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Antitrust

U.S. Court in Texas Enjoins Disputed Medical Board Rule Affecting Telehealth Services

A federal court in Texas granted May 29 a preliminary injunction to telehealth provider Teladoc, Inc. enjoining the enforcement of a Texas Medical Board (TMB) rule set to go into effect June 3 requiring a face-to-face visit before physicians may prescribe certain drugs to patients.

Teladoc, which provides physician consultations to members via the telephone, alleged the new rule, 22 Tex. Admin. Code § 190.8(1)(L), violates Section 1 of the Sherman Act and the Commerce Clause and sought preliminary injunctive relief.

The TMB issued New Rule 190.8 in April 10, citing concerns about quality of care and improving patient safety. The rule requires a “face-to-face visit or in-person evaluation” before a physician issues a prescription.

In granting the preliminary injunction, the U.S. District Court for the Western District of Texas found Teladoc had a likelihood of succeeding on its antitrust claim. The court did not reach the Commerce Clause issue.

Immunity Not Addressed

At the outset, the court noted that the TMB did not assert an immunity defense as a state agency charged with regulating a profession. The U.S Supreme Court recently addressed state action immunity for professional boards recently in North Carolina State Bd. of Dental Exam’rs v. FTC, 135 S. Ct. 1101 (2015).

In that case, the Court held that the North Carolina State Board of Dental Examiners was not entitled to immunity from antitrust scrutiny under the state action doctrine, which provides a narrow exception to the antitrust laws for anticompetitive conduct by the states when acting in their sovereign capacity. See Parker v. Brown, 317 U.S. 341 (1943).

Justice Kennedy, writing for the majority, said state action immunity was not available because the Board was controlled by “active market participants” and its decision to block non-dentists from providing teeth-whitening services was not “actively supervised” by the state.

Anticompetitive Effects

Leaving aside the immunity question, the court disagreed with the TMB’s argument that Teladoc failed to show the requisite anticompetitive effects to support the antitrust claim.

Teladoc maintained that the new rule would increase prices and reduce choice, access, and innovation.

According to the court, Teladoc presented sufficient evidence to support these claims. For example, Teladoc pointed to estimates that the average cost of a visit to a physician or an emergency room is $145 or $1975, respectively, compared to the typical cost of Teladoc’s consultation of $40. Teladoc also cited research finding the use of telehealth services reduced health care costs and increased access to care, which the court said was significant in light of evidence that Texas has a shortage of physicians.
“Elimination of physicians providing healthcare would thus negatively impact not just the competitor physicians, but consumers, a classic antitrust injury,” the court observed.

The court also was skeptical of the TMB’s justification for the new rule—i.e. improving quality of care. The court characterized the TMB’s evidence detailing deficiencies in telephone-only diagnosis as “anecdotal,” noting Teladoc similarly provided countervailing anecdotal evidence showing the value of telehealth services.

**Destruction of a Business Model**

Examining the other factors for granting a preliminary injunction, the court held Teladoc’s argument that the rule would destroy its business model was sufficient to show irreparable injury.

“At least two circuit courts have recognized destruction of a business model may constitute irreparable injury,” the court observed.

Finally, the court found the balance of respective interests weighed in favor of granting Teladoc the injunction.

“Not only is telehealth the wave of the future, but Texas physicians have been treating patients without a prior in-person visit for decades,” said Jason Gorevic, chief executive officer of Teladoc, following the court’s ruling.

“We are happy to be able to continue serving Texas citizens, employers and health plans by enabling them to access high-quality care in a cost-effective manner.”

**Third Circuit Holds Drug Patent Deal to Forgo Authorized Generic Subject to Antitrust Scrutiny**

A drug patent settlement that includes non-cash transfers of value like the brand-name drug maker’s agreement to forego producing an “authorized generic” (AG) during the generic manufacturer’s 180-day exclusivity period is subject to antitrust scrutiny under the rule of reason, the Third Circuit held June 26.

The closely watched ruling interpreted the Supreme Court’s 2013 decision in *FTC v. Actavis*, 133 S.Ct. 2223, which held that reverse settlement payments could be a restraint of trade under a rule-of-reason analysis if the payment was large and unjustified, even if the anticompetitive effects fell within the scope of the patent, as extending to no-AG agreements.

“We believe this no-AG agreement falls under Actavis’s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition,” the Third Circuit reasoned.

**‘071 Patent**

GlaxoSmithKline (GSK) held the ‘071 patent on lamotrigine, the active ingredient in brand-name drug Lamictal, which is used to treat epilepsy and bipolar disorder.

Before the patent’s expiration, Teva Pharmaceuticals Indus. Ltd., filed with the Food and Drug Administration to market generic lamotrigine tablets and chewables.
GSK then filed a patent infringement suit against Teva in federal court. After a federal judge ruled that the patent’s main claim was invalid, GSK and Teva reached a settlement.

Under the settlement, GSK agreed to allow Teva to market generic lamotrigine chewables before the patent was set to expire. GSK also agreed not to market an authorized generic until after Teva’s 180-day market exclusivity period expired.

Plaintiffs, including King Drug Co. of Florence, Inc. and Louisiana Wholesale Drug Co., are direct purchasers of Lamictal, alleged the no-AG agreement effectively was a “reverse payment” subject to antitrust scrutiny. Teva moved to dismiss, arguing that only cash payments are actionable “reverse payments.”

A federal district court in New Jersey agreed with Teva that only patent settlements involving exchanges of money are subject to antitrust scrutiny under Actavis.

**Actavis Not Limited to Cash**

In the appeals court’s view, “no-AG agreements are likely to present the same types of problems as reverse payments of cash.”

The no-AG agreement here in fact “may be of great monetary value to Teva”—potentially in the hundreds of millions.

Absent the agreement, it would be “economically rational” for GSK to launch an AG, thereby generating more competition for the generic.

“The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash,” the Third Circuit observed.

On remand, the district court should consider the dispute under the traditional rule of reason, the appeals court instructed.


**U.S. Court in Texas Allows Teledoc Antitrust Suit to Proceed**

In a case closely watched by telemedicine providers and medical boards, a federal court in Texas rejected December 14 the Texas Medical Board’s (TMB’s) effort to jettison telemedicine provider Teledoc’s antitrust and Commerce Clause lawsuit, finding state action immunity did not apply.

Plaintiffs Teladoc, Inc., Teladoc Physicians, P.A., and individual physicians sued 14 members of the TMB in their official capacities alleging recent regulatory changes adopted by the medical board violate antitrust law and the Commerce Clause.

At issue in the case are two regulations. As originally adopted in 2003, one provision prohibits prescription of any “dangerous drug or controlled substance” without first establishing a “proper professional relationship,” which requires “a diagnosis through the use of acceptable medical practices such as patient history, mental status examination, physical examination, and appropriate diagnostic and laboratory testing.” 22 Tex. Admin. Code § 190.8(1)(L). In 2004, the TMB adopted a second regulation at issue specifically governing telemedicine. 22 Tex. Admin. Code § 174.1, et seq.
Effective October 2010, the TMB amended its telemedicine regulations, and made clear that, to establish a "proper physician-patient relationship," telemedicine providers must conduct a physical examination of a patient.

In June 2011, the TMB issued a letter to Teladoc stating the language of “Old Rule” 190.8 required a "face-to-face" examination prior to prescription of a dangerous drug or controlled substance.

The U.S. District Court for the Western District of Texas, which previously granted Teladoc a temporary injunction, rejected the TMB’s arguments for dismissal that the action was time barred, that the medical board was immune from antitrust liability, and that Teladoc failed to state a Commerce Clause claim.

Statute of Limitations

The TMB argued that Teladoc’s antitrust claim under the Clayton Act should be dismissed under the four-year statute of limitations.

The court noted that New Rule 174 took effect on October 17, 2010, and Teladoc did not file its action until April 29, 2015, more than four years later.

The court agreed, however, with Teladoc’s argument that the limitations period failed to account for all of the named plaintiffs. Specifically, one physician plaintiff first became licensed to practice medicine in 2014 and another did not begin practicing telemedicine through Teladoc until 2013.

“Plaintiffs correctly maintain neither would have had standing prior to beginning the practice of telemedicine to assert any injury” from the regulations, the court said, citing Price v. City of San Antonio, 431 F.3d 890, 893 (5th Cir. 2005) (cause of action under Section 1983 accrues when plaintiff "knows or has reason to know of the injury which is the basis of the action.").

State Action Immunity

The TMB next contended that Teladoc’s antitrust claim was barred by the doctrine of state action immunity.

The U.S Supreme Court recently addressed state action immunity for professional boards in North Carolina State Bd. of Dental Examiners v. FTC, 135 S. Ct. 1101, 1109 (2015).

In that case, the Court held that the North Carolina State Board of Dental Examiners was not entitled to immunity from antitrust scrutiny under the state action doctrine, which provides a narrow exception to the antitrust laws for anticompetitive conduct by the states when acting in their sovereign capacity. See Parker v. Brown, 317 U.S. 341 (1943).

Justice Kennedy, writing for the majority, said state action immunity was not available because the board was controlled by “active market participants" and its decision to block non-dentists from providing teeth-whitening services was not "actively supervised" by the state.

After examining the relationship between the medical board and the state in this case, the court found “TMB has failed to show the active supervision required to merit dismissal on the basis of state action immunity.”
**Dormant Commerce Clause**

The court next turned to Teladoc’s argument that both New Rule 174 and New Rule 190.8 violate the so-called “dormant” Commerce Clause because they discriminate against physicians who are licensed in Texas, but are physically located out of state.

Under the dormant Commerce Clause, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors are prohibited.

The court rejected the TMB’s argument that Teladoc’s claim that the medical board was not subject to active state supervision couldn’t be reconciled with their Commerce Clause claim that TMB is a state actor.

According to the court, “the question of immunity from antitrust liability rests on a different determination” than the Commerce Clause inquiry. Antitrust immunity, the court explained, looks specifically at “whether the TMB is subject to active state supervision in its decisions which have an anti-competitive effect.”

The court found the “allegations sufficient at this early stage of the litigation” to overcome the TMB’s motion to dismiss Teladoc’s Commerce Clause claim.

“Resolution of Plaintiffs’ Commerce Clause challenge is ‘one of degree,’ requiring the Court to determine ‘the nature of the local interest involved, and [] whether it could be promoted as well with a lesser impact on interstate activities,’” the court said.


**First Circuit: Non-Cash Reverse Payments Subject to Antitrust Scrutiny**

Another federal appeals court has ruled drug patent settlements that include non-cash reverse payments including favorable promotional and other "side" deals between the brand-name manufacturer and generic drug maker are subject to antitrust scrutiny under the rule of reason.

The First Circuit vacated February 22 a district court decision holding that the Supreme Court’s decision in *FTC v. Actavis*, 133 S. Ct. 223 (2013), which held that reverse settlement payments could be a restraint of trade under a rule-of-reason analysis if the payment was large and unjustified, even if the anticompetitive effects fell within the scope of the patent, did not extend to non-cash reverse payments.

The First Circuit joins the Third Circuit in ruling that *Actavis* applies to non-cash reverse payments. See *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, No. 14-1423 (3d Cir. June 26, 2015).

**‘394 Patent**

Defendant Warner Chilcott held the ‘394 patent on Loestrin 24, a low-dose oral contraceptive that purports to reduce intermenstrual bleeding by having the patient take the pills for 24, as opposed to 21, consecutive days.

Shortly after receiving Food and Drug Administration (FDA) approval to market the oral contraceptive, two generic manufacturers—Watson Pharmaceuticals, Inc. and Lupin Pharmaceuticals, Inc.—announced plans to introduce a generic version of Loestrin 24.
Warner brought separate patent infringement lawsuits against both companies. The parties settled the lawsuits with the generic manufacturers agreeing to delay entry of their generic versions, and Warner agreeing to various favorable “side” deals and not to introduce its own authorized generic of Loestrin 24.

Plaintiffs direct and indirect purchasers of Loestrin 24 brought a putative class action alleging the settlement agreements included “reverse payments” subject to antitrust scrutiny under Actavis. The district court dismissed the antitrust claims, agreeing with Warner that Actavis applied only to reverse payments in cash.

**Actavis Not Limited to Cash**

The First Circuit held the district court erred in concluding that non-monetary reverse payments weren't within Actavis’ scope.

According to the appeals court, the district court overlooked the fact that the reverse payments in Actavis also involved so called “side deals” in which the generic drug maker agreed to promote the brand-name drug in exchange for multi-million dollar payments.

“This fact alone demonstrates that the Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court’s decision to pure cash payments,” the appeals court wrote.

The appeals court acknowledged that under Actavis the value of the reverse payment is a key element in determining whether it is unlawful. As part of the antitrust inquiry under Actavis, the factfinder must determine the size of the reverse payment.

Although quantifying the value of non-cash payments may be more challenging, the appeals court said this type of calculation often is par for the course in complicated antitrust litigation.

Plaintiffs must plead information sufficient to estimate the value of the non-cash reverse payments to determine whether they are large and unjustified, the appeals court said.


**Ninth Circuit Affirms Dismissal of Antitrust Allegations**

The Ninth Circuit March 2 in an unpublished decision affirmed the dismissal of a hospital management company's antitrust action against Kaiser insurance alleging it monopolized acute care emergency hospital services.


Plaintiff alleged that under the guise of the collective bargaining process and a labor-management agreement, defendants conspired to eliminate competing non-unionized hospitals in violation of Section 1.

The appeals court agreed with the lower court that the claim did not sufficiently plead facts showing defendants harmed competition in the acute care emergency hospital services market.
“Prime never alleges that any competitors have exited the market or reduced their production because of the Defendants’ actions. Nor does it allege that the Defendants’ actions actually caused health care consumers to face higher prices or a reduction in quality of care, quantity of services, or overall choice of providers,” the appeals court said.

The appeals court likewise found no error in the lower court’s dismissal of plaintiff’s claims against Kaiser under Section 2.

Plaintiff alleged that Kaiser monopolized, attempted to monopolize, and conspired to monopolize the acute care emergency hospital services market. To prevail under such a theory, a plaintiff must show possession of monopoly power in the relevant market, the appeals court noted.

However, the appeals court found no “direct or circumstantial evidence of Kaiser’s alleged monopoly power.”

Plaintiff merely alleged that (1) the relevant hospital market includes at least 125 hospitals, (2) Kaiser owns 15 of those hospitals, and (3) Prime owns 11 hospitals. "Kaiser’s ownership of 12% of the hospital market is simply not sufficient to show market dominance," the appeals court held.


### Sixth Circuit Reinstates Antitrust Challenge to Hospital Joint Operating Agreement

*By Jeffrey W. Brennan, McDermott Will & Emery LLP*

Last month, in *The Medical Center at Elizabeth Place v. Atrium Heath System*,[1] the Sixth Circuit reversed the district court and held that a complaint alleging anticompetitive conduct by a group of hospitals in the Dayton, OH area, collaborating through a joint operating agreement (JOA), may proceed under Sherman Act § 1. The ruling is important for its analytical approach and interpretations of facts going to the central issue on appeal: whether the hospital parties to the JOA are subject to conspiracy allegations for actions taken through the joint venture, or instead are a single entity beyond the reach of § 1.

The plaintiff/appellant is a physician-owned Dayton hospital that alleges that the JOA, its participating hospitals, and operating company (Premier Health Partners) harmed competition by entering network contracts with commercial insurers on the condition that new hospitals (like plaintiff/appellant) would be kept out of the network. The district court granted summary judgment for defendants, ruling that the JOA is a single entity that acting unilaterally cannot violate § 1’s prohibition on a “contract, combination . . . or conspiracy, in restraint of trade.”[2] The Sixth Circuit’s three-judge panel in *Medical Center at Elizabeth Place* reversed in a 2-1 decision, holding that the record “raises a genuine issue of material fact as to whether defendant hospitals have ‘separate’ corporate consciences or whether they should be considered a single entity for purpose of the antitrust laws.”[3]

In the opinion, the appeals court framed its analysis under *Copperweld Corp. v. Indep. Tube Corp.*, where the Supreme Court noted that § 1 of the Sherman Act “does not reach conduct that is wholly unilateral,”[4] that the Sherman Act “leaves untouched a single firm’s anticompetitive conduct (short of threatened monopolization) that may be indistinguishable in economic effect from the conduct of two firms subject to § 1 liability,”[5] and that “substance, not form” determines whether an entity is capable of conspiring under § 1.[6] The line between concerted and unilateral action, the appeals
court said, is “an often-difficult distinction”—particularly when competitors integrate partially through an entity such as a JOA or other joint venture that is less than a full-scale merger.

The appeals court said it was guided by another Supreme Court case, American Needle, Inc. v. National Football League, where the Court held that § 1 applied to an incorporated entity in which the 32 NFL teams collaborated to market each team’s intellectual property for apparel and like items. The Court said the facts there showed that the teams operated as “independent centers of decisionmaking” in the marketing entity, i.e., that each team was “separately controlled” and had “economic interests . . . distinct” from the other teams. The Sixth Circuit in Medical Center at Elizabeth Place concluded that these same characteristics of separateness also were present in the record regarding the JOA-related defendants.

The appeals court assessed the JOA’s formation documents to determine whether upon forming the JOA, the individual hospitals became a single integrated entity under the antitrust laws. It also examined notes of statements by various hospital defendant employees allegedly reflecting their personal views that the JOA hospitals were separate competitors rather than integrated entities—evidence excluded as inadmissible hearsay by the trial court. Before examining those issues, however, the Sixth Circuit first assessed whether defendants’ alleged anticompetitive conduct—its exclusive contracts with payers and other exclusionary practices—evidences coordination by competitors or unilateral activity by a single entity.

Conduct Evidence

“We look first to the actual conduct of the parties to the joint venture,” the appeals court said, to determine, as directed by American Needle, “how the parties actually operate.” This starting point was not the JOA’s structure and organization to determine its degree of integration, but rather the JOA’s alleged anticompetitive acts toward the plaintiff/appellant—an inquiry into the “stated intent on the part of the defendants to engage in coercive behavior, as well as conduct providing evidence of that intent.” This evidence includes statements by Premier’s Chief Executive Officer (CEO) of “his intention to keep plaintiff from entering the Dayton healthcare market,” the exclusivity provisions in the defendant hospitals’ payer contracts, payers’ refusals to deal with plaintiff at defendants’ request, and anticompetitive effects arising from alleged conduct. This evidence was a basis for the holding that a genuine issue of material fact exists concerning whether defendants’ actions were concerted or unilateral.

The opinion does not explain how evidence of anticompetitive intent and conduct advances the inquiry into whether defendants are independent centers of decision making working in concert or a single entity acting unilaterally through an integrated JOA. Certainly, single entities beyond § 1’s reach also can have exclusionary intent and enter into exclusive contracts like those in the record here that may or may not be anticompetitive. The dissent criticized as “flawed” this aspect of the majority’s reasoning, stating that intent to exclude rivals is irrelevant to whether defendants are a single entity, and that American Needle’s directive to courts to assess “how the parties actually operate” when determining whether conduct is joint or unilateral refers to how the defendants operate not against competitors but “amongst each other.”

Evidence of Integration

The appeals court provided an analysis of how the defendants operate among each another. It discussed internal JOA business relationships under certain provisions in the operating agreements. The appeals court said its analysis revealed “some degree of unitary management” through the JOA but “questions remain” that suggest the JOA hospitals retained their “separate corporate consciousness” (quoting American Needle). Evidence of separateness noted in the opinion
includes facts showing that the defendant hospitals remain separate legal entities, hold their own assets, file their own tax returns, maintain a separate corporate entity with its own CEO and Board of Directors, compete with each other for physicians and patients, continue to market certain hospital services to the public, and make material independent decisions concerning their respective medical operations (although some decisions are managed by the JOA’s operating company), including staffing decisions and medical strategies concerning patient care.[14] The opinion notes that the JOA requires hospital revenue sharing under an agreed formula, but says this is not enough to create single-entity status because “any cartel” could do the same thing and not escape liability under § 1.[15]

The dissent agreed revenue sharing is not dispositive but said that since the JOA’s revenue/loss allocations are not linked to individual hospital revenue or profitability, “no single hospital has any incentive to become more profitable by attracting more patients than the other,” making it incorrect for the majority to say that the defendant hospitals compete with each other for patients.[16] It also pointed to additional JOA provisions that it said grants Premier significant operational authority over each defendant hospital, including control over strategic plans and budgets, power to remove each hospital’s CEO, control over material debt incurrence and consolidation of programs, and other powers.[17] The majority did not discuss these provisions.

In the opinion’s “Conclusion,” the appeals court referred a second time to “the lack of shared assets by the defendants,”[18] which seems to underscore that fact’s importance to the ruling. The dissent took issue with the majority’s interpretation of asset ownership. It said the JOA “grants Premier substantial control over” each hospital’s assets, through among other things (not discussed by the majority) the authority to approve the sale, transfer, or other disposition of any material assets to any hospital other than a JOA hospital.[19] “Defendants’ inability to manage their own assets,” the dissent said, should “serve as another marker of Premier’s centralized control.”[20]

**Statements by Hospital Employees**

The record included a consultant’s notes of interviews by defendant hospital executives and senior management, which the appeals court called “compelling evidence” showing that the hospitals “view themselves as separate entities”; the notes contained statements that the hospitals “do not collaborate or act as a system,” “act as a confederacy that collaborates in a few areas,” and “compete with each other for market share,” among others.[21] The appeals court said the district court erred in excluding this evidence as inadmissible hearsay and that the evidence was support for the decision to reverse and remand. The dissent would have upheld the evidentiary ruling and said the excluded statements cast little doubt on the overall unity of interest among the defendant hospitals that it found in the evidentiary record.[22]

The split-panel decision in *Medical Center at Elizabeth Place* demonstrates the highly fact-intensive level of scrutiny that can go into a determination whether conduct by a joint venture among former (and allegedly current) competitors is concerted or unilateral under the antitrust laws. The majority did not address various operating agreement provisions identified by the dissent as consistent with a showing of integration into, and centralized control by, the JOA, such as provisions pertaining to the disposition of individual hospital assets, strategic planning and budgets, and the details of revenue and loss sharing. It is not clear how the majority weighed this particular evidence in reaching its decision to reverse the district court. Its reliance on evidence of intent and conduct to support its finding of a fact issue on the JOA’s status as a single or multi-party entity leaves open the question of how such evidence can help distinguish between concerted and unilateral activity, since single entities can be just as capable of intent and, when monopoly power is involved, conduct, that is anticompetitive. This case will be worth watching on remand, to see if it yields further judicial consideration on these questions and on the factors that determine § 1’s applicability to joint ventures formed by competitors.


