit also satisfied the fourth *Younger* requirement that the federal court action “would enjoin, or have the practical effect of enjoining, ongoing state [] proceedings.”

U.S. Court in Kentucky Dismisses All Claims Related to Patient Posting of Negative Comments About Surgeon on Website

The U.S. District Court for the Eastern District of Kentucky dismissed May 13 a host of claims and counterclaims that arose after a patient unhappy with her plastic surgery posted negative comments about the surgeon on an opinion website.

Catherine Nazari underwent plastic surgery performed by Dr. Jean Loftus, MD consisting of breast implants, a breast lift, an arm lift on both arms, and a “tummy tuck.” After the surgery Nazari posted three statements on opinion websites complaining about the results of the surgery.

Loftus and her medical group sued Nazari claiming defamation and interference with business relations. Nazari then counterclaimed asserting claims for wrongful use of civil proceedings, invasion of privacy, defamation, and intentional infliction of emotional distress.

The court first dismissed Loftus’ defamation claims finding the statements on the website were “clearly opinion.”

The court noted an expression of opinion may be defamatory, but it is “actionable only if it implies the allegation of undisclosed defamatory facts as the basis for the opinion.” Yancey v. Hamilton, 786 S.W.2d 854, 857 (Ky. 1989). Here, Nazari’s statements did not imply the existence of undisclosed facts, the court found.

The court also dismissed Loftus’ tortious interference with prospective business relationships claim. Under the Restatement (Second) of Torts Section 767, while fraudulent representations are “ordinarily a wrongful means of interference and makes an interference improper,” for purposes of this tort, “[a] representation is fraudulent when, to the knowledge and belief of its utterer, it is false in the sense in which it is intended to be understood by its recipient.”

Here, “[t]here is no evidence that Ms. Nazari did not honestly believe the opinions she set forth in the various postings she made,” the court found.

The court also dismissed all of Nazari’s counterclaims finding no evidence to support them.


U.S. Court in Vermont Dismisses Physician’s Lawsuit for Libel, Tortious Interference Involving Data Bank Report

The U.S. District Court for the District of Vermont dismissed May 6 a physician’s lawsuit against a hospital alleging tortious interference and libel for statements made to the Department of Health and Human Services (HHS) regarding his professional performance.

In 2005, plaintiff Raymond A. Long, MD, an orthopedic surgeon, sued Quorum Health Resources and Northwestern Medical Center (NMC) for libel and tortious interference. The parties settled the lawsuit, and the district court dismissed the case with prejudice in 2008.

The 2005 case arose from plaintiff’s allegations that someone at NMC deliberately contaminated his surgeries with bacteria, thereby infecting his patients. NMC initiated a peer review process to investigate plaintiff’s allegations and prohibited him from performing further surgeries until a psychiatrist evaluated him. Plaintiff resigned immediately thereafter.

In April 2004, NMC submitted an Adverse Action Report (AAR) to the National Practitioner Data Bank (NPDB) stating plaintiff voluntarily surrendered his clinical privileges at NMC “while under, or to avoid, investigation relating to professional competence or conduct.” Plaintiff argued NMC
initiated the peer review process to cast him as mentally unstable and to blame him for deliberately causing the infections.

In August 2011, NMC declined plaintiff’s request to remove the AAR from the NPBD, so plaintiff sought review by the Department Health and Human Services (HHS), which requested from NMC a chronology of events that led to the NPDB report, including supporting documentation.

NMC’s Chief Executive Officer, Jill Berry Bowen, provided HHS with a brief cover letter, two-page chronology, and supporting documentation that included correspondence within NMC, correspondence with plaintiff, plaintiff’s resignation letter, and the AAR.

HHS notified plaintiff in February 2012 that the AAR would remain in the NPDB. HHS also added a notation to the AAR that it was found to be properly filed and would be maintained.

According to plaintiff, Bowen’s response to HHS went beyond the original submission to the NPDB and that “a reasonable reader would reasonably understand” the report to be asserting that plaintiff was mentally unstable, his conspiracy theory evidenced his psychiatric problems, and that plaintiff resigned because he did not want to submit to a psychiatric exam. Plaintiff further alleged NMC knowingly made these false and fraudulent statements to ensure HHS did not remove the AAR from the NPDB.

Plaintiff’s lawsuit against Quorum and NMC asserted claims of libel per se and tortious interference with prospective business relationships. Defendants moved to dismiss plaintiff’s complaint as precluded by res judicata.

The court found plaintiff’s 2005 case constituted a final adjudication on the merits involving the same parties, so its application of res judicata or claim preclusion rested on whether the subject matter and causes of action were the same or substantially the same.

Applying the “transactional test” of time, space, origin, or motivation, the court found Bowen’s documents originated during the 2004 peer review process and therefore pertained to the same time and space as the facts underlying the 2005 case. The court therefore dismissed plaintiff’s libel and tortious interference claim as barred by claim preclusion.

The court also concluded that plaintiff invited any harm suffered by requesting the HHS review, which in turn led to the Bowen report.

Lastly, the court denied plaintiff leave to amend the complaint to add two new causes of action—violation of the state’s consumer fraud statute and deceit.