[5] Id. at 775.

[6] Id. at 773 n.21.


[10] Id.

[11] Id. at *14-17.

[12] Id. at *36 (what matters “is whether defendants remain in competition with each other, not whether they intend to ward off competition with a third party”) (emphasis in original).

[13] Id. at *19.

[14] Id. at *20-21.

[15] Id. at *20.

[16] Id. at *38-40.

[17] Id. at *40-42.

[18] Id. at *27.

[19] Id. at *44-45.

[20] Id. at *45.

[21] Id. at *22-25.

[22] Id. at *45-48.
U.S. Court in Louisiana Refuses to Dismiss Health Plan’s Monopolization Claims Against Hospital

The U.S. District Court for the Western District of Louisiana refused March 31 to dismiss a health plan’s antitrust action alleging a hospital’s past and present acquisitions in Shreveport and Bossier City, LA violated federal antitrust laws.

Plaintiff Vantage Health Plan, Inc. alleged that defendant Willis Knighton Medical Center’s prior acquisitions, physician referral practices, and non-compete employment contracts violated Section 2 of the Sherman Act, which prohibits monopolization and attempted monopolization.

According to plaintiff, defendant gained monopoly power in the Shreveport area in the markets for general acute care hospital services, adult primary care, and obstetrics/gynecology, where its share of commercially insured patients as of 2014-2015 was 78%, 80%, and 60%, respectively.

Plaintiff alleged that defendant, among other things, acquired physicians from competing providers, causing the rival to fail, and then in two instances moved to purchase the remaining physical assets of the shuttered entities.

Vantage said it tried repeatedly to contract with Willis-Knighton over a 15-year period, but defendant refused to deal with the health plan. Vantage sought roughly $67 million in damages.

A second plaintiff, BRFHH Shreveport, LLC, which operates a competing hospital in the area, University Health Hospital, and Vantage also asserted that Willis-Knighton is planning a new joint venture to open clinics located on its campus staffed by physicians from Louisiana State University (LSU), who are the same physicians staffing University Hospital.

According to plaintiffs, the clinics are designed to shift the treatment of University Health’s commercially insured patients to Willis-Knighton facilities, which would cause University Health to lose $15 million annually and endanger its survival.

Defendant moved to dismiss Vantage’s monopolization claims.

Anticompetitive Conduct

Defendant argued that Vantage failed to plead anticompetitive conduct because it had a rational business purpose for all of its challenged actions—namely, growing its business. According to defendant, its prior conduct only involved “hiring talent” from its rivals, which by itself was not anticompetitive.

The court agreed that four of the acquisitions at issue didn’t give rise to Section 2 liability because Vantage failed to plead that defendant hired the physicians to deny them to any of the target entities or to induce their disloyalty to their current employer. But the court found two other acquisitions amounted to “outright takeovers,” which could establish anticompetitive conduct under Section 2. In so holding, the court refused to hold that lack of a rational business purpose is required to show anticompetitive conduct.

The court instead found Vantage adequately pled anticompetitive conduct by alleging that defendant’s acquisition of a rival hospital and cardiology group lessened competition and increased its market share in the relevant market.
The court did hold that Vantage’s allegations involving defendant’s non-compete agreements with its physicians and its control of physician referrals did not amount to anticompetitive conduct under Section 2 because there was an underlying rational business purpose—i.e., to treat more patients.

**Antitrust Injury**

The court agreed with defendant that a refusal to contract isn’t an antitrust injury because Willis-Knighton could have done the same thing even if it lacked market power.

But the court found plaintiff had pled an antitrust injury to the extent it alleged Willis-Knighton demanded higher reimbursement rates from Vantage. This is precisely the type of injury that flows from market power—i.e., the ability to demand higher prices, the court noted.

**Future Harm**

The court also held that Vantage adequately pled that it would be injured by LSU physicians treating patients at defendant’s clinics.

Specifically, Vantage alleged that these physicians, who currently are in its network, would effectively become defendant’s employees when they participated in the new clinics. Vantage alleged the same pattern in the past when a physician under contract with Vantage joined defendant’s physician network and immediately terminated its contract with Vantage.

The court therefore refused to dismiss Vantage’s claims of future harm.


**U.S. Court in California Says Surgeon Alleged Antitrust Injury in Action Against Hospital**

A federal court in California held April 19 that a surgeon sufficiently alleged a hospital conspired to exclude him from the market for minimally invasive cardiac and thoracic surgery and harmed competition.

The U.S. District Court for the Northern District of California refused to dismiss the action under Section 1 of the Sherman Act, finding a plausible conspiracy between the surgeon’s former associate and hospital administrators to “force” plaintiff out of the hospital and then to damage his reputation at surrounding hospitals.

Notably, the court also held that the plaintiff surgeon “plausibly alleged that the scheme actually injured competition” in Napa and Solano counties “in terms of quality of care, the range of services offered, the number of surgeons, and cost.”

Dr. Ramzi Deeik operated a surgery practice with Dr. Robert Klingman (who is not a party to the lawsuit). The practice serviced defendant Northbay Medical Center’s cardiac, thoracic, and vascular surgery programs.

Deeik alleged that after he started raising concerns about NorthBay’s vascular surgery program, hospital administrators, Klingman, and others commenced a multi-prong scheme to squeeze him out of NorthBay while also destroying his reputation at other hospitals to eliminate him as a competitive threat.
The court found plaintiff sufficiently alleged a Section 1 claim, denying defendants' motion to dismiss.

Specifically, the complaint alleged that the conspirators disparaged plaintiff to other medical providers, persuaded doctors to decline to serve as his backup surgeon at the hospital, lured doctors who previously referred patients to him, and arbitrarily enforced surgical requirements only against him.

The court rejected defendants' contention that plaintiff only alleged injury to himself, not to competition in the broader market, as required to maintain an antitrust claim.

The court also held plaintiff pled a plausible geographic market for purposes of withstanding the motion to dismiss. The court pointed out that the validity of the relevant market generally is a factual, rather than legal, inquiry reserved for the jury. The court acknowledged the relevant geographic market was a viable argument for defendants to raise, but said the issue couldn’t be resolved on a motion to dismiss.


**U.S. Court in Pennsylvania Refuses to Enjoin Pennsylvania Hospital Merger But Temporarily Extends TRO**

A federal district court in Pennsylvania denied May 9 a preliminary injunction blocking the merger of two Pennsylvania hospitals, which the Federal Trade Commission (FTC) and the Pennsylvania Attorney General (AG) sought to enjoin as anticompetitive.

In refusing to block the merger, the U.S. District Court for the Middle District of Pennsylvania held the FTC failed to allege a relevant geographic market for its challenge to the merger of defendants Penn State Hershey Medical Center, a teaching hospital in Hershey, PA, and PinnacleHealth System, which operates community hospitals in Harrisburg and Cumberland County, PA.

According to the court, the FTC's alleged four-county geographic market was too narrowly drawn because it failed to "account for where the Hospitals . . . draw their business."

Following the decision, the FTC asked the court to enjoin the transaction, which otherwise could close as early as May 13, pending its appeal to the Third Circuit. Alternatively, the agency requested that the court delay the combination until the Third Circuit ruled on the FTC's emergency application for an injunction pending appeal.

"An injunction pending appeal is necessary to preserve the status quo, which would otherwise be irreparably altered if the merger occurs while appellate review proceeds," the FTC argued.

The court in a May 12 order agreed to extend the existing temporary restraining order for two weeks until May 27.

In December 2015, FTC issued an administrative complaint alleging the hospitals’ proposed merger would violate Section 7 of the Clayton Act and Section 5 of the FTC Act. The FTC and the Pennsylvania AG sought to prevent the hospitals from moving forward with the merger pending the conclusion of the administrative action, which is set to begin May 17.

The FTC alleged the relevant geographic market was four counties in the Harrisburg, PA area. According to the FTC, the geographic market for general acute care services is “inherently local.”
The hospitals contended, however, that the alleged relevant geographic market was too narrow and didn’t reflect “commercial realities facing patients and payors.”

Siding with the hospitals, the court noted the “uncontroverted fact” that 43.5% of Penn State Hershey patients originated outside the Harrisburg area, and several thousand of Pinnacle’s patients reside outside the four counties. The court also pointed to evidence that half of Penn State Hershey’s patients travel at least 30 minutes for care, and 20% travel more than an hour.

These facts, the court said, undermine FTC’s assertion that general acute care services are “inherently local.”

Citing the “realities of living in Central Pennsylvania,” which is largely rural, the court viewed the 19 hospitals within 65 minutes of Harrisburg as viable alternatives for consumers if defendants tried to raise prices or allowed quality to suffer.

Notably, the court also found the hospitals presented a “compelling efficiencies argument.”

“[T]he merger would immediately make additional capacity available to Hershey, causing near instantaneous benefits to Hershey’s patients,” the court said.

According to the court, the merger also would allow Penn State Hershey and Pinnacle “to remain competitive in a climate where nearby hospitals are routinely partnering to assist each other in achieving growth and dominance.”

Finally, the court found patients stood to gain from the merger, noting the current climate for the health care industry “virtually compels institutions to seek alliances such as the Hospitals intend here.”

“[T]he community medical center is a charming but increasingly antiquated concept,” the court wrote. “It is better for the people they treat that such hospitals unite and survive rather than remain divided and wither,” the court commented.


The Third Circuit agreed May 18 to enjoin the merger pending its review of the lower court decision.

Arbitration/Mediation

Sixth Circuit Says Power of Attorney Did Not Authorize Entry into Binding Arbitration Agreement

The Sixth Circuit held May 29 that a durable power of attorney (POA) granted by a prospective nursing home resident to her attorney-in-fact did not authorize entry into an arbitration agreement that was not a precondition of admission to the nursing home because the POA expressly granted the attorney-in-fact the authority only to make health care decisions.

Because entry into the agreement was voluntary and the POA did not provide a general authority to the attorney-in-fact to contract on the resident’s behalf, the arbitration agreement was not enforceable against the deceased resident’s estate, the appeals court held.

In 2007, Helen Elfrig executed a POA naming Joy Brooker as her legal representative. Upon Elfrig's admission to nursing home Regis Woods in October 2010, Brooker signed an arbitration agreement on Elfrig's behalf.

A year later, while a resident at Regis Woods, Elfrig died as the result of complications from a fall. The administrator of her estate sued the nursing home and others in state court.

In response to the state suit, the nursing home and affiliates filed an action in federal district court to enforce the arbitration agreement. Relying on Ping v. Beverly Enters., Inc., 376 S.W.3d 581 (Ky. 2012), cert. denied, 133 S. Ct. 1996 (2013), the district court held Elfrig’s POA did not vest Brooker with the authority to enter into an arbitration agreement and the agreement was not enforceable against the Elfrig Estate. The nursing home appealed.

On appeal, the nursing home attempted to distinguish Ping, arguing that unlike in Ping, the POA here granted Brooker unlimited power to act on Elfrig's behalf. But the appeals court rejected this argument, finding it "ignores the fact that the Ping POA contained nearly identical language."

The appeals court also rejected plaintiff’s contention that the cases were distinguishable because of differences in the specific authorizations granted, finding instead that Ping is "a reflection of the Kentucky Supreme Court's cautious approach to POAs that do not expressly authorize the attorney-in-fact to make decisions that may have significant legal consequences for the principal, such as waiver of his or her constitutional right to trial."

"The remaining cases cited by the plaintiffs--cases distinguishing Ping--merely underscore how apposite Ping is to this case and how distinct Elfrig's POA is from POAs that do provide for general authority to contract," the appeals court commented.


Florida Appeals Court Says Former Nursing Home Resident Bound by Husband’s Signature on Arbitration Agreement

A Florida appeals court held July 24 that a nursing home resident was bound by general principles of contract and agency law to arbitrate her dispute with a nursing home after her husband signed her admission documents.

In so holding, the Florida District Court of Appeals reversed a lower court’s finding that the arbitration agreement was not binding on the former resident.
According to the nursing home’s admissions director’s testimony in the case, when approached with admissions documents the patient responded that she wanted her husband to handle them. The husband proceeded to sign the documents, which included the arbitration agreement, in the presence of both his wife and the admissions director.

Relying on Stalley v. Transitional Hosps. Corp. of Tampa, 44 So. 3d 627 (2010), the trial court found that the husband was not authorized to sign the arbitration agreement on these facts.

But the appeals court disagreed. In Stalley there was no apparent agency because the principal (the patient) never represented that the person who signed the arbitration agreement was authorized to do so, the appeals court said.

Here, the patient expressly told the nursing home's admissions director that she wanted her husband to handle the documents on her behalf, “a clear representation, at least by implication, that she authorized him to do so,” the appeals court explained.

Because the nursing home “relied on the principal's representation that her husband was authorized to sign the admission documents for her, and changed its position by accepting the husband's signature as binding,” the patient was bound by the husband's signature under ordinary principles of contract law and agency, the appeals court held.

The appeals court rejected the lower court’s finding that a principal's general representation that her agent is authorized to sign contracts or other documents relating to admission to a medical facility does not include an arbitration agreement because that contract is not "necessary" for admission.

Under general agency and contract principles, the appeals court said, the question is not whether the arbitration agreement was "necessary" for admission, but whether it was reasonable for the nursing home to view the patient's representation that her husband was authorized to handle all admissions documents as including the arbitration agreement.

Here, the nursing home’s reliance on such representations was reasonable, the appeals court held.


Mississippi High Court Finds Decedent Not Bound by Nursing Home Arbitration Agreement Signed by Wife

The Mississippi Supreme Court found August 13 that a former nursing home resident who was deceased was not bound by an arbitration provision contained in the nursing home’s admissions agreement because no valid arbitration agreement ever existed.

When Leo Brown was admitted to Hattiesburg Health & Rehab Center, LLC (HHRC) in February 2012, his wife, Emma, signed an admission agreement both in her individual capacity and on Leo's behalf. When Leo died soon after his discharge, Emma brought a wrongful death suit against the nursing home.

HHRC moved to compel arbitration, but the trial court found the admission agreement was not binding on Leo and that the arbitration agreement was unconscionable.

The Mississippi high court agreed with the trial court that Leo is not bound by the arbitration provision. Because that issue is dispositive, the court said it would not address the unconscionability of the agreement.
HHRC first argued that Leo was a third-party beneficiary of the agreement. But the court said HHRC failed to discuss—or even cite—two recent, unanimous opinions from the court, which held that residents in almost identical factual scenarios were not third-party beneficiaries for purposes of enforcing an arbitration provision. See Adams Community Care Center, LLC v. Reed, 37 So. 3d 1155 (Miss. 2010); GGNSC Batesville, LLC v. Johnson, 109 So. 3d 562 (Miss. 2013).

HHRC argued next that Emma executed the admission agreement on behalf of Leo as his health care surrogate, but the state high court rejected this argument as well finding "no evidence in the record that Leo's primary physician ever made any capacity determination."

Lastly, the court rejected HHRC’s argument that Leo is estopped from denying the terms of the admission agreement because he received services from HHRC and benefitted from the terms of the agreement.

Here, the court found “no evidence that Leo ‘knowingly’ did anything, much less knowingly ‘seek and obtain direct benefits’ from the admission agreement.”

Further, the court said Leo’s estate was not suing to enforce the terms of the admission agreement because his claims are not "directly dependent" on the agreement.


Kentucky Supreme Court Requires Express Authorization for Agent to Enter into Arbitration Agreement

A divided Kentucky Supreme Court held September 24 that an attorney-in-fact may not enter into an arbitration agreement on behalf of the principal without an explicit grant of authority to do so.

According to the high court majority, the fundamental right to a jury trial was not waived by “non-specific, general, even universal, grant of authority” pursuant to a power of attorney.

The consolidated action involved three separate personal injury/wrongful death actions against two nursing home operators—Extendicare Homes, Inc. and Kindred Nursing Centers.

In all three cases, an attorney-in-fact for the nursing home resident signed admissions documents that included an agreement to arbitrate any claims or disputes.

Defendant nursing homes moved to compel arbitration pursuant to those agreements. The lower courts denied the motions, citing the Kentucky Supreme Court’s decision in Ping v. Beverly Enters., 376 S.W.3d 581 (Ky. 2012).

The Kentucky Supreme Court majority affirmed, finding in two of the cases, the authority to enter into a pre-dispute arbitration agreement was not among the powers granted to the attorneys-in-fact; and in the third case, where the grant of authority was broad and arguable implicitly covered entering into arbitration agreements, that a principal only waives the fundamental right to a jury trial “through a clear and convincing manifestation” of the intent to do so.

At the outset, the high court confirmed its holding in Ping that wrongful death claimants are not bound by arbitration agreements entered into by the decedent, or his attorney-in-fact, because such an action is not derivative of the decedent’s claims.
As to the personal injury claims, the high court focused on the scope of authority set forth in the written power-of-attorney (POA) instruments and found none of them included an explicit grant of authority to waive the principal’s constitutional right to a trial by jury.

One POA came close in the sense that it provided the attorney-in-fact a “universal grant of authority” to “generally do and perform for me in my name all that I might if present.” The high court couldn’t rule out this language implicitly granted the attorney-in-fact the authority to bind a principal to arbitration.

The high court concluded, however, that nothing short of an express grant of authority could waive a fundamental constitutional right like a jury trial.

For example, the high court said it wouldn’t infer from such a general grant of authority the waiver of the “principal’s civil rights; or the principal’s right to worship freely; or enter into an agreement to terminate the principal’s parental rights . . . .”

“So too, it would be absurd to infer from a non-specific, universal grant, the principal’s assent to surrender of other fundamental, even sacred, liberties,” the high court observed.

The high court took pains to distinguish its ruling form Supreme Court precedent, see Marmet Health Care Center, Inc. v. Brown, 132 S.Ct. 1201 (2012), and AT&T Mobility LLC v. Concepcion, 563 U.S. 333 (2011), which struck down state laws that prohibited arbitration of a particular type of claim.

“Our rule does nothing that even approaches that kind of restraint on arbitration. We simply require, as we do with any contract, that the parties to be bound by the agreement validly assented,” the high court said.

One dissenting opinion argued that the majority’s decision contravened “controlling” Supreme Court precedent and prohibiting an agent acting under an unrestricted general “power to contract” from entering into an arbitration agreement was “at best seriously misguided.”

A second dissenter who wrote separately said the majority “crafts a rule requiring special treatment of the right to a jury trial that conversely treats the right to arbitrate as a lesser process when the United States Supreme Court has held that it is at least an equal process of dispute resolution.”


**Fourth Circuit Says Hospital Must Arbitrate Payment Dispute with Aetna**

A South Carolina hospital must arbitrate its reimbursement dispute with Aetna Health Management, LLC pursuant to its provider agreement, the Fourth Circuit ruled October 13 in an unpublished opinion.

Affirming the decision below, the appeals court found the broad arbitration clause applied to the hospital’s payment claim because it “relat[ed] to” the provider agreement, even if it required interpretation of specific plan terms governed by the Employee Retirement Income Security Act (ERISA).

Greenville Hospital System entered into an agreement with Aetna for patients covered by Aetna insurance plans. The agreement included a provision requiring binding arbitration of “[a]ny controversy or claim arising out of or relating to” the agreement.

Greenville provided treatment to a minor child covered under a health plan that Aetna underwrote.
After obtaining the patient’s assignment, Greenville submitted claims directly to Aetna for the care rendered. Aetna denied the claim, however, on the ground that Greenville failed to comply with the provider agreement’s “precertification” requirements.

Greenville unsuccessfully appealed the denial through Aetna’s internal grievance process and then sought the Fourth Circuit’s review. Aetna moved to compel arbitration. The district court granted the motion and dismissed the case.

Affirming, the Fourth Circuit noted at the outset the “particularly comprehensive” arbitration clause included in the agreement, as well as the presumption in favor of arbitration under the Federal Arbitration Act.

“All on its face, that agreement to arbitrate plainly extends to Greenville’s claims against Aetna,” the appeals court said.

Greenville argued its claims required reference to the precertification rules of the patient’s insurance plan, not just to the terms of the agreement.

“But it does not follow that a dispute over precertification does not ‘relate’ to the Agreement as well, given that it is the Agreement that obliges Greenville to adhere to precertification protocols at all,” the appeals court observed.

Greenville also contented that its case was a “right to payment dispute” arising under ERISA, which required determinations under the plan, rather than the type of claim that called only for interpretation of provider agreements.

The Fourth Circuit noted, however, that the arbitration clause wasn’t limited to claims that “arise” exclusively under the agreement; rather, the provision only required that the dispute “related to” Greenville’s commitment under the agreement to abide by Aetna’s precertification rules.


**Pennsylvania Supreme Court Finds Arbitration Agreement Unenforceable Because Essential Term Void**

Pennsylvania Supreme Court held October 27 that an arbitration agreement between a nursing home and a former resident was unenforceable because an essential term—requiring the use of the National Arbitration Forum (NAF) Code procedures—was void.

Decedent signed the arbitration agreement as part of the admissions process for the defendant’s nursing home. After she died, decedent’s daughter sued the nursing facility for alleged negligence she said contributed to her mother’s death.

Defendant moved to compel arbitration pursuant to the arbitration agreement, which specified that the arbitration be conducted pursuant to NAF rules.

The lower courts refused to compel arbitration because NAF no longer conducts consumer arbitrations pursuant to a consent judgment with the Minnesota Attorney General. The courts found the selection of the NAF Code was integral to the agreement to arbitrate and could not be severed.

On appeal, the defendant nursing facility contended that the NAF rules could be administered by any competent arbitrator, an argument that has met with some success in several other jurisdictions. See
Defendant also pointed out that the agreement included a severability clause and that Section 5 of the Federal Arbitration Act (FAA) should be invoked to appoint a replacement arbitrator.

But the state high court rejected these arguments, instead siding with the majority of jurisdictions in finding that the NAF’s participation was integral to the arbitration agreement, and therefore could not be salvaged by the severability clause.

The high court said it was irrelevant whether the decedent admitted the NAF provision had nothing to do with her decision to sign the agreement, which defendant argued showed the term wasn’t integral.

“[W]e recognize that premising the integrality of a contractual term on the subjective understanding of a far less sophisticated non-drafting party is ill-advised public policy that would further distort an already lopsided balance of power,” the high court said.

The high court also found that Section 5 of the FAA could not preserve the arbitration agreement “unless the parties made the NAF’s availability non-essential by specifically varying the terms of its procedure.”

A concurring opinion commented that “it is not the courts’ role to compensate for the negligence of an entity presenting a form contract in a consumer-oriented setting which this entity knew or should have known could not be enforced on its own terms.”

A dissenting judge disagreed, however, with the majority’s conclusion that the NAF provision was integral and therefore voided the entire arbitration agreement.

“While the NAF may be out of the business of accepting arbitrations, that Code is still extant, and it is the Code, not the NAF itself, that is incorporated into the agreement,” the dissent said.

A second dissenting opinion also argued the agreement “invoked a set of procedural rules,” but was “silent on the identity of the arbitrator” and therefore “courts should not utilize logical fallacies or rely on nonexistent contractual terms to throw the baby out with the bathwater.”

**U.S. Court in Texas Compels Arbitration Pursuant to Nursing Home Admission Agreement**

The U.S. District Court for the Southern District of Texas held November 3 the family of a deceased nursing home resident must arbitrate its dispute pursuant to a validly signed and enforceable arbitration agreement.

Santos Valadez fell out of his wheelchair while under the care of defendant Live Oak Nursing Center. He sustained personal injuries that led to his death.

His family sued Live Oak and Skilled Healthcare, LLC, asserting claims for wrongful death and survival damages. Defendants moved to compel arbitration.
Plaintiffs argued that Valadez’s daughter, Katy Carrigan, did not validly sign the arbitration agreement upon his admission to Live Oak because the signature line was left blank. Instead, Carrigan’s name appeared in script writing on the line designated for a printed name.

The court noted that Carrigan’s name appeared in a form identical to that used when signing other documents; therefore, it was “not the appearance of the name that Plaintiffs rely on to invalidate the arbitration agreement, but its location on the document.”

Under Texas law, “a signature appearing anywhere on the document may support a finding that the document was appropriately signed,” the court noted.

Plaintiffs next argued that, even if Carrigan signed the arbitration agreement, she did not have authority to do so as Valadez’s agent. The court agreed, finding defendants failed to supply any evidence of Valadez’s capacity to confer agency authority or any acts of him, as principal, conferring that authority on Carrigan.

But the court nevertheless found the estate bound to the agreement by direct benefits estoppel. The estate must take the unfavorable terms of the relationship with the favorable ones, the court commented. Carrigan’s allegations against defendants were based on the relationship between Valadez and defendants created by the agreement. “Thus Katy Carrigan may be bound by direct benefits estoppel because she affirmatively secured the agreement in exchange for the care of her father and because she sues on the relationship created by the agreement,” the court held.

The court also agreed with defendants that they may rely on equitable estoppel principles and the terms of the agreement to allow Skilled Healthcare to benefit from the arbitration agreement even though it was not a signatory.

The court found “no dispute” that Skilled Healthcare provided services at the request of Live Oak and that plaintiffs’ claims are stated against both defendants for the same conduct. “Under the terms of the arbitration agreement, Plaintiffs must arbitrate their complaints against Skilled Healthcare in the same proceeding as the arbitration against Live Oak,” the court held.


**Ohio Appeals Court Finds Provider Waived Right to Arbitration by Participating in Discovery**

The Ohio Court of Appeals refused December 10 to grant a rehabilitation hospital’s motion to compel arbitration pursuant to an arbitration clause in its admissions agreement, finding the provider waived its right to arbitration by participating in the litigation process.

Richard Fravel, as the personal representative of the estate of Jack Fravel (decedent), sued defendant Columbus Rehabilitation and Subacute Institute alleging that inadequate care caused decedent to develop a pressure ulcer that became infected and resulted in his death.

Defendant pled the affirmative defense that some of plaintiff’s claims were subject to an arbitration agreement that Jack Fravel’s spouse executed at the time of admission. Defendant also submitted written discovery and requested depositions.

The trial court denied defendant’s motion to compel arbitration, finding it waived the right to demand arbitration.
Defendant argued on appeal that the circumstances of the case did not permit a finding of waiver. While acknowledging that it submitted requests for discovery, defendant argued that its timely answer to the complaint raised the affirmative defense that issues in dispute were subject to an arbitration agreement.

"Waiver attaches where there is active participation in a lawsuit evincing an acquiescence to proceeding in a judicial forum," the appeals court noted. Here, defendant did not promptly move for a stay and instead actively used the court proceedings to obtain discovery.

“Moreover,” the appeals court held, “enforcement of the arbitration agreement would engender proceedings in two separate forums, as appellants concede that only decedent's claims which survive him are subject to arbitration.”

The wrongful death claims of the statutory beneficiaries would not be subject to arbitration because each of them did not sign the agreement, the appeals court said.

“On account of the litigation activities of appellants, their delay in seeking an arbitration stay and the potential prejudice via piecemeal litigation to appellee, the trial court acted within its sound discretion to find waiver and deny appellants' motion for stay,” the appeals court concluded.

The court also affirmed the lower court’s order granting plaintiff’s motion to compel production of defendant’s patient-care policies.


**U.S. Supreme Court Passes on Reviewing Decision Finding FAA Preemption of Texas Arbitration Requirements**  

The U.S. Supreme Court denied review January 11 of a Texas Supreme Court decision holding a provision of the Texas Medical Liabilities Act (TMLA) requiring an agreement to arbitrate health care liability claims include a conspicuous, written notice was not exempt from Federal Arbitration Act (FAA) preemption as a law regulating the business of insurance. See _The Fredericksburg Care Co. v. Perez_, No. 13-0573 (Tex. Mar. 6, 2015).

The state high court ruled the courts below should have granted a nursing home’s motion to compel arbitration of a negligence/wrongful death action filed by the family of a former resident who signed an admission agreement that included an arbitration clause.

The Texas high court held a provision of the state’s comprehensive tort reform legislation was not exempt under the McCarran-Ferguson Act (MFA) from federal preemption.

_Perez v. The Fredericksburg Care Co., No. 15-365 (U.S. Jan. 11, 2016)._  

**Sixth Circuit Refuses to Compel Arbitration of Wrongful Death Claim, Finds No FAA Preemption**  

The Sixth Circuit affirmed a decision refusing to compel arbitration claim of a wrongful death claim against a nursing home.

The appeals court agreed the case was governed by the Kentucky Supreme Court’s decision in _Ping v. Beverly Enters., Inc._ 376 S.W.3d 581 (Ky. 2012), which found wrongful death claimants are not
bound by arbitration agreements that a decedent entered into because their claim is statutorily distinct from any claim held by the decedent.

In so holding, the Sixth Circuit rejected the nursing home’s argument that the Federal Arbitration Act (FAA) preempted Ping. Instead, the appeals court found Ping survived under the U.S. Supreme Court’s analysis in AT&T Mobility LLC v. Concepcion, 563 U.S. 333 (2011), because it didn’t categorically prohibit arbitration of wrongful death claims or disfavor arbitration agreements.

Arbitration Dispute

On his admission to Kenwood Nursing & Rehabilitation Center, Charlie Nichols signed an agreement that required arbitration of “any and all disputes,” including wrongful death claims.

Nichols later sued the nursing facility, which now is operated by Richmond Health Facilities, in Kentucky state court for negligence.

After Nichols passed away, the administratrix of his estate added a wrongful death claim against the nursing facility, which then turned to federal court for an order compelling arbitration pursuant to the agreement that Nichols signed.

The district court granted the motion to compel arbitration with the exception of the wrongful death claim, and stayed proceedings on that cause of action until arbitration of the other claims was complete.

Ping Controls

Affirming the district court decision, the Sixth Circuit noted that the FAA doesn’t alter basic principles of state contract law, meaning the Kentucky Supreme Court’s decision in Ping applied.

Under Ping, which the state high court reaffirmed twice, a wrongful death claim wasn’t derivative of any claim that Nichols had so he could not agree to arbitrate such a cause of action—even though the agreement purported to extend to wrongful death claims.

The appeals court also rejected the nursing facility’s argument that wrongful death claimants are third-party beneficiaries of the arbitration agreement.

“Mr. Nichols’ purported agreement to do something he was not authorized to do is not legally enforceable,” the appeals court said.

No FAA Preemption

The nursing facility also argued that the FAA preempted Ping under the Supreme Court’s decision in Concepcion.

According to the appeals court, Ping did not categorically prohibit arbitration but rather concluded only that wrongful death beneficiaries aren’t bound by agreements that are executed by a decedent.

In other words, Ping doesn’t preclude wrongful death claimants from arbitrating claims if they choose to do so.

The appeals court distinguished Ping from the state rule at issue in Marmet Health Care Center, Inc. v. Brown, 132 S.Ct. 1201 (2012), which the Supreme Court found categorically prohibited pre-dispute arbitration clauses in nursing home admissions agreements.
Unlike in *Marmet*, where the family members signed the arbitration agreement, in this case, only Nichols signed, the appeals court said. In the Sixth Circuit’s view, this was a critical distinction because the wrongful death beneficiaries here were never parties to the agreement.

The appeals court also held that *Ping* did not have a “disproportionate impact” on arbitration agreements, noting no evidence that Kentucky courts have enforced other types of contracts against wrongful death beneficiaries without them being a party to the agreement.

“[F]ederal law does not force arbitration upon a party that never agreed to arbitrate in the first place under the guise of preemption principles,” the appeals court wrote.


**Supreme Court Denies Review of Pennsylvania Case Refusing to Enforce Arbitration Agreement**

The U.S. Supreme Court denied review February 29 of a Pennsylvania Supreme Court decision that an arbitration agreement between a nursing home and a former resident was unenforceable because an essential term—requiring the use of the National Arbitration Forum (NAF) Code procedures—was void.

Decedent in the case signed the arbitration agreement as part of the admissions process for the defendant’s nursing home. After she died, decedent’s daughter sued the nursing facility for alleged negligence she said contributed to her mother’s death.

The lower courts refused to compel arbitration because NAF no longer conducts consumer arbitrations pursuant to a consent judgment with the Minnesota Attorney General. The courts found the selection of the NAF Code was integral to the agreement to arbitrate and could not be severed.

On appeal, the defendant nursing facility contended that the NAF rules could be administered by any competent arbitrator, an argument that has met with some success in several other jurisdictions. *See Meskill v. GGNSC Stillwater Greely LLC*, No. 12-851 (RH/JJG) (D. Minn. May 25, 2012); *Wright v. GGNSC Holdings LLC*, 2011 S.D. 95 (S.D. Dec. 28, 2011); *Jones v. GGNSC Pierre LLC*, No. 09-3011-RAL (D.S.D. Feb. 3, 2010).

But the state high court rejected these arguments, instead siding with the majority of jurisdictions in finding that the NAF’s participation was integral to the arbitration agreement, and therefore could not be salvaged by the severability clause. *Wert v. ManorCare of Carlisle PA, LLC*, No. 62 MAP 2014 (Pa. Oct. 27, 2015).


**Arkansas Supreme Court Requires Arbitration Even Though Arbitral Forum Not Available**

The Arkansas Supreme Court reversed February 18 a lower court decision refusing to compel arbitration of a negligence action against a nursing home. The high court held performance of the arbitration agreement was not impossible even though the arbitral forum named in the agreement was no longer available to perform the arbitration.

According to the high court, the agreement did not mandate arbitration before the National Arbitration Forum (NAF), which no longer conducts pre-dispute consumer arbitrations pursuant to a
consent judgment to resolve litigation with the Minnesota Attorney General, but rather only specified the use of the NAF’s rules, which another arbitrator could still apply.

The high court also found the NAF was not “integral” to the arbitration agreement and a substitute arbitrator could be appointed pursuant to the Federal Arbitration Act (FAA), 9 U.S.C. § 5.

Jessie James Bullock and his wife Annie Bullock both resided at Courtyard Gardens Health and Rehabilitation LLC. At the time of their respective admissions, the Bullocks’ daughter signed on their behalf optional arbitration agreements with Courtyard Gardens.

After Jessie Bullock died, plaintiff, as the personal representative of his estate and as Annie Bollock’s personal representative, sued Courtyard Gardens for negligence, medical malpractice, and various statutory violations.

Courtyard Gardens moved to compel arbitration, which the trial court refused to do, agreeing with plaintiff that the arbitration agreement was impossible to perform, and therefore unenforceable, because the agreement specified as the arbitrator NAF, which was no longer available to conduct consumer arbitrations.

The high court reversed, finding NAF’s unavailability did not render the agreement unenforceable.

In the high court’s view, the NAF was an “ancillary,” not integral, term and therefore Section 5 of the FAA applied and provided a procedure for appointing a substitute arbitrator.

The agreement specifically required “binding arbitration,” but did not similarly mandate that claims be arbitrated with the NAF, the high court noted.

“A review of the arbitration agreement demonstrates that the integral term of the arbitration agreement is ‘arbitration,’ not the ‘NAF’ as an arbitrator,” the high court said.

Moreover, the agreement required only the use of the NAF’s Code of Procedure, not that the NAF itself conduct the arbitration.

The agreement also included a severability clause, “which further evidences the parties intent to arbitrate even if a portion of the arbitration agreement is unenforceable.”

A dissenting judge argued that the NAF Code specifies that it be administered only by the NAF, and that this term was integral to the agreement, meaning Section 5 did not apply.


Fifth Circuit Rejects Formal-Device Requirement in Nursing Home Arbitration Disputes

The Fifth Circuit held two federal district court judges misinterpreted Mississippi law in requiring a formal legal device to show actual agency for purposes of binding nonsignatories to arbitration agreements in nursing home admissions documents.

The appeals court vacated the two lower court decisions refusing to compel arbitration of wrongful death and negligence actions against the defendant nursing homes.
In the appeals court’s view, the Mississippi Supreme Court would not adopt a “formal-device requirement” and instead would permit the parties to establish the existence of an agency relationship with other types of evidence.

The appeals court remanded both cases for the factfinder to determine whether an actual agency relationship existed.

**Wrongful Death/Negligence Lawsuits**

In the first case, Sammy Gross brought an action in state court on behalf of the estate of his mother Pauline Tillman Wagner against Golden Living Southaven, which ran the nursing home where Wagner formerly resided.

Similarly, Shirley Cotton brought an action on behalf of the estate of her mother Ida Roberson against Golden Living Center Batesville.

The two nursing homes removed the actions to federal court and moved to compel arbitration on the basis of arbitration agreements that Gross and Cotton signed for their mothers as part of the nursing home admissions process.

In both cases, different judges in the Northern District of Mississippi refused to compel arbitration, finding Gross and Cotton lacked actual agency, under their interpretation of Mississippi law, to bind their mothers to the arbitration agreements in the absence of a formal legal device.

**State Agency Law**

The Fifth Circuit disagreed with the lower courts’ assessment of Mississippi contract law as requiring a formal legal device for actual agency authority.

“In addition to lacking a basis in general Mississippi agency law, a formal device requirement also stands in tension with the Federal Arbitration Act,” the appeals court said.

“It is hard to see how the district court’s categorical rule that nonsignatories can be bound by nursing-home arbitration agreements only if the signatory possessed a durable power of attorney or other ‘formal legal device’ would not, in practice disproportionately impact arbitration agreements,” the appeals court observed.

Mississippi case law that the lower court decisions interpreted didn’t compel a different result, the appeals court said. The cases showed only that there has to be some proof of agency, not that a formal legal device is required.

The appeals court remanded both cases to determine whether actual agency was established by other evidence.

**Apparent Agency, Ratification**

The appeals court affirmed the decision below that the nursing homes lost on their estoppel argument.

As to the estoppel argument, Gross and Cotton brought the actions on behalf of their mothers’ estates, not in their individual capacities. Neither nursing home explained why Wagner and Roberson should be estopped from denying the enforceability of the agreements, the appeals court said.
Batesville argued that the arbitration agreement was enforceable as to Roberson because Cotton had apparent agency. But the appeals court agreed with the district court that the nursing home relied entirely on Cotton’s conduct, not Roberson’s as the principal, in making this argument. Batesville also didn’t show detrimental reliance.

Finally, for purposes of its ratification argument, Batesville failed to show that Roberson knew the admissions documents that Cotton signed in Roberson’s presence included an arbitration agreement.


**Supreme Court Declines to Weigh in on Nursing Home Arbitration Dispute**

The U.S. Supreme Court denied review April 25 of a federal appeals court decision refusing to require arbitration of a wrongful death suit against a nursing home after finding an essential part of the agreement involving the National Arbitration Forum (NAF) code was no longer in force. *Beverly Enters. Inc. v. Cyr*, No. 15-821 (U.S. cert denied Apr. 25, 2016).


The arbitration agreement at issue provided that all disputes would be resolved in accordance with the NAF Code of Procedure. In the event of its cancellation, the code provides that “any Party may seek legal and other remedies.”

The Eleventh Circuit found the code was effectively cancelled because NAF no longer conducts consumer arbitrations pursuant to a 2009 consent judgment with the Minnesota Attorney General.

According to the appeals court, the selection of the code was integral to the agreement to arbitrate and could not be severed.

The issue has come up before at the Supreme Court. In February, the Court declined to review a Pennsylvania Supreme Court decision that found a nursing home arbitration agreement was unenforceable because an essential term—also requiring the use of the NAF code—was void.

The defendant nursing facility contended that the NAF rules could be administered by any competent arbitrator, an argument that has met with some success in several other jurisdictions. See *Meskill v. GGNSC Stillwater Greely LLC*, No. 12-851 (RHK/JJG) (D. Minn. May 25, 2012); *Wright v. GGNSC Holdings LLC*, 2011 S.D. 95 (S.D. Dec. 28, 2011); *Jones v. GGNSC Pierre LLC*, No. 09-3011-RAL (D.S.D. Feb. 3, 2010).

But the Pennsylvania high court rejected these arguments, instead finding that the NAF’s participation was integral to the arbitration agreement, and could not be salvaged by the severability clause. *Wert v. ManorCare of Carlisle PA, LLC*, No. 62 MAP 2014 (Pa. Oct. 27, 2015).

In another recent decision, the Arkansas Supreme Court held that performance of an arbitration agreement was not impossible even though the arbitral forum named in the agreement—the NAF—was no longer available to perform the arbitration.

According to the Arkansas high court, the agreement did not mandate arbitration before the NAF, but rather only specified the use of its rules, which another arbitrator could still apply. The high court
also found the NAF was not “integral” to the arbitration agreement and a substitute arbitrator could be appointed pursuant to the Federal Arbitration Act, 9 U.S.C. § 5. Courtyard Gardens Health and Rehabilitation, LLC v. Arnold, No. CV-14-1105 (Ark. Feb. 18, 2016).
Fraud and Compliance

U.S. Supreme Court Won’t Review Decision Reviving Whistleblower Suit Against Purdue Pharma

The U.S. Supreme Court declined June 1 to review a Fourth Circuit decision that vacated the dismissal of a qui tam action against Purdue Pharma LP and Purdue Pharma, Inc. as barred by res judicata.

The appeals court found its previous dismissal of a prior suit concerning the same conduct that was brought by the husband of one of the relators in the instant action did not have preclusive effect. The prior decision was based on the husband’s execution of a release waiving his right to sue. The release did not apply to the relators in the instant action, the appeals court said. United States ex rel. May v. Purdue Pharma L.P., No. 12-2287 (4th Cir. Dec. 12, 2013).

Steven May and Angela Radcliffe initiated the whistleblower suit against defendant Purdue Pharma, alleging the company marketed its controlled-release pain relief drug OxyContin to physicians as more potent than a cheaper alternative.

The instant action followed another civil action, initiated in 2005 and ultimately dismissed with prejudice, which was asserted by Mark Radcliffe, relator Angela Radcliffe’s husband. Mark Radcliffe was a former Purdue drug representative and district manager. The allegations in Mark Radcliff’s qui tam action were nearly identical to those in the instant whistleblower suit. The Fourth Circuit ultimately found, however, a release Mark executed after leaving the company prevented him from suing Purdue Pharma.

The district court agreed with Purdue Pharma that the instant action was barred by res judicata, giving preclusive effect to the Fourth Circuit’s decision dismissing Mark Radcliff’s qui tam action. United States ex rel. May v. Purdue Pharma L.P., No. 5:10-cv-01423 (S.D.W.V. Sept. 14, 2012).

On appeal, the Fourth Circuit found the district court erred by giving the decision preclusive effect. The release applied only to Mark Radcliff and “did not prohibit the government or another relator from pursuing similar claims against Purdue,” a point the Fourth Circuit actually articulated in the Radcliff decision.

Purdue Pharma also argued the action was barred by the FCA’s public disclosure provision, but the Fourth Circuit declined to resolve the issue on appeal, since the district court had not addressed it.


U.S. Supreme Court Lets Stand Decision Allowing FCA Claims Against HMA

The U.S. Supreme Court declined June 1 to review an Eleventh Circuit decision partially reversing the dismissal of a qui tam action alleging a health system and one of its subsidiaries violated the False Claims Act (FCA) by submitting claims to Medicare and Medicaid for patients whose referrals violated the Anti-Kickback Statute and Stark Law.

The appeals court found the whistleblower provided “indicia of reliability” to survive dismissal under Fed. R. Civ. P. 9(b) because of the alleged insider knowledge he gained during his time as a Vice President at the system, and later as Chief Executive Officer (CEO) of one of its hospitals. United States ex rel. Mastej v. Health Management Assocs., Inc., No. 13-11859 (11th Cir. Oct. 30, 2014).
The Eleventh Circuit also ruled, however, that his FCA claims for the time period after he left defendants' employment were properly dismissed because the “indicia of reliability” that existed in this particular case “disappeared” at that point.

Defendant Health Management Associates, Inc. (HMA) operates approximately 56 hospitals in 15 states. HMA’s subsidiary, defendant Naples HMA, LLC, does business as Physicians Regional Medical Center, which operates two campuses—Collier Boulevard (Collier) and Pine Ridge (Pine Ridge).

From 2001 to February 2007, relator Michael Mastej served as a Vice President of HMA and then, from February 2007 to October 2007, he served as Collier’s CEO.

Mastej’s complaint described two financial relationships defendants had with ten physicians that he alleged violated the Stark Law and the Anti-Kickback Statute and resulted in the submission of false claims to federal health care programs.

A federal district court in Florida agreed to dismiss the complaint in its entirety under Rule 9(b). According to the trial court, relator’s complaint failed to allege the actual submission of a false claim stemming from any patient referred by one of the ten doctors. United States ex rel. Mastej v. Health Mgmt. Assoc., No. 2:11-cv-89-FtM-29DNF (M.D. Fla. Mar. 19, 2013).

The appeals court acknowledged that relator’s complaint did not provide any details about the patients the ten physicians allegedly referred to defendants or any claims that were submitted or payments that were made for the referred patients.

But citing the personal knowledge gained in his management roles at HMA, the appeals court held relator offered sufficient other “indicia of reliability” to avoid dismissal.


U.S. Court in Virginia Dismisses FCA Action Against Mental Health Provider Alleging Medicaid Fraud

A federal court in Virginia granted May 21 a motion to dismiss a False Claims Act (FCA) qui tam action alleging that Agape Counseling and Therapeutic Services (Agape) billed the government for mental health services that were not eligible for Medicaid reimbursement because they weren’t performed by licensed and qualified personnel.

The U.S. District Court for the Eastern District of Virginia found the complaint failed to meet the Fed. R. Civ. P. 9(b) specificity threshold because relator did not allege the presentment of an actual false claim to the government for payment.

Relator Lisa Phipps worked as Agape’s Director of Community Mental Health Services. Relator alleged that she found files containing assessments signed by individuals who did not actually complete them and was asked to alter records to make it appear assessments were performed by qualified personnel.

Phipps’ complaint against Agape, its owner, and certain staff members alleged the submission of false claims to the Virginia Medicaid program, reverse false claims, and conspiracy to submit false claims. The United States and the Commonwealth of Virginia declined to intervene.

The court found that the complaint failed to allege any claims were actually submitted to the government for payment. Under the Fourth Circuit decision in Nathan v. Takeda Pharm. North
American, Inc., an FCA plaintiff cannot “merely describe a private scheme in detail but then allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the government.”

Instead, Rule 9(b) requires “some indicia of reliability” to support relator’s allegation that a false claim was actually presented to the government, the court said.

Although relator provided lists of cases that allegedly were completed by individuals other than the persons she knew completed them and descriptions of Agape staff editing client case files, the court found these allegations did not suffice to satisfy the Rule 9(b) heightened pleading standard.

The court also found the complaint did not state a retaliation claim because relator failed to show Agape had notice of her actions or that those actions had the reasonable possibility of leading to litigation.


U.S. Court in Illinois Refuses to Dismiss Whistleblower Action Alleging Fraudulent Inducement of Radiopharmaceuticals Contract

A federal court in Illinois found May 15 that a whistleblower action under the False Claims Act (FCA) alleging several contracts with a public health system for radiopharmaceuticals were fraudulently induced, thereby tainting subsequent invoices for payments, survived a motion to dismiss.

The court held relator Matthew Blaum adequately pled a vertical bid-rigging conspiracy among the defendants to procure the contracts by fraud, triggering potential liability under the FCA given that the health system treated Medicare and Medicaid patients and received public funds from Cook County, IL.

The court did reject, however, antitrust claims brought against the defendants, finding a failure to plead an injury to competition beyond the contracts at issue.

Relator brought the qui tam action, in which the federal government and state of Illinois declined to intervene, against Covidien, Inc. its acquirer Triad Istopes, Sami Distributors, and two individuals, alleging they fraudulently procured contracts in 2008, 2010, and 2011 for supplying radiopharmaceutical drugs to Cook County Health and Hospitals System (CCHHS).

According to relator, who formerly worked for Covidien, defendant Dr. Trepashko, a nuclear radiologist for CCHHS, provided insider information to defendant Mr. Giba, a sales representative for Covidien, so his company could secure the contracts.

As part of the alleged scheme, Covidien used Sami Distributors—a Minority- or Women-Owned Business Entity, to submit the company’s bid even though Sami would provide no actually services under the contract. Cook County had a goal of awarding 35% of its contracts to minority-owned businesses and using Sami, which misrepresented that it would be performing the services under the contract, to submit Covidien’s bid made it more likely the company would be awarded the contract.

CCHHS awarded contracts to Sami in 2008 and 2010 and, in 2011, to Triad, which had acquired Covidien by that time.
Relator left Covidien in 2010 and joined competing radiopharmaceutical provider Hot Shots NM, LLC, which lost the bid for the CCHHS contract in 2011. As part of the action, Hot Shots asserted antitrust and tortious interference claims against defendants regarding the 2011 contract award, which the court dismissed.

The court rejected defendants’ motion to dismiss the FCA claims, however, finding relator adequately pled a fraudulent inducement theory of liability regarding the 2008, 2010, and 2011 contract awards.

Relator did not allege any of the companies’ actual invoices to CCHHS were fraudulent, but that they were tainted by the underlying fraudulent inducement. “This is sufficient to state an FCA claim,” the court said.

The court also found the fact CCHHS received about 39% of its revenue from Medicare and Medicaid, as well as considerable funding from Cook County, was sufficient to show at least some of CCHHS’ radiopharmaceutical expenditures were reimbursed by the government.

In addition, the court rejected defendants’ argument that the complaint failed to meet the Fed. R. Civ. P. 9(b) pleading standard, noting relator adequately spelled out the “who, what, when, where, and how” of the alleged bid-rigging scheme.


U.S. Court in Pennsylvania Says Maker of Cancer Drug Must Face FCA Claims Alleging Off-Label Promotion

The U.S. District Court for the Eastern District of Pennsylvania refused June 3 to dismiss a whistleblower action under the False Claims Act (FCA) against Cephalon, Inc. alleging it marketed its chemotherapy drug Treanda for off-label uses and paid illegal kickbacks to physicians to further the scheme.

Applying the Third Circuit’s more lenient pleading standard, see Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153 (2014), the court found relator Matthew Cestra, a former Cephalon employee, satisfied Fed. R. Civ. P. 9(b) by alleging with particularity the “who, what, when where and how” of the alleged scheme and “reliable indicia that permit a strong inference false claims were actually submitted as a result of Cephalon’s off-label promotion efforts.”

Front-Line Treatment

Cestra alleged Cephalon promoted Treanda as a front-line treatment for indolent non-Hodgkins lymphoma even though the Food and Drug Administration approved the drug only as a second-line treatment when other regimens already had failed.

According to relator, Cephalon carried out the off-label marketing through sales force presentations and meetings, continuing medical education (CME) programs, speaker programs, advisory boards, market studies, and false and misleading minimization of Treanda’s safety risks.

Relator also alleged Cephalon used illegal kickbacks—including payments to CME providers, speaker fees, financial inducements to group purchasing organizations, payments of honoraria and travel expenses, free reimbursement of services through its Core Oncology Reimbursement program, and payments to drug compendia to conduct clinical studies—to induce the prescription of Treanda off-label.
In addition, relator asserted Cephalon violated a 2008 corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General, resulting in reverse false claims; conspired with health care professionals to violate the FCA; and retaliated against him after he reported his concerns to the company's compliance department.

Cephalon moved to dismiss the second amended complaint.

**Fraud Sufficiently Detailed**

The court refused to dismiss the complaint under Rule 9(b), finding relator adequately alleged the particular details of the off-label promotion scheme and provided “reliable indicia” to permit a strong inference false claims were submitted to the government.

In the court’s view, relator supplied reliable indicia by alleging Cephalon’s off-label promotion actually increased sales of Treanda and yielded a substantial return on investment, and that the company worked to ensure the government would reimburse off-label prescriptions through a program geared at supporting physicians in submitting their claims.

**Kickback Claims Survive**

The court also held relator’s allegations that Cephalon paid kickbacks to physicians to induce off-label prescriptions survived the motion to dismiss.

Relator alleged with particularity how Cephalon’s kickbacks increased off-label sales of Treanda, the court noted, pointing to the same evidence in the complaint—i.e., the increase in sales and the company’s efforts to ensure government reimbursement—to establish the necessary causal link.

**Drug Compendia**

Cephalon also argued that the off-label claims failed because Treanda is reimbursable by federal health care programs as a front-line treatment for insolent non-Hodgkins lymphoma as supported in several drug compendia used by Medicare and Medicaid to set reimbursement.

The court declined to decide this issue on a motion to dismiss, noting the complexity of reviewing drug compendia evidence.

The court also cited case law implying that alleging an off-label use of a drug was "medically risky" could support a claim that the off-label use was not medically necessary and therefore not reimbursable regardless of the drug compendia.

Finally, the court noted the possibility that the drug compendia were tainted by the allegedly false or misleading information the company promoted. For example, “[r]elator alleges that Cephalon took illegal measures to ensure that the off-label use of Treanda gained support in the drug compendia.”

**Remaining Claims**

The court dismissed, with leave to amend, relator’s allegations of reverse false claims, finding he failed to “identify a financial obligation or how such an obligation is connected to alleged false CIA reports” in the second amended complaint.

The court also dismissed, with leave to amend, relator’s conspiracy claim for failing to reference any formal agreements between Cephalon and various physicians to defraud the government.
Finally, the court held relator sufficiently stated a claim for retaliation at this stage of the litigation, citing his allegations that he was shut out of meetings he previously attended and was passed over for a promotion after reporting his concerns to the compliance department.


**U.S. Court in Georgia Nixes Stark Law Claim Against Radiation Oncologist, But Allows Kickback Claim in FCA Action**

On June 3, a federal court in Georgia granted summary judgment to radiation oncologist Dr. Thomas Tidwell in a False Claims Act (FCA) whistleblower action on a claim that he violated the Stark Law by referring patients to a hospital that he had a financial relationship with after it purchased his radiation oncology clinic.

The U.S. District Court for the Middle District of Georgia found sufficient evidence that the services he provided met the “consultation exception” to the Stark Law.

The court refused, however, to resolve on summary judgment the relator’s claims that Tidwell violated the Anti-Kickback Statute (AKS) and submitted false claims to the government for reimbursement, citing disputed facts as to whether he knew the equipment used to perform the services at issue failed to meet the standard of care and whether the sale of the treatment center to the hospital was above fair market value.

Tidwell owned the Tidwell Cancer Treatment Center (Center), a freestanding radiation oncology clinic in Columbus, GA. In 2002, the Center purchased “DynART” radiation equipment. According to Tidwell, at the time of the purchase, he was told the technology satisfied requirements for Medicare billing of intensity modulated radiation therapy (IMRT).

External auditors reviewed the Center’s billing practices in 2006, 2008, 2010, and 2011 and raised no concerns regarding the IMRT billing. In 2010, however, another company evaluated the Center and found its equipment was not "competitive with current standard-of-care models" and needed replacement.

That same year, Columbus Regional Healthcare System (Columbus Regional) purchased the Center for $10.5 million. After the purchase, Tidwell continued to work at the Center.

Relator Richard Barker alleged that Tidwell billed Medicare and Medicaid for treatments using technology that did not satisfy reimbursement requirements. He also alleged Columbus Regional paid more than fair market value for the Center in exchange for patient referrals. Specifically, relator alleged Tidwell submitted false claims to Medicare and Medicaid for IMRT and violated the Stark Law and AKS.

The U.S. District Court for the Middle District of Georgia granted Tidwell summary judgment on the claimed Stark violation, finding relator failed to contradict evidence that the services at issue involved a permitted "consultation" rather than a prohibited "referral" under the Stark Law.

The consultation exception provides that "radiation therapy . . . furnished by (or under the supervision of) . . . radiation oncologist pursuant to a consultation requested by another physician" is not a "referral" by a "referring physician."

Here, Tidwell submitted evidence that, after Columbus Regional purchased the Center, he saw patients there "in consultation at the request of and referral from other physicians," the court noted.
Tidwell provided evidence detailing the Center's consultation practices, which Barker failed to refute, the court said.

With no evidence to the contrary, the court found no legal basis to support a Stark violation.

The same was not true, however, for the false billing and AKS claims. The court noted a genuine factual dispute for a jury to resolve as to whether Tidwell knew the DynART system satisfied the requirements for billing IMRT under Medicare. Likewise, the court pointed to conflicting evidence about whether Columbus Regional paid fair market value for the Center.


**U.S. Court in Florida Dismisses FCA Retaliation Action Against Health System**

A federal court in Florida granted May 29 a motion to dismiss a False Claims Act (FCA) qui tam action alleging that a health system retaliated against the plaintiff due to her knowledge of hospital false billings and her attempts to prevent the hospital from submitting false claims to the Centers for Medicare & Medicaid Services (CMS).

The U.S. District Court for the Middle District of Florida found the amended complaint failed to demonstrate that the plaintiff was engaged in protected conduct, a requirement to state an FCA retaliation claim.

Plaintiff Brenda Farnsworth worked for Northside Hospital as Vice President of Quality and Risk Management. HCA is the parent corporation of Northside Hospital and directs policies and procedures followed by staff at Northside Hospital.

Farnsworth alleged defendants fraudulently billed Medicare and Medicaid for treatments performed by medical interns in the absence of attending physicians; falsified billing documentation; “double billed” for unauthorized medical research; and engaged in deliberate understaffing to increase profits.

To state an FCA retaliation claim, a plaintiff must show she was acting in the furtherance of an FCA enforcement action or engaged in other efforts to stop violations of the FCA. Under 2009 amendments to the FCA, protected activity now includes not only actions in furtherance of a potential or actual whistleblower lawsuit but also steps to remedy fraud through alternative means like internal reporting to a supervisor or compliance department.

The court found, however, that plaintiff failed to demonstrate she engaged in protected activity, even under the broader standard. While plaintiff generally alleged she voiced concerns regarding defendants’ practices, the complaint failed to detail any specific actions she took to prevent or stop the alleged illegal activity.

The court granted defendants’ motion to dismiss without prejudice, noting the second amended complaint should focus on instances where plaintiff reported billing violations (and not a compliance issue as part of her job) to her superiors.

Fifth Circuit Affirms Health Care Fraud Convictions

The Fifth Circuit affirmed June 5 the health care fraud convictions of two defendants in connection with a home health care fraud scheme. The appeals court found sufficient evidence to support their convictions for conspiracy to commit health care fraud and conspiracy to pay illegal kickbacks.

Defendant Louis Age owned and operated South Louisiana Home Health Care, Inc. Defendant Verna Age served as the Director of Nursing for the company.

According to evidence produced during their trial, defendants paid kickbacks to patient recruiters to obtain Medicare beneficiary information and to medical doctors to sign fraudulent referrals.

They also falsified documents to make it appear the beneficiaries qualified for home health services, and used false documents and beneficiary information to receive over $17.1 million in Medicare reimbursements.

The court sentenced Louis to 120 months of imprisonment on one count and to a consecutive 60-month sentence on another, for a total of 180 months, to be followed by three years of supervised release.

Verna was sentenced to concurrent prison terms of 60 months on each count, to be followed by two years of supervised release.

The court held them jointly and severally liable for $17.1 million in restitution and imposed a forfeiture money judgment on both defendants totaling more than $9.2 million.

Verna’s argued, among other things, that the loss amount attributed to her by the district court was error because it didn't take into account any legitimate services that may have been rendered.

The appeals court found, however, that Verna failed to present any evidence of legitimate services.

"[W]here the government has shown that the fraud was so extensive and pervasive that separating legitimate benefits from fraudulent ones is not reasonably practicable, the burden shifts to the defendant to make a showing that particular amounts are legitimate," the appeals court held. See United States v. Hebron, 684 F.3d 554, 563 (5th Cir. 2012).

The court also rejected Louis’ argument regarding questions the prosecutor asked that allegedly suggested he was responsible for a death in connection with the case.

The appeals court found no prejudicial error. "[T]he overwhelming evidence of Louis’s guilt demonstrates that he suffered no prejudice from the limited questioning . . . ," the appeals court said.

The appeals court then dispatched the defendants’ other challenges as having no merit.


U.S. Court in Missouri Dismisses Whistleblower Action Against Anesthesiology Practice, Citing Regulatory Ambiguity

The U.S. District Court for the Western District of Missouri held June 9 that Medicare regulations governing the reimbursement of anesthesiology services were ambiguous and a group practice’s reasonable interpretation belied the scienter needed to establish a violation of the False Claims Act (FCA).
The court dismissed a qui tam action alleging Anesthesia Associates of Kansas City (AAKC) submitted false claims to Medicare and Medicaid because the group’s anesthesiologists failed to personally participate in a patient’s “emergence” from anesthesia in the operating room.

AAKC practices the “Medical Direction” model in which Medicare reimburses for anesthesiology services at the second-highest rate when an anesthesiologist is directing a certified registered nurse anesthetist (CRNA) in two to four cases concurrently, and all conditions of the “Seven Steps” regulation, as set forth in 42 C.F.R. §§ 414.46(d) and 415.110(a)(1), are satisfied.

The third step of the Seven Steps regulation— at issue in the instant action— requires that the anesthesiologist “personally participate[] in the most demanding aspects of the anesthesia plan including . . . induction and emergence.” (Emphasis added).

The term "emergence" is not defined by the regulations, the Centers for Medicare & Medicaid Services, a National Coverage Determination, or AAKC’s regional carrier. The American Society of Anesthesiologists (ASA) also provides no definition, and national and state anesthesiology organizations do not define the term because “emergence is a process, and each patient is different.”

AAKC defined emergence to include the patient’s recovery in the recovery room. Relator, on the other hand, argued emergence occurs in the operating room.

The U.S. District Court for the Western District of Missouri found relator failed to establish that AAKC knowingly submitted false claims. Relator’s theory of liability was that AAKC billed at the Medical Direction rate even though its anesthesiologists violated step three of the Seven Steps regulation by “virtually never ‘personally participat[ing]’ in the ‘emergence’ of a patient coming out of a general anesthetic” in the operating room. According to relator, emergence ended as the patient was wheeled into the recovery room.

The court cited two Eighth Circuit cases—United States ex rel. Ketroser v. Mayo Found., 729 F.3d 825 (8th Cir.2013), and United States ex rel. Hixson v. Health Mgmt. Sys., Inc., 613 F.3d 1186 (8th Cir.2010)—to discern the scienter necessary to establish an FCA violation.

The Ketroser court held that where a regulation is unclear, a party’s “reasonable interpretation of any ambiguity inherent in the regulation belies the scienter necessary to establish a claim of fraud under the FCA.” The Ketroser decision was consistent with Hixson, which held that a bill submitted based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute.

In this case, the court found that step three of the Seven Steps regulation was ambiguous as to what “personally participates in . . . emergence” means.

The court further held that AAKC’s interpretation of the regulation was reasonable. The court found that AAKC’s view that the regulation was satisfied by seeing the patient in the recovery room—while not the most widely held definition—was a reasonable interpretation of the ambiguous regulation.

Third Circuit Rejects Relator's Bid for Share of FCA Settlement

Dr. Gursheel Dhillon lost a bid for a relator’s share of a False Claims Act (FCA) settlement after the Third Circuit ruled June 11 that the district court correctly awarded another whistleblower the sole relator’s share as the “first to file.”

Dhillon filed his qui tam action in February 2011 against Endo Pharmaceuticals alleging that its sales representatives promoted Lidoderm, an adhesive pain patch, for off-label uses. At the time of Dhillon’s filing, two other cases alleging the off-label marketing of Lidoderm were pending: Peggy Ryan’s case filed in 2005 and Max Weatherby’s case filed in 2010. In addition, Ryan filed an amended complaint in 2009.

On February 21, 2014, the government elected to intervene on behalf of relators for settlement purposes. In exchange for a release from liability, Endo Pharmaceuticals agreed to pay $171.9 million.

Following the settlement, Ryan requested that she be awarded the sole relator’s share as the “first to file.” Dhillon argued, however, that he was the first to state a plausible claim to relief.

The district court sided with Ryan, finding she met the “more nuanced” Fed. R. Civ. P. 9(b) pleading standard as articulated by the Third Circuit in Foglia v. Renal Ventures Management, LLC, 754 F.3d 153 (3d Cir. 2014). The court also found Dhillon’s claims were barred by the FCA’s public disclosure provision.

The first-to-file provision prohibits a relator from bringing a case based on the same “essential facts” as an earlier filed complaint. The appeals court noted that by design only the first-filed relator is entitled to a relator’s share from a settlement.

Although Dhillon argued he was an “original source” because his “home run” complaint led to Endo agreeing to settle, the appeals court found that this argument failed to address the threshold first-to-file question.

“[W]e note further that Dhillon’s complaint was indeed the last one filed before the claims were settled, but he provides no support for his argument that the temporal relationship between a qui tam complaint and a settlement has any bearing at all on the ‘original source’ determination,” the appeals court commented.

Finally, the appeals court found Ryan’s amended complaint met the requirements of Rule 9(b) under Foglia. Ryan, a former Endo sales representative, provided particular details regarding the scheme to submit false claims and additional evidence to support a “strong inference” that false claims actually were submitted to the government.


Third Circuit Upholds Fraud Conviction, Sentence of Home-Based Hospice Care Owner

The Third Circuit wasn’t persuaded that a defendant accused of defrauding Medicare through his home-based hospice care business was convicted in error or sentenced unreasonably by the district court.

The appeals court upheld defendant Matthew Kolodesh’s jury convictions on charges of health care fraud, conspiracy to defraud a health care benefit program, mail fraud, and money laundering. The
appeals court also found the 176-month prison sentence and $16.2 million restitution order reasonable under the circumstances.

Defendant started a company called Home Care Hospice, Inc., which was managed by Alex Pugman. According to the opinion, defendant, Pugman, and Pugman’s wife, Svetlana Ganetsky, engaged in various fraudulent schemes, including paying “kickbacks” to physicians in exchange for patient referrals; billing Medicare for hospice care provided for patients who were not eligible for hospice care; and falsifying records to conceal the fraud.

Pugman and Ganetsky who previously pled guilty to charges against them testified at trial against defendant. Following his conviction, defendant appealed alleging prosecutorial misconduct, certain evidentiary issues, and other errors.

The Third Circuit rejected all defendant’s bases for appeal, finding to the extent any errors occurred, they were harmless.

Defendant also challenged his sentence on procedural and substantive grounds. He argued, for example, that the government did not establish the health care fraud resulted in a $16.2 million loss, which triggered a 20-level sentence enhancement.

The appeals court disagreed, however, rejecting defendant’s contention that the loss had to be established through statistical sampling. In particular, the appeals court noted the government’s estimate was based on the testimony of Pugman and Ganetsky, who were intimately involved in managing the hospice business.

“It is difficult to imagine who would have been more competent to testify based on personal knowledge as to the loss involved in this case,” the appeals court observed. The appeals court also noted no requirement that the district court rely on statistical analysis to determine the loss amount.

Defendant also disputed his four-level sentencing enhancement based on his role as an organizer or leader of the fraudulent activity and a two-level enhancement for obstructing justice. The appeals court found both enhancements reasonable, however, noting no clear area on the district court’s part.

Finally, the appeals court found the sentence substantively reasonable, pointing out the district court granted a downward departure from the guidelines range of 188 to 235 months.


**Fifth Circuit Finds Improper Restitution Order Imposed on Health Care Fraud Defendant**

The Fifth Circuit vacated and remanded June 23 a health care fraud defendant’s restitution amount, finding the court below committed plain error in including amounts outside the temporal scope of the defendant’s guilty plea. After six days of trial, defendant San Juanita Gallegos Lozano pled guilty to Count Two of a 13-count indictment relating to a conspiracy to defraud Medicare and Medicaid.

Count Two referred to a conspiracy involving La Hacienda Clinic that began “on or about” April 30, 2005. Count One referred to a conspiracy pertaining to the Mission Clinic that began “on or about” September 20, 2001.

At sentencing, the district court ordered restitution based on losses traceable to both La Hacienda Clinic and Mission Clinic beginning on September 20, 2001.
Lozano argued that the lower court erred in including losses related to Mission Clinic, but the appeals court found substantial evidence that Lozano understood her guilty plea to encompass fraud related to the Mission Clinic scheme.

"After arguing before the trial court that Lozano should be held accountable only for losses relating to Mission Clinic, Lozano's argument on appeal that she should not be held ‘responsible for losses related to the Mission Clinic conspiracy' because she did not understand that her guilty plea encompassed that 'separate' fraudulent scheme is unconvincing," the appeals court said.

The appeals court agreed, however, with Lozano that the restitution amount was improper because it required restitution for losses sustained outside the proper temporal scope.

According to both the indictment and the factual basis recited by the government, the temporal scope of the offense of conviction was April 30, 2005 through January 10, 2006, the appeals court noted.

Because the district court ordered restitution based on losses beginning September 20, 2001, the order was plain error and remand was appropriate, the appeals court held.

A lengthy dissent argued the court below did not commit plain error in ordering restitution for the whole temporal scope of the Mission Clinic fraud, “which was outlined in the indictment and admitted to by Lozano.”


**U.S. Court in South Carolina Certifies Two Questions to Fourth Circuit in FCA Action**

A federal court in South Carolina asked June 25 for the Fourth Circuit to resolve two certified questions related to a False Claims Act (FCA) action: (1) whether the government has an unreviewable right to object to a settlement in a qui tam action in which it hasn't intervened; and (2) whether the relators in the case could use statistical sampling to prove liability and damages.

Relators Brianna Michaels and Amy Whitesides brought the whistleblower action against their former employer Agape Senior Community, Inc. and related entities, which operate 24 nursing homes in South Carolina. Relators alleged Agape submitted false claims to Medicare, Medicaid, and Tricare for hospice care and general inpatient services.

The parties disputed the number of patients and the total number of false claims submitted by those patients, but the range was roughly between 10,000 to 20,000 patients and 53,000 to 62,000 claims. Expert review of a single patient’s services was estimated to cost between $1,600 and $3,600, for a total projected price tag of $16.2 million to $36.5 million.

Given the magnitude of a full-blown expert review, relators asked to use statistical sampling to determine damages, but the court refused, noting each claim at issue was fact-dependent and wholly unrelated to each and every other claim.

The parties subsequently reached a $2.5 million settlement, but the government, relying on statistical sampling, objected under 31. U.S.C. § 3730(b)(1), contending that potential damages was around $25 million.

Section 3730(b)(1) makes the government’s consent a prerequisite to the settlement of an FCA action.
The parties moved to enforce the settlement. In its order, the court said it was constrained by the statute, which was plain on its face, to deny the motion to enforce the settlement. The court noted only one federal appeals court—the Ninth Circuit in United States ex rel. Killingsworth v. Northrup Corp., 25 F.3d 715 (9th Cir. 1994)—has held that the government’s consent is not required after it declines to intervene in a case and is subject to a “reasonableness review” by the court.

By contrast, the Fifth and Sixth Circuits have both held that a qui tam action cannot be settled without the government’s consent. The court suggested that the government’s objection in this case likely wasn’t reasonable given the circumstances, but added that the Fourth Circuit would have to resolve whether such a review was allowed.

As to statistical sampling, the court noted a division in the case law as to whether this manner of determining damages is permissible in FCA actions. In the court’s view, this was not one of those cases where statistical sampling should be allowed—the medical charts were available for both party’s review and each claim presented the question of whether the services furnished were medically necessary, requiring individualized review.

But the court nonetheless said this issue also was appropriate for interlocutory review by the Fourth Circuit.


Tuomey Loses Fourth Circuit Appeal of $237 Million Judgment

The Fourth Circuit upheld July 2 a $237.5 judgment against Tuomey Healthcare Systems for violating the Stark Law and the False Claims Act (FCA) in connection with certain physician compensation arrangements.

In May 2013, a jury found Tuomey submitted 21,730 false claims to Medicare, with a total monetary value of $39.3 million. The U.S. District Court for the Southern District of Carolina ordered Tuomey to pay the government damages and civil penalties totaling almost $237.5 million.

In a statement, Tuomey said it is considering its options, including seeking review by the full Fourth Circuit. “Tuomey will also continue settlement discussions with the government in light of this new decision,” the statement said.

Employment Arrangements

Relator Michael K. Drakeford, MD filed the qui tam action under the FCA against Tuomey, which owns and operates Tuomey Hospital in Sumter, SC. Drakeford is an orthopedic surgeon who Tuomey attempted to hire as a part-time physician.

The complaint alleged Tuomey entered into part-time employment contracts with 19 physicians that violated the Stark Law because they exceeded fair market value, were not commercially reasonable, and took into account the volume or value of the referrals or other business generated between the physician and the hospital.

Under the employment contracts, which had ten-year terms, physicians were paid a base salary but earned the bulk of their compensation in the form of productivity bonuses, which were set at 80% of their collections for that year. Physicians also were eligible for an incentive bonus of up to 7% of their earned productivity bonus. Under the agreements, physicians had to perform outpatient surgical procedures exclusively at the hospital.
In May 2005, Tuomey and Drakeford jointly sought advice from attorney Kevin McAnaney about the proposed employment contracts. He advised that the contracts raised significant “red flags” under the Stark Law, the opinion said. Drakeford ultimately declined to enter into a contact with Tuomey. Tuomey went ahead with the contracts after seeking advice from other attorneys.

Drakeford alleged that because the part-time employment contracts violated Stark, Tuomey knowingly submitted false claims for payment to Medicare. The government intervened in the qui tam action.

Jury Verdicts

A jury subsequently found Tuomey violated the Stark Law, but not the FCA. The district court set aside the jury verdict in its entirety and ordered a new trial on the FCA claim, but entered a nearly $45 million judgment against the hospital on the federal government’s equitable claims (payment by mistake and unjust enrichment).

On appeal, the Fourth Circuit vacated the judgment, finding the district court violated the hospital’s Seventh Amendment right to a jury trial by basing its judgment with respect to the equitable claims on the jury’s finding of a Stark violation, which essentially was nullified by the court’s decision to grant a new trial. United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., No. 10-1819 (4th Cir. Mar. 30, 3012). The appeals court remanded the case for a new trial.

Unlike the first trial, the second trial included McAnaney’s testimony, which the first trial judge had excluded. The jury this time found Tuomey violated both the Stark Law and the FCA.

Knowledge Element

On appeal, Tuomey argued the district court erred in granting the government’s motion for a new trial on the FCA claim.

But the appeals court found the government was prejudiced in the first trial by “the exclusion of McAnaney’s testimony and other related evidence of his warnings to Tuomey regarding the legal peril that the employment contracts posed.”

In the appeals court’s view, McAnaney’s testimony was key to showing Tuomey “knowingly” submitted false claims under the FCA, i.e. “that Tuomey knew that there was a substantial risk that the contracts violated the Stark Law, and was nonetheless deliberately ignorant of, or recklessly disregarded that risk.”

Tuomey argued that it reasonably relied on the advice of counsel in entering into the employment contracts and therefore lacked the requisite intent to violate the FCA, pointing to other legal opinions that were favorable to the arrangements. But the appeals court found the record “replete with evidence indicating that Tuomey shopped for legal opinions approving the employment contracts, while ignoring negative assessments.”

Compensation Varied with “Volume or Value” of Referrals

The appeals court concluded that a reasonable jury could have found Tuomey’s contracts compensated the physicians in a manner that varied with the volume or value of referrals.

Specifically, the appeals court noted that the physicians were paid a base salary that was adjusted depending on their collections, and received the bulk of their compensation in the form of productivity bonuses that were tied to collections.
Although aggregate compensation was based solely on collections for personally performed professional services, “the more procedures the physicians performed at the hospital, the more facility fees Tuomey collected, and the more compensation the physicians received in the form of increased base salaries and productivity bonuses,” the appeals court said.

**Judgment Upheld**

The appeals court also rejected Tuomey’s challenges to the judgment, including that the district court improperly calculated the civil penalty and that the award was unconstitutional.

In this case, the jury awarded actual damages of $39.3 million, which the district court trebled. The district court also added a civil penalty of $119.5 million, which it calculated by multiplying the number of false claims by the $5,500 statutory minimum penalty.

Tuomey argued the civil penalty was inflated because it took into account both inpatient and outpatient procedures.

But the appeals court disagreed, noting “[i]f a physician has a financial relationship with a hospital, then the Stark Law prohibits the physician from making any referral to that hospital for the furnishing of designated health services.”

Tuomey also argued the government suffered no actual damages under the FCA because the hospital provided and billed for legitimate services.

The Fourth Circuit also rejected this argument, noting the “Stark Law expresses Congress’s judgment that all services provided in violation of that law are medically unnecessary,” and therefore the government owed nothing on the claims that Tuomey submitted.

Finally, the appeals court held the damages award did not violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth Amendment. “[T]he ratio of punitive damages to compensatory damages is approximately 3.6-to-1, which falls just under the ratio the Court deems constitutionally suspect,” the Fourth Circuit reasoned.

**“Troubling Picture”**

A concurring opinion agreed with the outcome, but wrote separately “to emphasize the troubling picture this case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.”


**Ninth Circuit Overrules Prior Precedent on FCA Original Source Requirements**

The Ninth Circuit overruled July 7 its prior interpretation of who qualifies as an “original source” under the False Claims Act (FCA) and announced a new two-part test.

In so holding, the appeals court said its decision in *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992), which required an original source to have a hand in the underlying public disclosure was “wrongly decided.”

Relators Steven Hartpence and Geraldine Godecke brought the consolidated qui tam actions, alleging their former employer Kinetic Concepts, Inc. and KCI USA, Inc. fraudulently claimed reimbursements from Medicare.
Relators filed suit after the allegations of Medicare fraud were publicly disclosed. Under the public disclosure bar, the district court lacked jurisdiction over the actions unless relators qualified as “original sources” under the FCA.

The district court held that neither relator qualified as an original source because they did not have a “hand in the public disclosure” of the fraud as required by *Wang*.

On appeal, the Ninth Circuit invalidated its prior precedent, finding the Supreme Court’s decision in *Rockwell Int’l Corp. v. United States* “makes clear that Congress did not intend ‘to link original-source status to information underlying the public disclosure.’”

The appeals court said an original source under the FCA must meet only two requirements: (1) before filing the action, the whistleblower must voluntarily inform the government of the facts underlying the complaint's allegations; and (2) the whistleblower must have direct and independent knowledge of the allegations underlying the complaint.

The appeals court also held that the first-to-file bar did not preclude Godecke’s claims even though they were filed six months after Heartpence’s suit, because Godecke’s allegations involved different underlying facts.

The appeals court remanded the action for the district court to consider whether relators qualified as original sources under the two-part test announced in its opinion.


**D.C. Circuit Reverses Finding of FCA Violation, Penalty**

The D.C. Circuit said July 10 that the District of Columbia did not violate the False Claims Act (FCA) when it reasonably relied on its former contractor to fulfill its obligation to maintain records “capable of being audited.”

The appeals court reversed the lower court’s judgment finding the D.C. government filed a false claim and imposing an $11,000 penalty.

The case involved the federal government's reimbursement to the District of a portion of the cost of providing health-related services to Medicaid-eligible children.

In 1995, the District of Columbia Public Schools (DCPS) retained a subcontractor, Davis & Associates, who, “acting on behalf of DCPS,” was responsible for collecting and submitting data for the payment of claims; reconciling approved, denied, and pending claims; and “maintaining original claim documentation for audit purposes.”

An audit determined that the District should return approximately $7.6 million in federal funds for fiscal year 1998 and noted incomplete cost information from DCPS.

Michael L. Davis filed a qui tam lawsuit alleging that the District violated the FCA by submitting, through DCPS, year-end cost reports prepared by its new subcontractor when it knew it “did not have in [its] possession documentation to support and verify that Medicaid reimbursable services were provided.”

The district court agreed with Davis, finding that the District made a false claim when DCPS submitted the FY 1998 cost report for payment because Davis & Associates, not DCPS, had
physical possession of the required supporting documentation, maintaining such documentation was material to the federal government's reimbursement decision, and DCPS submitted the false claim knowingly. The court imposed the maximum $11,000 penalty for one false claim, and both parties appealed.

The appeals court reversed, finding the District arranged with Davis & Associates to maintain appropriate documentation supporting its Medicaid claims, and that DCPS reasonably understood when it submitted its 1998 cost report that it could produce the underlying documentation for audit. Accordingly, the cost report contained no implied false certifications, and the District made no false claim, the appeals court said.

“Nothing in the District's State Plan or the Medicaid regulations on which Davis relies conditioned payment on DCPS's physical possession of documentation supporting its year-end cost reports. DCPS was required only to ‘maintain’ documentation such that the information could be ‘obtained’ for audit,” and it did so, the appeals court held.


**U.S. Court in Texas Tosses FCA Retaliation Claims Against Solvay**

Solvay Pharmaceuticals, Inc. continued to chip away at a False Claims Act (FCA) whistleblower action filed against it for alleged off-label promotion, winning a partial summary judgment ruling in the U.S. District Court for the Southern District of Texas on the two relators' retaliation claims.

Applying a “but for” causation standard, the court rejected relators’ claims that they were fired because they complained about Solvay’s promotional practices. Instead, the court found the temporal proximity between the protected activity and the terminations and the relators' prior positive performance reviews weren’t enough evidence of pretext to overcome Solvay’s stated reason for firing them—i.e., that they violated company policy.

Relators John King and Tammy Drummond formerly worked for Solvay as district sales managers. Relators filed a qui tam action alleging violations of the federal and ten state (plus the District of Columbia) FCAs. According to relators, Solvay caused the submission of false claims to several government programs by using allegedly fraudulent marketing tactics to promote off-label uses of several drugs, including AndroGel.

Both relators alleged Solvay fired them for complaining about the company’s allegedly illegal promotion practices and asserted retaliation claims under the FCA. Solvay moved for partial summary judgment on the retaliation claims.

In granting the motion, the court walked through the three elements of a retaliation claim under the pre-amended version of the FCA: (1) that relators engaged in protected conduct; (2) that Solvay knew relators engaged in protected conduct; and (3) that Solvay took adverse action against relators as a result.

The court found King, but not Drummond, raised a genuine issue that he engaged in protected conduct, drawing a distinction between the former’s specific complaints to his supervisors that certain activities were “illegal” or “kickbacks” and the latter’s complaints as “mere criticisms about the way Solvay was doing business.”

In contrast to King, Drummond “did not raise a distinct possibility” that she may file an FCA claim, the court held. Despite its conclusion, the court went on to examine the remaining elements of Drummond's retaliation claim “in an abundance of caution.”
The court summarily concluded that assuming relators engaged in protected activity, Solvay knew about it.

Relators’ retaliation claims, however, both came up short on the third element—whether they were terminated because of the protected activity.

Although relators argued for a “mixed-motive” standard of causation, i.e., that they were terminated at least in part for their protected activity, the court instead sided with Solvay, which contended “but for” causation was the appropriate standard, citing both Fifth Circuit and Supreme Court precedent in support of this approach.

Solvay’s purported reason for firing King was that he violated company policy by altering a marketing presentation package. Drummond allegedly was terminated for working with two doctors on an unapproved letter writing campaign also in violation of company policy.

Relators contended that the temporal proximity between their complaints and their terminations, coupled with evidence of exemplary past performance, was enough to show Solvay’s reasons for firing them was pretextual.

The court disagreed, however, finding the evidence insufficient for a “reasonable juror to conclude that Relators would not have been fired but for engaging in protected activity.”


**U.S. Court in Pennsylvania Grants Whistleblower 24% Relator’s Share over Government’s Objections**

A federal trial court in Pennsylvania said July 15 that relator Peggy Ryan was “indispensable” to the investigation that prompted a $171.9 million settlement with Endo Pharmaceuticals, Inc. of allegations that it violated the False Claims Act (FCA) by promoting its drug Lidoderm for off-label uses.

The U.S. District Court for the Eastern District of Pennsylvania therefore awarded Ryan a 24% share of the total federal government’s recovery, which amount to nearly $140 million.

The government argued that Ryan’s contribution to the eventual settlement of the qui tam action, which she initiated in 2005, wasn’t substantial enough to warrant a higher-end award. Instead, the government urged the court to award Ryan 19% as her relator’s share.

Under the FCA, when the government intervenes in a qui tam action, as it did here, the relator is entitled to between 15% and 25% of the settlement award, depending on how much the whistleblower contributed to the prosecution of the action.

The court found Ryan, who worked for Endo, was entitled to the 24% award that she sought, noting without her assistance “the probability of the Government recovering any funds for the FCA violations would have been slim at best.”

“Ryan accumulated evidence from otherwise unobtainable sources at the senior management level of Endo,” including wearing a wire to record over 200 hours of conversations that proved crucial to uncovering the alleged unlawful marketing of Lidoderm for off-label uses, the court observed.
Ryan also helped the government tailor its subpoena of documents and information from Endo to target the most relevant evidence and provided the government with a "bounty of documentary evidence" it otherwise would have been hard press to obtain.

The government argued that a 24% share was too much because the case didn’t proceed to trial and instead settled in 2014. But the court said the government was unjustified in downplaying Ryan’s role, and that lowering her share because the case didn’t proceed to trial was counterintuitive.

“Applying the Government’s argument to cases like this would punish a relator, such as Ryan for providing a level of incriminating information that would make the defendant’s prospects of winning at trial less likely.” The government also failed to take into account the resources it saved by settling.

Finally, the court rejected the government’s argument that the size of the settlement justified a lower percentage award. The statute only speaks in terms of the relator’s contribution, not the size the settlement. Moreover, the court noted no precedent for the government’s position.

In June, the Third Circuit upheld the district court’s determination that Ryan was entitled to the sole relator’s share of the Endo settlement as the “first to file.” The appeals court found a second qui tam action against Endo filed in 2011 by Dr. Gursheel Dillon was precluded under the FCA first-to-file provision. United States ex rel. Dhillon v. Endo Pharmaceuticals, No. 14-3377 (3d Cir. June 11, 2015).

The district court’s determination of Ryan’s share of the settlement proceedings had been stayed pending the Third Circuit decision.


**Fifth Circuit: District Court Improperly Granted New Trial on Bribery, Fraud Convictions**

The Fifth Circuit admonished a lower court to reinstate the convictions of a hospital official and the owner of a nurse staffing business in connection with a bribery and kickback scheme involving a Mississippi community hospital and sentence them accordingly.

The case was before the Fifth Circuit for a second time after the district court, on remand, granted defendants a new trial on finding the government withheld potentially exculpatory evidence in violation of *Brady v. Maryland*, 373 U.S. 83 (1963).

The appeals court said the district court exceeded its authority in granting the new trial on a basis not previously raised by defendants and in contravention of the Fifth Circuit’s mandate in the first appeal.

A jury convicted defendants Lamont Shoemaker, a hospital chief operating officer/chief executive officer, and Levi Garner, the owner and operator of a nursing staff agency, on 12 counts relating to the scheme involving bribery and kickbacks.

Both defendants moved for judgment of acquittal or, in the alternative, a new trial. The court granted each defendant either acquittal or a new trial on several counts, finding the government failed to prove agency. It declined to rule on Garner’s argument that the government withheld *Brady* material.
The government appealed all judgments of acquittal and grants of new trials, and Shoemaker appealed his remaining convictions, teeing up the case for the Fifth Circuit.

The appeals court in April 2014 reversed the decision below and affirmed the remaining convictions. The appeals court remanded for reinstatement of the jury verdict and sentencing.

On remand, however, the district court granted the pair a new trial on five counts based on three Brady issues: the government’s failure to provide defendants with the sealed, 26-count indictment against its star witness; with copies of Federal Bureau of Investigation interview forms of the witness; and to inform defendants of a false statement by the witness during his plea.

Back before the Fifth Circuit a second time, the appeals court found the lower court overstepped in granting a new trial.

Defendants raised the two of the Brady claims during the first appeal and therefore the Fifth Circuit’s mandate in the original case barred the grant of a new trial on those claims, even if the appeals court did not specifically address those arguments in its initial decision. Had the two Brady issues been winning arguments, the Fifth Circuit would have said so at the time of its first opinion, the appeals court said.

The third Brady claim was not previously before the appeals court, and the district court lacked discretion to grant a new trial on an issue not raised by either defendant.

The appeals court reversed and remanded with instructions for the lower court to reinstate the jury verdict, enter judgments of conviction on all counts, and resentence accordingly.


**U.S. Court in Ohio Says Relators Must Arbitrate False Claims Act Allegations**

The U.S. District Court for the Southern District of Ohio said July 27 that three relators must arbitrate their qui tam allegations, as each signed an arbitration agreement with their defendant employer that encompasses such claims.

Relators Sara Curtis Hicks, Leah Broderick, and Debbie Turner are all registered nurses who have worked for defendant Evercare Hospice, Inc.

The relators alleged in their qui tam suit that Evercare admitted patients without mandatory consent and/or power-of-attorney designations, billed for continuous care when such care was neither reasonable nor necessary, and provided inadequate services. They also claimed Evercare retaliated against them.

The district court previously dismissed one category of relators’ allegations as second to-file behind a similar case and defendant then moved to dismiss the retaliation claims and stay the whistleblower claims pending arbitration, which it argued is mandated by an arbitration policy that relators signed as a condition of employment.

The court first pointed out that the agreement signed by each of the three relators “broadly defines the scope of disputes subject to arbitration, including ‘any dispute UnitedHealth Group might have with a current or former employee which arises or relates to employment’ and specifically references ‘whistleblower or retaliation claims’ as being covered.”
Relators conceded that their retaliation claims would be covered by the agreement but argued that defendants should not be able to send their qui tam claims to arbitration.

According to relators, the real party in interest in the case is the government, which did not agree to be subject to arbitration. However, the court rejected that argument, finding that the government “does not object to arbitration here, so long as any arbitration ruling is deemed a non-binding recommendation, subject to the government's consent.”

Accordingly, finding the agreement clear and unambiguous, the court said there is no reason why it should not be followed.


U.S. Court in Kentucky Holds Home Health Company Can’t Escape Allegations Gifts to Physicians Violated Stark

A federal court in Kentucky refused July 15 to grant a home health company and its owners summary judgment on claims in a whistleblower action that they violated the Stark Law by giving certain referring physicians a gift basket and event tickets.

According to the U.S. District Court for the Eastern District of Kentucky, a general issue of material fact as to whether the instances of alleged remuneration violated the Anti-Kickback Statute (AKS) precluded application of the Stark "non-monetary compensation" exception at this juncture of the litigation.

Relators Alisia Robinson-Hill and David A. Price both worked at Nurses’ Registry and Home Health Corporation. Price as a Registered Nurse Case Manager and Robinson-Hill as Vice President of Clinical Operations and Administration.

Relators filed a qui tam action under the False Claims Act (FCA) alleging defendants submitted false and fraudulent claims to the government by upcoding patients’ symptoms and providing medically unnecessary therapy visits to obtain greater Medicare reimbursements.

The government intervened in the action, adding allegations that defendants violated the FCA by falsely certifying compliance with the Stark Law. Specifically, the government pointed to one instance where defendants sent a gift basket to a referring physician and to other instances where a number of referring physicians were invited to a private event and to radio shows hosted by University of Kentucky coaches and sponsored by Nurses’ Registry.

According to the government, these instances of remuneration created “financial relationships” between Nurses’ Registry and the referring physicians under the Stark Law that gave rise to FCA liability when defendants submitted claims for the services they referred, including the establishment of plans of care and certifications or re-certifications.

Defendants moved for partial summary judgment, arguing the remuneration at issue fell within the non-monetary compensation exception to the Stark Law.

To satisfy the non-monetary compensation exception, the compensation can’t exceed a total of $300 per calendar year, as adjusted for inflation, and must satisfy all of the following conditions:

- The compensation doesn’t take into account the volume or value of referrals or other business generated by the referring physician;
- The physician or the physician’s practice does not solicit the compensation; and
- The compensation arrangement doesn’t violate the AKS.
In ruling against defendants, the court noted the government specifically alleged the instances of alleged remuneration violated the AKS because it was intended to induce or reward referrals and proffered sufficient evidence to raise a factual dispute on this issue; thus, precluding summary judgment.


**U.S. Court in Pennsylvania Says Failure to Report CIA Breach May Amount to “Reverse False Claim”**

A federal district court in Pennsylvania refused July 21 to dismiss whistleblower allegations that Cephalon Inc.’s failure to comply with a Corporate Integrity Agreement’s (CIA’s) reporting requirements to avoid its obligation to pay stipulated penalties under the CIA constituted a “reverse false claim” triggering False Claims Act (FCA) liability. See 31 U.S.C. § 3729(a)(1)(G).

In so holding, the U.S. District Court for the Eastern District of Pennsylvania rejected the drug maker’s argument that it incurred an obligation to pay stipulated penalties under the CIA only if the Department of Health and Human Services Office of Inspector General (OIG) exercised its discretion to demand payment of the penalties.

Instead, the court sided with relators who argued that the obligation to pay the stipulated penalties arose when Cephalon breached the CIA’s reporting requirements.

“Cephalon’s contractual obligation to pay the government is an ‘established duty’ . . . upon breach of the CIA’s relevant requirements,” the court said.

**Off-Label Marketing Scheme**

Several whistleblowers—Bruce Bosie, Keith Dufour, and Andrew Augustine—brought the qui tam action against Cephalon alleging it promoted two of its drugs—Provigil and Nuvigil—for off-label uses and paid unlawful kickbacks.

Relators alleged the off-label promotion and kickback schemes violated the terms of a CIA that Cephalon entered into with the OIG in 2008.

The CIA required Cephalon to notify the OIG of any “reportable events,” including any probable violations of criminal, civil, or administrative laws. The CIA also set forth specific contractual remedies for a violation of the agreement including stipulated penalties.

According to relators, Cephalon’s failure to report the alleged breaches of the CIA to OIG allowed the company to avoid its obligation to pay the stipulated penalties under the agreement.

Cephalon moved to dismiss the reverse false claims allegations, arguing it did not incur an “obligation” within the meaning of the FCA upon breach of the CIA because the imposition of the stipulated penalties was contingent on the exercise of OIG’s discretion.

**Contractual Obligation**

In *Booker*, the court rejected relator’s allegation that Pfizer made reverse false claims by failing to comply with a CIA because the agreement did not impose on the company an “obligation” to pay the government until payment was demanded.

The *Ruscher* court, however, found that penalties arising from contractual obligations, like the CIA’s reporting requirements, could give rise to liability for reverse false claims before the OIG demanded payment.

The court in this case agreed with *Ruscher’s* reasoning, finding “Cephalon’s obligation to pay stipulated penalties under the CIA cannot be construed as arising only when the OIG demands payment of those penalties.”

The court noted that the existence of a “specific contract remedy” in the form of stipulated penalties created a less contingent obligation to pay than other contractual obligations where enforcement requires litigation.


**U.S. Court in New York Holds Identification of Potential Overpayments Triggers ACA-60 Day Rule**

A federal court in New York issued August 8 the first interpretation of what an “identified” overpayment means for purposes of triggering the Affordable Care Act's (ACA's) 60-day report and return requirement.

Refusing to dismiss a False Claims Act (FCA) action against Medicaid managed care organization HealthFirst, Inc., Continuum Health Plans, and three related hospitals, the U.S. District Court for the Southern District of New York found the 60-day period begins to run when a provider is "put on notice of a potential overpayment," rather than when an overpayment is "conclusively ascertained."

The federal government and state of New York intervened in June 2014 in a qui tam action filed by relator Robert P. Kane against his former employer Continuum Health Partners, Inc., the three hospitals it operates—Beth Israel Medical Center D/B/A Mount Sinai Beth Israel, St. Luke’s-Roosevelt Hospital Center D/B/A Mount Sinai St. Luke’s, and Mount Sinai Roosevelt (SLR)—and HealthFirst.

The government alleged defendants delayed in fully repaying Medicaid overpayments for almost two years after the overpayments were discovered in violation of the FCA’s "reverse false claims" provision.

The ACA added the requirement that providers and suppliers report and return any identified Medicare and Medicaid overpayments within 60 days of discovery or face potential liability under the FCA.

The complaint alleged Continuum submitted hundreds of improper claims to Medicaid in 2009 and 2010 on behalf of the hospitals due to a software problem attributable to HealthFirst's Medicaid managed care plan.

The government alleged that, despite becoming aware of the software issue in late 2010 and, further, being provided in early February 2011 with a spreadsheet by Kane identifying virtually all of the claims affected by the issue, Continuum and the hospitals failed to take appropriate steps to timely repay the claims.
The court spent the bulk of its opinion determining what an “identified” overpayment means for purposes of the ACA 60-day rule. A term the statute doesn't define.

Defendants argued that “identified” should mean “classified with certainty,” while the government urged the court to adopt a “put-on-notice” interpretation. Employing a multi-pronged analysis that included considering dictionary definitions, legislative history, and canons of statutory construction, the court sided with the government.

The court also held the government adequately alleged at this stage of the litigation that defendants knowingly and improperly avoided its obligation to repay the overpayments.


**U.S. Court in Massachusetts Tosses FCA Action Alleging CVS Overcharged Medicare, Medicaid for Generics**

A federal court in Massachusetts dismissed July 29 a False Claims Act (FCA) whistleblower action against CVS Caremark Corp. alleging the pharmacy chain billed Medicare and Medicaid inflated prices for hundreds of generic drugs.

The U.S. District Court for the District of Massachusetts found the FCA public disclosure provision barred the action because the substance of the allegations were widely reported in the media and discussed at congressional hearings.

Relators contended the public disclosures only related to the Federal Employee Health Benefits Program (FEHBP), not Medicare and Medicaid, but the court found their allegations “substantially similar” to those in the public domain that CVS deprived the government the benefit of its discounted generic prices offered to other customers.

The court also held relators were not “original sources” because the additional information they offered “was neither unavailable nor ‘of great significance’ beyond what was publicly disclosed.”

**Inflated Billings**

Relators Myron D. Winkelman and Stephani Martinsen brought the qui tam action against CVS and related entities on behalf of the federal government and a number of states.

According to relators, CVS offered a generic discount program—the Health Savings Pass (HSP)—to certain customers but avoided reporting its HSP discount prices as its “usual and customary” prices when submitting claims to Medicaid and Medicare Part D.

Before the qui tam action was filed in 2011, various media reports contended that CVS failed to offer its lowest price on hundreds of generic drugs to the FEHBP, costing taxpayers “hundreds of millions of dollars.” A congressional subcommittee also held a hearing on the alleged overcharges in 2010.

CVS moved to dismiss the qui tam action, citing the public disclosure bar.

**“Substantially Similar”**

At the outset of its analysis, the court noted that the public disclosure bar was no longer jurisdictional as amended by the Affordable Care Act.
Turning to the merits, the court found the media and congressional reports amounted to disclosures to the public that CVS was overcharging federal and state governments by not offering them the same prices as those available through the HSP program.

Relators did not dispute the prior public disclosures, but argued their complaint specifically detailed fraud as to the Medicare Part D and Medicaid programs.

But the court wasn’t persuaded, pointing out little dispute that relators’ allegations were “substantially similar” to the publicly disclosed media and congressional reports.

**No Original Source Status**

Finally, the court determined that relators did not have original source status, even if they had first-hand knowledge of how the HSP program worked and that CVS did not treat HSP as usual and customary prices.

The substance of the alleged fraudulent conduct already had been disclosed, and any additional information that relators provided did not “materially add” to what was known publicly.


**Class Action**

In a complaint filed July 30, several named plaintiffs seeking class status sued CVS alleging it "knowingly and intentionally overcharged pharmacy customers for generic prescription drugs by submitting claims for payment to third-party payors at fraudulently inflated prices."

According to the complaint, filed in the U.S. District Court for the Northern District of California, the alleged "false and deceptive pricing scheme" caused customers with third-party coverage to pay higher copayments than cash-purchasing customers who purchased the same generics through the HSP program.

Plaintiffs contended that the alleged scheme caused them and the other members of the proposed class to pay generic drug prices that were three to four times higher than the usual and customary price.

*Corcoran v. CVS Health Corp.*, No. 3:15-cv-03504-JCS (N.D. Cal. complaint filed, July 30, 2015).

**U.S. Court in Florida Refuses to Dismiss FCA Claims by Relator with No Relationship to Defendants**

The U.S. District Court for the Middle District of Florida refused to dismiss False Claims Act allegations by a relator who had no relationship with the defendants.

The court found the relator presented sufficient indicia of reliability to survive a motion to dismiss. BayCare Health System, a Florida nonprofit corporation that owns St. Anthony's Hospital, Inc. and St. Anthony's Professional Buildings and Services, Inc., leased land at St. Anthony's Hospital to St. Pete MOB, LLC, and agreed that St. Pete MOB would build a medical office building.

Relator Thomas Bingham, a commercial real estate appraiser, alleged that free parking, rent concessions, and valet services that Bay Care provided to St. Pete MOB was actually for the
BayCare argued that the complaint failed to satisfy Fed. R. Civ. P. 9(b) because the relator "does not allege one single illegally-referred patient was treated by the Hospital or that a false claim exists or was submitted for that patient's care."

The court noted at the outset that in order to survive a motion to dismiss under Rule 9(b) the complaint must provide some "indicia of reliability . . . to support the allegation of an actual false claim for payment being made to the Government."

The court found the relator sufficiently pled a violation of the Stark Statute because his claim provides "indicia of reliability" that physicians at the Heart Center and the Suncoast Medical Clinic referred Medicare patients to BayCare and that BayCare submitted claims to the government for those referrals. Thus, the relator complies with Rule 9(b) by alleging "facts as to time, place, and substance" of the compensation arrangements, the court held.

Also, to demonstrate that the free parking, the rent concessions, and the valet services each constitute remuneration, the relator calculated the fair market value, the court pointed out.

The court also found the relator's allegations sufficiently pled a violation of the Anti-Kickback Statute.

As previously determined, the complaint states that BayCare paid remuneration to physicians at the Heart Center and the Suncoast Medical Clinic and alleges that BayCare paid the remuneration "knowingly and willfully" because BayCare certified compliance with the Anti-Kickback Statute by signing "provider applications and cost reports."

Further, the relator alleged that BayCare paid remuneration to physicians one purpose of which was "inducing or rewarding referrals of items and services to be paid for by federal and state healthcare programs," the court found in refusing to dismiss the claims.

Quest moved to dismiss based on Rule 9(b) and the public disclosure bar. The district court concluded that the public disclosure provision barred Judd's claims regarding Quest's scheme with providers other than HMA before 2010.

The court found that Judd’s claims previously were disclosed publicly in two other court cases, and Judd was not an original source of the information on which his allegations about health care providers other than HMA were based.

In so ruling, the district court applied the version of the public disclosure bar prior to the enactment of the Affordable Care Act (ACA) because the alleged conduct began before the ACA amended the FCA in 2010.

Concluding that Congress did not intended the ACA amendments to be retroactive, the appeals court found no dispute that the pleadings in the two previous cases “qualify as public disclosures under the public disclosure bar in both its pre-ACA and ACA-amended forms.”

The appeals court also agreed with the lower court that although Judd could be an original source regarding Quest's dealings with HMA, he was not an original source regarding Quest's dealings with other health care providers.

The appeals court also found that despite its adoption of a more lenient Rule 9(b) pleading standard--allowing a plaintiff to allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"--Judd fails to meet that standard.

According to the appeals court, Judd “provides no reason to believe that Quest submitted claims for Medicare reimbursement in connection with its kickbacks” and the complaint’s specific allegations “have nothing to do with Quest's dealings with non-HMA medical providers.”


**U.S. Court in Texas Tosses FCA Action Alleging Debt Forgiveness Violated AKS**

A federal court in Texas granted summary judgment to Omnicare Inc. in a seven-year old False Claims Act (FCA) whistleblower action that alleged the long term care pharmacy illegally forgave its skilled nursing facility (SNF) customers’ debts to induce their continued business under preferred provider agreements.

The U.S. District Court for the Southern District of Texas found relator Susan Ruscher, who worked in Omnicare’s collections department from July 2005 until her termination in August 2008, failed to raise a question of material fact that the company’s intent in making the write-downs was to induce referrals.

Instead, the evidence showed that the significant write-down of the SNF customers’ debts were aimed at resolving legitimate billing disputes, not to induce the SNFs to continue to contract with Omnicare to provide pharmacy services to their Medicare Part A and Part D patients.

“The collection practices of Omnicare,” the court noted “would not seem exceptional, much less fraudulent, to most law firms dealing with their own past-due accounts receivable.”

At issue in the qui tam action were Omnicare’s dealings with eight SNF chains from 2005 through 2008.
Many of the SNF residents for whom Omnicare provides pharmaceuticals and pharmacy services are enrolled in Medicare Part A, Medicare Part D, and/or Medicaid.

For Medicare Part A patients, the SNFs pay long term care pharmacies like Omnicare directly from the per die revenue they receive for the first 100 days of a stay in their facilities. After the 100-day Part A benefits are exhausted, for SNF residents covered by Part D or Medicaid, the long term care pharmacy bills the private plan sponsors, or the state program, respectively.

Relator alleged that Omnicare intentionally avoided collecting on SNF Part A debt to maintain its preferred provider relationships with them and to continue servicing their Part D and Medicaid patients. At the end of 2008, the opinion said, Omnicare had significant past-due account receivables totaling $300 million from some or all of the eight chains.

Omnicare argued that the mounting account receivables stemmed from billing and auditing errors and disputes with SNFs about pricing.

The court acknowledged that debt forgiveness can constitute “remuneration” under the Anti-Kickback Statute (AKS) and the undisputed evidence that Omnicare did in fact write down the balances owed by the SNFs.

But where the complaint failed to raise a genuine issue of material fact that “one purpose” of Omnicare’s debt forgiveness was to induce referrals, the court concluded.

The court examined the dealings between Omnicare and the SNFs over the account receivables and found, even those that occurred “in the shadow of contract negotiations,” suggested only “an honest, if business-minded, desire to maintain good customer relationships.”

Even if relator could prove Omnicare violated the AKS, the court continued, she also failed to sufficiently alleged FCA liability.

With respect to Medicare, the court noted no evidence of a false certification by the SNFs or that Omnicare knew that false certifications were being made.

With respect to Medicaid, the court also found a “total lack of evidence related to the FCA scienter requirement.”

The court rejected relator’s remaining federal and state claims, including an alleged “reverse false claim” arguing Omnicare violated a Corporate Integrity Agreement (CIA) previously signed with the government when it failed to report an email she wrote raising concerns about potential fraud.

According to the court, Omnicare reasonably could have concluded the email was not a “reportable event” under the CIA because it referred to the SNFs’ potentially fraudulent conduct, not Omnicare’s.


**U.S. Court in New Jersey Narrows Allegations That Plavix Promotion Caused Improper “On-Label” Prescriptions**
A federal court in New Jersey dismissed the bulk of False Claims Act (FCA) whistleblower allegations against Bristol-Myers Squibb Company (BMS) and Sanofi-Aventis, which jointly marketed the blood-thinner Plavix (clopidogrel bisulfate).

Relator Elisa Dickson, a former Sanofi sales representative, sued the drug makers alleging they promoted Plavix as being superior to aspirin in treating stroke patients, when they knew it wasn't more effective.

According to relator, the false information about Plavix prompted physicians to prescribe the drug over cheaper alternatives, causing the submission of false claims to Medicare Part D and various states’ Medicaid programs for a drug that wasn’t “medically necessary” or “reasonable and necessary.”

The U.S. District Court for the District of New Jersey wasn’t persuaded that relator stated a claim under the FCA because the allegations involved prescriptions for Plavix that were “on-label”—i.e. for indications approved by the Food and Drug Administration (FDA)—and therefore reimbursable by Medicare Part D.

The court made a similar ruling with respect to relator’s allegations of Medicaid false claims, with the exception of a handful of states that included a requirement in their programs that drugs be “cost effective.” For those states, the court allowed the federal and state FCA allegations to proceed, although it narrowed those claims to after March 30, 2005 based on the six-year statute of limitations.

Relator initiated the original whistleblower action in the U.S. District Court for the Southern District of Illinois on behalf of the United States and various states. That court rebuffed defendants’ motion to dismiss the complaint, see United States ex rel. Dickson v. Bristol Myers Squibb Co., No. 11-cv-246-DRH-SCW (S.D. Ill. Jan. 30, 2013), but the case was subsequently transferred to the District of New Jersey by the Judicial Panel on Multidistrict Litigation.

The court addressed a number of FCA issues, starting with the public disclosure bar, which it rejected as a basis for dismissing the complaint.

A previous court case and newspaper articles about Plavix were public disclosures, but relator, as an insider with knowledge of the alleged fraudulent scheme, also qualified as an original source under either the pre- or post-Affordable Care Act versions of the FCA, the court said.

In the court’s view, however, the complaint faltered where it came to allegations that prescriptions of Plavix for FDA-approved indications weren’t “reasonable and necessary” for Medicare Part D reimbursement purposes.

“By operation of the Medicare statute, this Court holds that a FDA approved drug that has been prescribed for its on-label use is necessarily covered under Medicare Part D,” the opinion said, in holding relator could not state a claim under the FCA in this context.

The court reached largely the same holding with respect to Medicaid, which reimburses “covered outpatient drugs” prescribed for a “medically accepted indication.”

The court noted, however, that several state Medicaid statutes include a requirement for cost effectiveness. And at this stage of the litigation, the court concluded relator sufficiently alleged that cost effectiveness was a condition of government payment in those states.
The court also rejected relator’s allegations that defendants violated the FCA by “dup[ing] each state’s Medicaid program into including Plavix on its formulary.” According the court, relator failed to identify any false certification that was a prerequisite to payment and, in any event, the allegations were too speculative as to how the Plavix promotional materials influenced formulary placement.


**U.S. Court in Indiana Allows Physician’s FCA Retaliation Claim**

A federal court in Indiana held August 24 that an emergency room physician sufficiently stated a retaliation claim under the False Claims Act (FCA) when he was fired shortly after voicing concerns about potential fraud to supervisors.

The U.S. District Court for the Southern District of Indiana refused to apply the Fed. R. Civ. P. 9(b) heightened pleading standard because the physician, Dr. James Thomas, MD, alleged an FCA retaliation claim, not an FCA fraud claim.

Although the Seventh Circuit hasn’t addressed this issue, the court sided with numerous other decisions in finding Rule 9(b)’s heightened pleading standard did not apply to FCA retaliation claims, which don’t depend on allegations of fraud.

Instead, the court said Fed. R. Civ. P. 8(a)’s more liberal pleading regime was the appropriate standard.

Thomas filed the action under the FCA’s retaliation provision, 31 U.S.C. § 3730(h), against EmCare, Inc., Constitutional Elm Emergency Physicians, LLC, and Harrison County Hospital in December 2014.

Throughout his employment at the hospital, which started in June 2014, Thomas complained both verbally and in writing to his supervisors about issues regarding patient tests and admission procedures, including concerns relating to Medicare, Medicaid, and other insurance fraud, the opinion said.

According to Thomas, shortly after forwarding his complaints to EmCare’s regional director, his employment was terminated without further explanation. Thomas sued for retaliation under the FCA and the hospital moved to dismiss.

Under the Rule 8(a) pleading standard, the court found Thomas stated an FCA retaliation claim—specifically, that he was engaged in protected conduct under the statute; that defendants knew he was engaged in protected conduct; and that defendants were motivated, at least in part, to terminate him because of the protected conduct.

The hospital argued that the complaint failed to plead the first element, but the court disagreed, noting that 2009 amendments to the FCA expanded Section 3730(h)’s protections to include employees who reported alleged violations to an internal supervisor.

Thomas’ claim that he reported alleged misconduct to two internal supervisors was sufficient to allege he engaged in protected activity under the statute, the court said.

The court also found Thomas’ allegations satisfied the remaining elements of an FCA retaliation claim, noting the complaint alleged Thomas never received a complaint about his work performance.
before his termination and was fired without explanation shortly after voicing his concerns to the regional director.


**Fifth Circuit Upholds Convictions, Sentences in Physician House Call Scheme**

A lower court did not err in including Medicare claims filed by third-party home health agencies (HHAs) in the intended loss amounts of two defendants who ran a physician house call company that falsely certified patients were homebound, the Fifth Circuit ruled September 9.

The appeals court upheld the convictions and sentences of defendant Lawrence Dale St. John, who founded the company A. Medical, which certifies patients as homebound and develops plans of care, and his son Jeffry St. John, an employee of the firm.

**“Steady Stream” of Patients**

According to the opinion, the government alleged that A Medical fraudulently billed Medicare for care plan oversight (CPO) services that it did not provide and ensured a “steady stream” of patients by falsely certifying for various HHAs that patients were homebound.

The government alleged that HHAs referred patients to A Medical in exchange for the company’s “near-certain certification” of those patients' homebound status.

A third co-conspirator in the scheme, Dr. Nicholas Padron, who ultimately pled guilty, testified against the St. Johns at trial. Padron admitted that he certified almost all patients as homebound and didn’t supervise A Medical nurses and physician assistants as required for billing Medicare for CPO services.

A jury convicted defendants of conspiracy to commit health care fraud and 13 substantive counts of health care fraud.

The pre-sentence report (PSR) recommended that defendants be held culpable for losses stemming from the fraudulent CPO claims as well as all of the bills that the HHAs submitted to Medicare for patients A Medical certified as homebound for a total intended loss of nearly $11.2 million and an actual loss of more than $9.6 million.

Based on those loss calculations, the PSR recommended a base offense level of 29 for both defendants. The district court adopted the PSR’s recommendations and also ordered Dale to pay restitution of more than $9.6 million and Jeffery to pay restitution of more than $8.6 million.

**Intracorporate Conspiracy Doctrine**

Jeffrey argued that his involvement in A Medical’s scheme did not satisfy conspiracy’s plurality requirement because a corporation can’t conspire with itself.

Rejecting this argument, the Fifth Circuit declined to apply the “intracorporate conspiracy doctrine” in the criminal context.

**Loss Calculation**
The appeals court also found no error in the district court’s calculation of the intended loss. Dale argued that the loss calculations included sums that were not “relevant conduct” and should have been reduced by the value of legitimate services.

“We conclude that the HHA amounts were properly included as ‘relevant conduct’ as part of the same ‘common scheme’ as the offense of conviction,” the appeals court held.

The appeals court also found that the fraud was so pervasive that the district court did not plainly err in failing to subtract the value of legitimate services from the actual loss calculation absent specific evidence, which Dale failed to provide.

**Restitution**

Finally, the appeals court upheld the restitution award as including the HHA’s Medicare reimbursement claims.

“The HHAs’ Medicare reimbursement claims were a necessary component of A Medical’s scheme to defraud Medicare” and therefore were sufficiently referenced in the indictment, the Fifth Circuit found.


**Eleventh Circuit Vacates Judgment Against Lab in Dispute Basing State Law Claims on Alleged AKS/Stark Violations**

A panel of the Eleventh Circuit vacated September 3 a judgment finding Millennium Laboratories, Inc. engaged in unfair competition and tortious interference under various state laws based on alleged violations of the federal Anti-Kickback Statute (AKS) and Stark Law.

The appeals court found the U.S. District Court for the Middle District of Florida abused its discretion in exercising supplemental jurisdiction over “novel and complex” state law claims—i.e., that an AKS or Stark violation could be used to prove statutory unfair competition and common law torts in nine states.

“Allowing the state-law claims to be tried using the Stark/AKS theory was egregious, constituting a clear error of judgment,” the Eleventh Circuit panel concluded.

**“High-Stakes” Litigation**

Ameritox Ltd. and Millennium are competing clinical laboratories that screen urine specimens for drugs. According to Ameritox, Millennium engaged in unfair competition and tortious interference through a program that provided free Point-of-Care Testing (POCT) cups to physicians in exchange for confirmatory-testing business.

Ameritox sued Millennium, asserting a violation of the federal Lanham Act and of state unfair competition/tortious interference laws in nine states. Although the Lanham Act claim eventually was mooted, the district court retained supplemental jurisdiction over the state law claims.

At the summary judgment stage, Ameritox argued that the POCT cup testing agreements with physicians violated the AKS and Stark Law, and that these violations, while not actionable through a private cause of action, could be used to prove the central elements of unfair competition and tortious interference under state law.
In opposing summary judgment, Millennium did not challenge Ameritox’s AKS/Stark state-law incorporation theory, but instead disputed that any violation of the federal laws occurred.

In May 2014, the district court held Ameritox’s provision of the free POCT cups to physicians could constitute prohibited remuneration under the Stark Law and AKS in certain circumstances. Ameritox, Ltd. v. Millennium Labs., Inc., No. 8:11-cv-775-T-24-TBM (M.D. Fla. May 5, 2014).

Following a ten-day trial, a jury found Millennium violated the AKS and the Stark Law and that Ameritox had proven its state law claims.

The jury awarded Ameritox $14.755 million in damages, the bulk of which—$12 million—was for punitive damages. The district court later reduced the punitive damages awarded to $8.5 million based on state statutory caps.

Novel and Complex Claims

The Eleventh Circuit said the district court erred in exercising supplemental jurisdiction over the state law claims because they raised a “novel and complex” theory that these states would incorporate the federal fraud and abuse laws as a basis for proving violations of unfair competition statutes and common law torts.

“Ameritox did not cite to any state-law precedent to support this point,” the appeals court observed. The appeals court in fact noted no cases in eight of the states at issue connecting either Stark or AKS to tortious interference or unfair competition laws. And in the remaining state, Texas, a state court rejected an apparent attempt “to co-opt state common law into providing a private right of action where Congress” didn’t establish one. See Reliable Ambulance Serv., Inc. v. Mercy Hosp. of Laredo, No. 04-02-00188-cv (Tex. App. Ct. Aug. 20, 2003).

“Simply put, whether or not Stark or AKS are relevant to any of the claims in this case is a novel question. It is also a complex question, laden with important policy choices,” the appeals court observed.

Abuse of Discretion

The appeals court found the district court abused its discretion in retaining supplemental jurisdiction and effectively “ratifying new legal theories in nine different states” that had never considered the issue in question.

“[W]hile a needless decision of law in one state is bad, creating law in nine states is beyond the pale,” the appeals court said.


U.S. Court in Florida Refuses to Dismiss FCA Retaliation Action Against Health System

A federal court in Florida refused September 8 to dismiss a False Claims Act (FCA) retaliation claim against a hospital and its parent health system. The U.S. District Court for the Middle District of Florida found the second amended complaint adequately stated the plaintiff engaged in protected conduct—i.e., internally reporting allegedly false and fraudulent Medicare and Medicaid billings to hospital and health system managers.
Plaintiff Brenda Farnsworth worked for Northside Hospital, a 288-bed teaching hospital, as Vice President of Quality and Risk Management for six-months in 2011 and 2012. HCA, Inc. is the parent corporation of Northside Hospital.

Farnsworth filed an FCA whistleblower action against the hospital and HCA after she was placed on administrative leave in February 2012, purportedly for insubordination. The federal government declined to intervene. Farnsworth later voluntarily dismissed the complaint, but later refiled and attempted to assert only an FCA retaliation claim under 31 U.S.C. 3760(h).

The court in May granted defendants’ motion to dismiss the complaint without prejudice, finding Farnsworth failed to demonstrate she engaged in protected conduct. Farnsworth v. HCA, Inc., No. 8:15-cv-65-T-24-MAP (M.D. Fla. May 29, 2015)

To state an FCA retaliation claim, a plaintiff must show she was acting in the furtherance of an FCA enforcement action or engaged in other efforts to stop violations of the FCA. Under 2009 amendments to the FCA, protected activity includes not only actions in furtherance of a potential or actual whistleblower lawsuit but also steps to remedy fraud through alternative means like internal reporting to a supervisor or compliance department.

In its previous decision, the court concluded that while Farnsworth generally alleged she voiced concerns about defendants’ billing practices, the complaint didn’t detail any specific actions she took to prevent or stop the alleged illegal activity.

Farnsworth filed a second amended complaint, and defendants again moved to dismiss. Denying the motion, the court found the second amended complaint remedied the previous defects in her retaliation claim.

Farnsworth alleged defendants routinely billed Medicare and Medicaid for treatments performed by medical interns in the absence of attending physicians; falsified medical records for procedures and services ordered by a suspended physician; “double billed” for unauthorized medical research; and fraudulently billed for medically unnecessary tests and treatments.

In her second amended complaint, Farnsworth also outlined specific instances where she internally reported the alleged incidents and practices to specific members of Northside Hospital’s and HCA’s management.

“These internal reports indicate an effort to stop or prevent continued violations of the FCA,” the court held.

Finding the other requirements for stating an FCA retaliation claim satisfied, the court declined to dismiss the complaint against Northside and HCA.

The court did agree, however, to dismiss the claim as to defendant Parallon Business Solutions, LLC, a subsidiary of HCA, which provides medical records personnel to Northside and is responsible for billing Medicare and Medicaid for services provided at the hospital.

According to the court, the second amended complaint included no allegations that Farnsworth made any internal reports of potential fraudulent billings to Parallon.


First Circuit Reverses Lower Court’s Refusal to Allow Amendment in FCA Action
The First Circuit reversed September 29 the dismissal of a False Claims Act (FCA) case, finding the lower court applied the wrong standard in its refusal to allow the relator to amend his complaint.

Relator Jeffrey D’Agostino filed a qui tam action against his former employer, ev3, Inc., and others alleging the company engaged in improper conduct in connection with the manufacturing and marketing of two medical devices (Onyx and Axium) and knowingly caused health care providers to submit false claims to various government entities.

The relator filed second and third amended complaints, and defendants timely filed motions to dismiss.

Defendants argued that the court lacked jurisdiction under the FCA's public disclosure bar, and that the third amended complaint failed either to state a cognizable claim or to plead fraud with sufficient particularity.

Four days before his opposition to the motions to dismiss was due, relator filed a fourth amended complaint. Defendants moved to strike the fourth amended complaint, and the district court granted the motion and dismissed the case with prejudice. *United States ex rel. D’Agostino*, No. CIV.A. 10-11822 (D. Mass. Sept. 30, 2014).

Relator appealed, arguing the district court improperly thwarted his efforts to amend his complaint.

According to relator, Fed. R. Civ. P. 15(a)(1) granted him an absolute right to file the fourth amended complaint. The appeals court noted, however, that Rule 15(a)(1) explicitly states that a party is entitled to amend "once as a matter of course."

The appeals court noted the lower court applied Fed. R. Civ. P. 16(b)'s more stringent "good cause" standard and found no good cause to allow amendment.

But the appeals court said the district court erred in applying Rule 16(b)'s good cause standard to the relator's proposed fourth amended complaint.

Instead, on remand, the lower court should apply Rule 15(a)'s “leave freely given standard,” the appeals court said.


**U.S. Court in Illinois Again Rejects Whistleblower Action Against Psychiatric Hospital Alleging Over Census Medicaid Billing**

The U.S. District Court for the Northern District of Illinois dismissed, with prejudice, a relator's amended qui tam complaint against a psychiatric hospital alleging it fraudulently billed Medicaid for inpatient care provided to patients who weren't given a room. In April, the court dismissed the original complaint without prejudice.

Relator George Bellevue works as a nursing counselor for defendant Universal Health Services of Hartgrove, Inc., (Hartgrove), a psychiatric hospital. Relator alleged Hartgrove violated the False Claims Act (FCA) and the Illinois False Claims Act by taking in more patients than it had authorized beds between December 3, 2008 and February 28, 2009.

Relator alleged that Hartgrove routinely houses new patients suffering from acute mental illness in “dayrooms” on “rollout beds” until a patient room is available.
According to relator, when Hartgrove sought Medicaid reimbursement for patients who were admitted beyond the facility’s authorized capacity, “Hartgrove knowingly submitted a false or fraudulent claim for that patient.”

In the amended complaint, relator also cited to the definition of “inpatient” in the Illinois Hospital Report Card Code, the definition of a “patient room” in the Illinois administrative code governing construction requirements for hospitals, and 42 C.F.R. § 441.150 to support his argument that inpatient claims submitted for patients not assigned a room are false in violation of the FCA.

Hartgrove moved to dismiss the amended complaint for failure to state a claim. Granting the motion, the court said relator’s new theory of liability “borders on frivolous.”

According to relator, Section 441.150 provides that patients who aren’t provided a room do not meet the definition of an inpatient. “But there is no such provision in that section of the regulations,” the court said.

And the Illinois administrative code provisions defining “inpatient” and “patient room” were “entirely unrelated to Medicaid payment conditions,” the court added.

The court also found relator provided no new allegations to support his previously rejected “worthless services” theory of liability.

Relator alleged that an individual room is an “essential requirement for inpatients being treated for acute mental illness.”

As noted in its earlier opinion, relator could not claim the services were worthless without alleging Hartgrove’s failure to provide a room destroyed the effectiveness of the treatment provided to those patients. Relator failed to cure this deficiency in his amended complaint, the court concluded.


**U.S. Court in Illinois Refuses to Dismiss Whistleblower Action Against Diagnostic Testing Facility**

A federal trial court in Illinois refused October 19 to dismiss a whistleblower action under the False Claims Act (FCA) against an independent diagnostic testing facility (IDTF) for allegedly submitting claims to federal health care programs for remote heart-monitoring services performed by non-U.S.-based technicians. Relator Matthew Cieszynski is a certified technician for defendant LifeWatch Services, Inc., an IDTF that provides remote heart-monitoring services for patients covered by Medicare, Medicaid, TRICARE, and the Veterans Administration Health Care.

According to relator, LifeWatch uses technicians in India, and/or non-certified technicians, to perform a substantial number of remote cardiac monitoring tests, including for patients covered by federal health care programs.

Relator alleged that LifeWatch regularly submitted reimbursement claims for work performed by foreign-based or non-certified technicians, which it then took steps to conceal by replacing the non-certified technician’s name on subsequently generated reports with LifeWatch technicians who were certified. Relator provided four examples in 2012 and 2013 of this alleged practice where Medicare was billed for the procedure, the opinion said.
Medicare prohibits reimbursement for services “which are not provided within the United States,” including diagnostic services that are performed remotely. 42 U.S.C. § 1395y(a)(4) and 42 C.F.R. § 411.9(a).

LifeWatch moved to dismiss the complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6) and for failure to plead fraud with particularity under Fed. R. Civ. P. 9(b).

The U.S. District Court for the Northern District of Illinois denied the motion, with the exception of the claims involving non-certified technicians.

According to the court, the complaint “plausibly alleges that Life Watch violated the FCA every time a claim was presented to [federal health care programs] for payment based on services that LifeWatch knew were not eligible for reimbursement.”

LifeWatch argued that it didn’t specifically certify its compliance with Section 1395y(a)(4) or Section 411.9(a). But the court said a “false presentment” claim does not include a certification requirement as a prerequisite of FCA liability.

In the court’s view, relator satisfactorily alleged that claims presented to federal health care programs on CMS Form 1500 were false, that LifeWatch knew the claims were not reimbursable and that government payers would deny them had they known the underlying service took place outside the United States.

Relator also sufficiently alleged a theory of FCA liability for express false certification, the court said. The court wasn’t persuaded that liability could not attach under this theory unless LifeWatch specifically certified compliance with the exact government statute or regulation requiring procedures take place in the United States by certified technicians.

“The Seventh Circuit has held that a promise like the one on Form 1500—to abide by all Medicare and Medicaid laws and regulations—is specific enough to support an express false certification theory of liability,” the court said.

The court also found relator’s claims would succeed under an implied false certification, rejecting LifeWatch’s contention that the Seventh Circuit foreclosed such a theory of liability. See United States v. Sanford-Brown, Ltd., 788 F.3d 696 (7th Cir. 2015).

The court distinguished the Sanford-Brown, saying unlike that case, the instant action involved conditions of payment, not participation, and the complaint alleged LifeWatch knew the claims were false at the time it submitted them for reimbursement.

The court did find, however, that Sanford-Brown foreclosed claims that LifeWatch was liable for using non-certified technicians because those requirements were part of the provider’s agreement to become an IDTF—i.e., a participation agreement—and were not a condition of payment.

Finally, the court held the complaint satisfied the Rule 9(b) pleading requirement, finding relator sufficiently alleged details to reasonable infer the fraudulent scheme.

U.S. Court in Idaho Won’t Dismiss FCA Action Alleging Physician Recruitment Agreement Violated Stark, AKS

The U.S. District Court for the District of Idaho refused September 28 to dismiss a False Claims Act (FCA) whistleblower action alleging a hospital and physician practice entered into physician recruitment agreements that violated the Anti-Kickback Statute (AKS) and Stark Law as implemented. Relator Dr. Jeffrey Jacobs initiated the qui tam action, in which the government declined to intervene, against his former employer, defendant CDS, PA, d/b/a Pocatello Women’s Health Clinic and Pocatello Hospital LLC, d/b/a Portneuf Medical Center, LLC, and its parent company.

Relator alleged defendants submitted claims to Medicare and Medicaid falsely certifying compliance with the Stark Law and AKS.

Specifically, relator contended that the hospital and clinic engaged in a scheme to illegally shift CDS’ overhead costs to the hospital in exchange for CDS making referrals to the hospital.

Relator alleged CDS recruited physicians to join its practice and then used hospital-subsidized income guarantees for overhead expenses that were unrelated to the additional incremental costs associated with the physicians.

According to relator, the allegedly prohibited financial relationship between the hospital and CDS made fraudulent every claim for Medicare or Medicaid reimbursement during his employment from August 2010 to May 2013.

Although relator failed to plead the correct standard for scienter, the court refused to dismiss his claim predicated on the AKS, finding the complaint plausibly gave rise to the inference that the hospital made payments that exceeded the actual additional incremental costs associated with his joining CDS. The court gave relator leave to amend his complaint and properly plead the scienter requirement under the AKS.

The hospital argued that the physician recruitment agreement was a “facially valid financial arrangement” and therefore FCA claims predicated on alleged Stark violations should be dismissed.

The court agreed that, on its face, the agreement complied with the physician recruitment exception to the Stark Law.

Relator alleged, however, that the agreement violated the Stark Law as implemented because the payments the hospital made to CDS exceeded the actual additional incremental costs attributed to relator.

In the court’s view, relator’s allegations sufficiently detailed, at this stage of the litigation, a potentially improper financial relationship between CDS and the hospital implicating Stark.

The court also refused to dismiss the complaint for failure to plead fraud with required particularity under Fed. R. Civ. Proc. 9(b).

CDS also claimed that relator failed to sufficiently plead false certification regarding Medicaid because the Medicaid provider agreement and Form CMS-1500 do not expressly require compliance with federal statutes as “a condition of payment.”

But the court pointed out that both the AKS and the Stark Law expressly condition payment of a Medicaid claim on compliance, even if the forms don’t include such a requirement explicitly.

**Fifth Circuit Upholds FCA Conviction**

The Fifth Circuit upheld October 23 a defendant’s False Claims Act convictions for conspiracy to commit health care fraud and conspiracy to pay and receive kickbacks, finding no error below. The government alleged that James Hunter recruited Medicare beneficiaries for services that were not medically necessary or were never provided and received and paid kickbacks.

Hunter contended on appeal that (1) the evidence was insufficient to prove he had the requisite knowledge to be convicted, (2) the district court abused its discretion when it instructed the jury on willful blindness, and (3) his lawyer rendered ineffective assistance of counsel.

The appeals court first found the evidence presented at trial “was sufficient to prove that Hunter had the requisite knowledge for conspiracy to commit health care fraud and conspiracy to pay and receive kickbacks.”

In so holding, the court reviewed the evidence, highlighting, among other things that Hunter met with co-conspirators after the government began investigating and told them that he would lie if questioned and that he had instructed patients to do likewise.

Viewed in the light most favorable to the government, that testimony “permitted the jury to infer that Hunter had the requisite knowledge,” the appeals court said.

The appeals court also found the lower court’s willful blindness jury instruction was “warranted” and refused to reach Hunter’s ineffective assistance of counsel claim because it was not raised before the district court.


**U.S. Court in Illinois Tosses FCA, Retaliation Claims as Untimely**

The U.S. District Court for the Northern District of Illinois dismissed October 30 with prejudice a relator’s action alleging False Claims Act (FCA) violations and retaliation, finding the claims time-barred. Ahmed Jajeh, MD, was employed as an attending physician in the Hematology and Oncology Department at John J. Stroger Hospital from December 1995 until April 2007, at which time he was terminated.

According to Jajeh, he observed Dr. Thomas Lad, who was Jajeh’s supervisor from at least 2004 until 2007, disbursing funds from National Institutes of Health (NIH)-issued research grants in a manner he believed was illegal and in violation of NIH policy.

Jajeh made internal complaints about these actions and also complained to the Federal Bureau of Investigation (FBI).

After his termination, Jajeh sued the hospital and others (defendants) for violations of the FCA and retaliation. Defendants moved to dismiss, arguing that Jajeh’s claims were time-barred.

The FCA provides that a relator must bring his claims within six years of a violation of the FCA or within three years of when the violation was or should have been discovered by an official of the government, whichever is later.
Jajeh’s fraud claim was time-barred, the court held, because the alleged fraud occurred prior to June 28, 2007, more than six years before the complaint was filed.

Jajeh maintained that the limitations period did not begin to run until after his last contact with the FBI in 2011, but the court rejected this argument, finding the statute clearly cites when the violation was committed as a reference for timeliness. Jajeh’s last contact with the FBI was irrelevant, the court said.

The court found Jajeh’s retaliation claim also time-barred for failing to allege any retaliatory acts that occurred within the three-year statute of limitations for FCA retaliation claims.

Jajeh argued his claim was saved by equitable estoppel, which tolls the statute of limitations for any period during which a defendant prevents a litigant from obtaining the information needed to file his claim. See *Jay E. Hayden Found. v. First Neighbor Bank, N.A.*, 610 F.3d 382, 385 (7th Cir. 2010).

But Jajeh’s retaliation claim ripened once alleged adverse employment actions were taken against him for investigating the fraud, even before he had all the information needed to confirm his suspicions, the court held.


**Tenth Circuit Affirms Dismissal of FCA Whistleblower Action Against Physician Group, Health System**

The Tenth Circuit affirmed October 28 the dismissal, with prejudice, of a qui tam action against a physician group and an affiliated health system, finding the relator failed to plausibly allege that Medicare payment was conditioned on compliance with any contract, statute, or regulation that required only physicians to obtain History of Present Illness (HPI) from patients during office visits. Relator Mark Troxler was a physician employed by defendant Warren Clinic (Clinic), a large physician group practice affiliated with defendant Saint Francis Health System.

Relator filed a qui tam action alleging defendants violated the False Claims Act (FCA) by allowing non-physician, unqualified personnel to obtain and record patients’ HPI and then billing Medicare and Medicaid as if they were performed by physicians. The United States declined to intervene. Defendants moved to dismiss.

The U.S. District Court for the Northern District of Oklahoma concluded that any theory of FCA liability based on factual falsity failed because nothing in relator’s complaint indicated claim forms required defendants to identify the individuals who performed the HPIs or that any information on the forms was false on their face.

The court also held that relator failed to plausibly allege FCA liability based on a false certification theory—either express or implied. *United States ex rel. Troxler v. Warren Clinic, Inc.*, No. 4:11-cv-00808-TCK-FHM (N.D. Okla. Nov. 5, 2014).

The Tenth Circuit affirmed, agreeing with the lower court that the complaint failed to allege the clinic submitted anything false to the government or that the services were not provided.

“[A]bsent allegations that the clinic was required to identify who collected HPI information, the complaint fails to state a factually false claim,” the appeals court said.
The appeals court also found the complaint failed to state a legally false claim. The complaint did not identify any expressly false certification or statement nor “a statute, regulation, or contract requiring that only physicians collect HPI information as a prerequisite of payment,” the appeals court said.

Absent underlying legal authority making compliance a prerequisite of payment, “there can be no false certification,” the appeals court observed.

While Troxler cited to *1997 Documentation Guidelines for Evaluation and Management Services*, the appeals court found no indication the guidelines “legally mandate and condition payment of services on a health-care provider’s certification that HPI information was collected exclusively by physicians.”


**Sixth Circuit Affirms Dismissal of FCA Retaliation Claim**

A divided Sixth Circuit panel affirmed summary judgment November 2 for a health care provider finding the plaintiff did not make out a prima facie case of retaliatory discharge under the False Claims Act (FCA) because she failed to demonstrate the reasonableness of her belief that the FCA was violated. As such, plaintiff failed to create a genuine issue of material fact that her actions constituted protected activity and therefore the FCA retaliation provisions did not apply, the appeals court held.

Plaintiff Sara Jane Jones-McNamara worked as Vice President for Corporate Compliance at Holzer Health Systems, Inc., a health care delivery system comprised of several hospitals and care facilities.

Shortly after starting work, McNamara began investigating allegations that Holzer’s dealings with a patient transport company called Life Ambulance violated the Anti-Kickback Statute (AKS). She voiced her concerns to superiors and shortly after was terminated.

McNamara sued alleging she was terminated in retaliation for her investigation of Holzer’s alleged FCA violations. The district court granted Holzer’s motion for summary judgment, citing lack of direct evidence of retaliation, and McNamara’s inability to prove that Holzer’s stated reasons for her termination were pretextual.

The appeals court affirmed, but on different grounds.

According to the appeals court, the district court assumed McNamara had stated a prima facie case in holding she failed to rebut Holzer’s non-discriminatory reasons for her discharge with evidence of pretext. But the appeals court found McNamara did not establish a prima facie case because she failed to create a genuine issue of material fact as to whether she engaged in protected activity.

In *McKenzie v. BellSouth Telecommunications, Inc.*, 219 F.3d 508, 516 (6th Cir. 2000), the Sixth Circuit held that internal reports “may constitute protected activity,” provided such internal reports “allege fraud on the government.”

“Although McNamara need not establish that Holzer actually violated the FCA, she must show that her allegations of fraud grew out of a reasonable belief in such fraud,” the appeals court said.

McNamara claimed her emails to Holzer senior management constituted protected activity because they alleged violations of the AKS that also violated the FCA. But, “[e]ven if we assume that McNamara had a subjective, good faith belief that Holzer employees accepted remuneration as an
inducement to refer patients to Life, this belief was not objectively reasonable based on the facts in McNamara’s knowledge at the time she reported AKS violations to other upper management,” the appeals court held.

According to the court, McNamara identified only two gifts delivered to Holzer employees—one jacket and some hotdogs and hamburgers at an annual health and wellness fair. “It cannot plausibly be suggested that one jacket valued at $23.50 . . . and occasional servings of hotdogs and hamburgers . . . could induce a reasonable person to prefer one provider over another,” the appeals court said.

These items represent such a low monetary value they clearly would be characterized as “token” gestures of good will under relevant Department of Health and Human Services Office of Inspector General guidance, the appeals court noted.

In addition, the appeals court pointed out that McNamara presented no evidence to suggest a connection between the gifts and the referrals.

A dissent argued that McNamara’s belief arose in the context of an ongoing investigation, and “was not unreasonable as a matter of law.”

Summary judgement is inappropriate because a jury should assess whether McNamara’s belief was reasonable, the dissent argued.


**U.S. Court in New Jersey Rejects Whistleblower Action Against Makers of Cancer Drug**

A federal court in New Jersey dismissed a whistleblower action against defendants Genentech, Inc. and Hoffman La-Roche Inc. alleging their regulatory submissions for the cancer drug Avastin were based on patient databases that didn’t give a full picture of the drug’s safety risks. The U.S. District Court for the District of New Jersey found relator Gerasimos Petratos, who was Global Head of Healthcare Data Analytics for defendants, failed to show the existence of any false claims for purposes of liability under the False Claims Act (FCA).

Relator alleged “defendants’ data deficiencies were the result of an intentional campaign to maximize profits by suppressing clinical and epidemiological information” for Avastin, one of the world’s highest-grossing cancer drugs that works by preventing the growth of blood vessels that feed tumors.

Relator also alleged defendants failed to report adverse events promptly to the Food and Drug Administration (FDA).

According to relator, if defendants revealed the complete information about Avastin, many physicians would have considered the additional risks before prescribing the drug, and federal and state health care programs would have reimbursed far fewer indications, for lower dosages, or not at all.

*No Factually False Claim*
The court first found that relator failed to show any factually false claims based on the “reasonable and necessary requirement.”

The court noted defendants’ submissions to the FDA to get Avastin approved, as well as its submissions to the third-party compendia, “are not claims for payment.” The only claims to Medicare and Medicaid that potentially could have been false were those made by physicians.

Most courts hold that it is the agency, not the individual physicians, that determine what is “medically reasonable and necessary” under the regulations.

Agreeing with those decisions, the court said the complaint didn’t allege the Centers for Medicare & Medicaid Services would have changed its reimbursement schedule or that any compendia would have changed its support for any Avastin indication. “Thus, Avastin would have legally still been reasonable and necessary for the uses at issue,” the court reasoned.

**Implied False Certification Theory Fails**

The court also held relator failed to allege an implied certification theory of FCA liability based on defendants’ claimed regulatory violations—reliance on self-serving data sources; inadequate examination or reporting of dose-related effects of Avastin; and delay in reporting adverse events.

These regulations are not preconditions of payments, dooming relator’s implied certification claim, the court said.

**Fraud on Compendia**

Next, the court rejected relator’s fraud on the compendia theory of FCA liability.

“A false statement is not the same as a false claim for payment,” the court said. “Congress used particular words, and this statutory scheme is not a broad-based consumer protection statute designed to punish generalized wrongdoing.”

Finally, the court held the complaint’s allegations “do not plausibly show that Defendants were obligated to pay funds to the Government,” for purposes of showing reverse false claims.


**U.S Court in Tennessee Tosses FCA Claims**

The U.S. District Court for the Middle District of Tennessee dismissed November 5 with prejudice a relator’s claims that her employer violated the False Claims Act (FCA), finding the claims lacked sufficient particularity to pass muster under Fed. R. Civ. P. 9(b). Relator Marjorie Prathera, who was employed as a Utilization Review Nurse by defendant Brookdale Senior Living, Inc., alleged in her qui tam suit that Brookdale submitted requests for anticipated payment (RAPs) that violated Medicare conditions related to plans of care orders, which she alleged contained primary diagnoses (to justify home health care billable to Medicare) that were inconsistent with the care actually provided to the patient.

In addition, she alleged that a large number of the claims were for therapy and home health care services that were not provided under a properly physician-document plan of care, and face-to-face encounter documentation was often incomplete, or was not completed until after the care was provided.
Specifically, relator’s second amended complaint alleged that defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment for both RAPs and final episode billing claims. The amended complaint also alleged reverse false claims.

Defendants moved to dismiss, arguing relator failed to satisfy her Rule 9(b) pleading-with-particularity obligations.

Defendants first contended relator did not plead the presentment of the RAPs as false claims with sufficient specificity.

The court agreed, noting that while relator did present evidence to show the individuals for whom she alleged false RAPs were submitted, “the remainder of the necessary information is missing.”

“It is insufficient for Prather to point to a patient that received home health care services and allege that a RAP was, or must have been, submitted, by some corporate authorization, for some amount, at some date around the date of treatment, and that some payment was likely received in return from the government, based just on the generally delineated circumstances of the patient’s receipt of home health services from a defendant entity,” the court said.

Although the court found relator’s final episode payment claims were sufficiently pled as to presentment, she could not point to an express certification made by the defendants that they were in compliance with the Medicare rules at issue.

In dismissing the remainder of the claims, the court found relator did not allege a violation of Medicare regulations or laws concerning physician plan of care signed documentation, final episode payment claims, or face-to-face physician encounter documentation sufficient to plead legal falsity under Rule 9(b).


U.S. Court in Connecticut Dismisses Whistleblower Action Against Ambulance Company

A federal district court dismissed November 6 with prejudice a whistleblower action alleging American Medical Response, Inc. (AMR) violated the False Claims Act (FCA) by submitting claims to Medicare and Medicaid for ambulance transports that weren’t reimbursable. According to whistleblower Paul Fabula, who formerly worked as an emergency medical technician (EMT) at AMR’s New Haven, CT location, the company often instructed EMTs and paramedics to alter patient care reports (PCRs) to make it appear an ambulance transport was “medically necessary” so the run would qualify for Medicare reimbursement.

The complaint, which was refiled by Fabula’s bankruptcy estate (plaintiff) after his initial action was dismissed on standing grounds, described a number of instances where Fabula, or other EMTs and paramedics, allegedly were asked to change PCRs so the transport at issue would qualify for Medicare coverage.

Citing Fed. R. Civ. P. (9)(b), the U.S. District Court for the District of Connecticut dismissed the complaint, saying it failed to plead any “factual detail regarding actual requests for payment submitted to the government.”
The complaint included “no specification of invoice numbers, invoice dates, or amounts billed or reimbursed,” the court said. “In short, [the complaint] alleges no facts indicating that the medically unnecessary ambulance services it describes were actually billed to a government payor.”

Plaintiff sought to invoke the more “relaxed” pleading standard for Rule 9(b), arguing that the billing information needed to show the actual submission of false claims was in the custody and control of AMR.

But the court said the complaint didn’t satisfy even the relaxed standard because it failed to plead the factual basis for relator’s belief that Medicare was billed for the transports at issue. In fact, the court continued, the allegations in the complaint actually suggested that many of the transports AMR provided were not billed to the government, noting that only 40% to 70% of the New Haven location’s runs were billed to Medicare.


U.S. Court in California Allows FCA Claim Alleging Referral Scheme to Proceed Against SNF CEO

A federal district court declined to dismiss a False Claims Act (FCA) whistleblower action alleging the chief executive officer (CEO) of North American Health Care, Inc. (NAHC) directed a scheme to provide kickbacks to physicians so they would steer acute care patients to the provider’s skilled nursing facilities (SNFs) and “regenerate” patients’ eligibility for Medicare payments. The U.S. District Court for the Northern District of California found relator John Orten, who formerly worked for NAHC, plausibly alleged that the CEO implemented a referral and regeneration scheme that resulted in the submission of false claims to Medicare.

The court did dismiss, however, relator’s other FCA claims against the CEO, including one alleging that the CEO and other NAHC managers illegally inflated its Medicare star ratings.

Relator alleged two main schemes naming NAHC and its CEO Sorensen as defendants. First, he alleged that defendants paid physicians to dispute deficiencies found at the SNFs and misreported staffing levels to obtain higher star ratings.

Second, relator contended NAHC, directed by Sorensen, provided illegal and excessive remuneration to physicians who served on its facilities’ boards—disguised as consulting fees, compensation, and gifts—for referring Medicare patients to NAHC. As part of the scheme, physicians also were encouraged to “regenerate” Medicare coverage by having patients who had exhausted their 100 days of skilled nursing coverage needlessly be readmitted to acute care hospitals for three days and then sent back to NAHC facilities, allowing for compensation at a higher Medicare rate.

As evidence of the scheme, relator said NAHC’s overall percentage of Medicare patients exceeded the statewide and national averages.

Sorensen moved to dismiss the FCA claims against him and was partially successful. The court agreed with Sorensen that relator failed to state an FCA claim based on the star ratings allegations.
Relator didn't allege a sufficient relationship between the star ratings, allegedly procured through bribes to physicians and inflated staffing data, and any false claim for payment submitted by NAHC, the court said.

In addition, while relator may have alleged NAHC engaged in fraudulent conduct related to the surveys that determined its star ratings, the regulations at issue at most related to conditions of participation, not payment, and therefore any alleged violations of them were not actionable under the FCA, the court concluded.

The court nonetheless allowed relator leave to amend the claims to identify any conditions of payment that may have been violated.

The court also dismissed relator’s claims of conspiracy and retaliation. As to the latter claim, the court found Sorensen, as CEO, was not relator’s “employer,” even under the amended version of the FCA’s “retaliation” provision.

The court did find, however, the complaint sufficiently alleged that Sorensen directed an illegal referral and regeneration scheme at NAHC.

While relator did not allege facts showing Sorensen personally approved kickbacks to any specified physicians or that particular false claims were submitted, the court found this level of detail wasn’t necessary to meet the Fed. R. Civ. P. 9(b) particularity requirement.

Relator provided specific examples of alleged kickbacks being provided by NAHC facilities and other examples of the scheme being carried out. He also pointed to statistics demonstrating the alleged scheme resulted in a “stark statistical shift” in the percentage of Medicare patients at NAHC.

“While none of these examples alone would be sufficient under 9(b), taken together they plausibly support Orten’s assertion that Sorensen implemented a referral and regeneration scheme and that false claims were actually submitted,” the court held.


U.S. Court in Alabama Says Government Must Show More Than Difference of Opinion to Prove Falsity in FCA Action

A federal trial court in Alabama granted November 11 a hospice provider’s motion for a new trial in a False Claims Act (FCA) case alleging it knowingly submitted false claims to Medicare for patients who were not terminally ill.

The court found reversible error in its jury instruction that left out two key points—that “the FCA requires ‘proof of an objective falsehood’” and “a mere difference of opinion, without more, is not enough to show falsity.”

In granting the new trial, the court also indicated it would consider, sua sponte, granting the hospice provider summary judgment, questioning whether “under the correct legal standard,” the government had “sufficient admissible evidence of more than just a difference of opinion to show that the claims at issue are objectively false as a matter of law.”

The FCA whistleblower action, in which the government intervened, alleged that AseraCare Inc. submitted false claims to Medicare by certifying patients as eligible for hospice who did not have a prognosis of “a life expectancy of 6 months or less if the terminal illness runs its normal course,” as specified in Medicare regulations. 42 C.F.R. § 418.22(b)(1).
In May, the court decided to bifurcate the trial into two phases: one on the falsity element of the government’s claims and a second on all other issues, including knowledge and damages.

To show falsity, the government relied on testimony of its medical expert and the patients’ medical records. The expert testified that based on his clinical judgment, the 123 sample of patients at issue were ineligible for hospice care.

The court instructed the jury “[a] claim is ‘false’ if it is an assertion that is untrue when made or used” and “[p]ractices that may be improper, standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare.”

Following a ten-week trial, the jury found AseraCare submitted false claims for 104 patients during all or some of their hospice stays.

The court concluded its jury instructions, while correct statements, were incomplete and for that reason amounted to reversible error.

“The case law, the regulations, and even the testimony of the Government’s witnesses support the court’s conclusion that it should have instructed the jury that a mere difference of opinions among physicians, without more, is insufficient to show falsity under the False Claims Act,” the opinion said.

The court said before setting a new trial date, it would first consider whether summary judgment was appropriate given that the government “consistently maintained” its only evidence for proving falsity was the expert’s testimony and the medical records of the patients at issue.


**Ninth Circuit Says Health Care Fraud Is Continuing Offense, May Be Charged as Single Scheme**

The Ninth Circuit, on a matter of first impression, held December 3 that health care fraud in violation of 18 U.S.C. § 1347 is a continuing offense that may be charged as a single scheme in a single count. Defendant Dr. Curtis Holden, a podiatrist, owned Advanced Podiatry Specialists, PS, in Yakima, WA.

The government initially charged Holden in a 59-count indictment with health care fraud and “false statements relating to health care matters.” Holden moved to dismiss 16 of the health care fraud counts, which stemmed from a single visit to a nursing home, as being outside the five-year limitations period.

The district ruled that health care fraud may be a continuing offense, but could not be where the government charged each alleged fraudulent act as a separate count. The court therefore dismissed those counts without prejudice.

The government then filed a second superseding indictment, consolidating the 16 counts into one revised count, alleging a continuing scheme to defraud. The court this time rejected Holden’s motion to dismiss.

Following his conviction, Holden appealed, arguing, among other things, that the revised count should have been dismissed for violating the statute of limitations.

Citing Fifth Circuit precedent, *United States v. Hickman*, 331 F.3d 439 (5th Cir. 2003), the Ninth Circuit found health care fraud in violation of Section 1347 is a continuing offense.
The one remaining question, the appeals court said, was whether the government could charge the multiple acts completed regarding the 2006 nursing home visit together as a single scheme to avoid the statute of limitations.

In the Ninth Circuit’s view, while the government could have charged the fraudulent claims as multiple counts, it also was not precluded from charging them in a single count.

“So long as the 'indictment was written so as to allege only one execution of an ongoing scheme,' . . . we hold that the government may charge a single health care fraud scheme in violation of 18 U.S.C. § 1347 even when several acts in furtherance of the scheme fall outside the statute of limitations,” the appeals court said.

Rejecting Holden’s other arguments, the appeals court affirmed his conviction on 32 counts of health care fraud.


**U.S. Court in Texas Tosses Kickback Allegations in FCA Action Against Drug Maker**

Solvay Pharmaceuticals, Inc. (SPI) continued to chip away at a False Claims Act (FCA) whistleblower action filed against it, obtaining a partial summary judgment ruling in the U.S. District Court for the Southern District of Texas on all of relators’ claims based on violations of the Anti-Kickback Statute. The court found relators—John King and Tammy Drummond, who formerly worked for SPI as district sales managers—failed to present sufficient evidence of a nationwide kickback scheme to induce physicians through honoraria, consulting fees, and other gifts to prescribe three of the company’s drugs: AndroGel, Aceon, and Luvox.

Relators could not “survive summary judgment on their multi-state multi-year kickback scheme theory with evidence relating to a confined list of physicians who allegedly received remuneration from the defendant in one state.”

Relators examples of the alleged kickback scheme were limited to 46 physicians in Texas, the court noted. “Since Relators provide no examples outside of Texas, the multi-state claims fail,” the court said.

SPI also argued it was entitled to summary judgment as to the 46 Texas physicians who allegedly wrote prescriptions tainted by kickbacks, thereby causing the submission of false claims to the state’s Medicaid program.

The court found insufficient evidence of causation for most of the physicians on the list. For example, the court noted the temporal link between some of the alleged kickbacks and the submission of a claim for payment was too attenuated.

Although there was enough evidence of causation for at least some of the listed physicians to survive summary judgment, the court agreed with SPI that the complaint failed because it included no evidence that “the programs in which the physicians received payments were crafted with the *intent* that the physicians receiving payments would write prescriptions” for the drugs. (Emphasis added).

“While a jury could possibly infer that these payments caused the physicians to prescribe the Drugs at Issue for payments that are close in time to the prescriptions, there has been no evidence presented that would allow a reasonable juror to conclude that SPI intended for the payments to the
physicians linked to claims data to result in prescriptions for the Drugs at Issue,” the court concluded.


Eleventh Circuit Affirms Dismissal of Whistleblower Action for Failure to Plead False Claim Submission

The Eleventh Circuit agreed December 10 with a lower court decision to dismiss with prejudice a whistleblower action under the False Claims Act against Lincare, Inc., an oxygen respiratory company, for failing to plead fraud with particularity as required by Fed. R. Civ. P. 9(b). The whistleblower in the case, Willie Britton, worked for Lincare delivering nebulizers to patients. Britton alleged that, although he wasn’t trained to do so, he also often performed demos for operating the equipment, despite internal Lincare guidelines providing that only licensed clinicians provide patient educational services.

According to Britton, Lincare only employed one certified respiratory therapist in the Birmingham area, which wasn’t enough to serve all their patients.

Britton alleged “[u]pon information and belief” that Lincare billed Medicare and Medicaid for the patient education services that he performed.

The district court granted Lincare’s motion to dismiss, finding Britton failed to plead the actual submission of a false claim. The court granted the motion with prejudice and without leave to amend because Britton did not attach a copy or otherwise set forth the substance of a proposed amended complaint.

Citing its precedent, the Eleventh Circuit said a whistleblower is not permitted “merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegally payments must have been submitted, were likely submitted or should have been submitted.”

According to the appeals court, “Britton is unable to muster any facts tending to show that Lincare asked the Government to pay amounts it does not owe.” Britton did not claim any knowledge as to Lincare’s billing practices, and did not allege the “who,” “what,” “where,” “when,” and “how” of fraudulent submissions to the government.

The appeals court also found the district court did not abuse its discretion in denying Britton an opportunity to submit an amended complaint before dismissal.


U.S. Court in Missouri Says No Punitive Damages for FCA Retaliation

Joining a number of other courts to consider the issue, the U.S. District Court for the Eastern District of Missouri held December 21, 2015 that punitive damages aren’t recoverable under the False Claims Act (FCA).

The issue arose in the context of a lawsuit brought by plaintiff Jennifer Gierer against her former employer defendant Rehab Medical, Inc. asserting a claim for FCA retaliation.
Gierer was a sales representative for Rehab Medical, which supplies electric-motorized wheelchairs. Gierer alleged she was subject to retaliation in violation of the FCA after she raised concerns about the company’s alleged falsification of Medicare documentation.

Rehab Medical moved to dismiss her request for punitive damages, and the court agreed.

According to the court, the “prevailing analysis” is that Congress refused to enact the FCA with a punitive damages provision, which was omitted in the final version of the 1986 amendments to the statute, and “the plain meaning of the FCA does not authorize punitive damages.”

The court also held, however, that Gierer could assert a claim for wrongful discharge in violation of public policy under Missouri law.

Rehab Medical argued the FCA preempted a state-law wrongful discharge claim, but the court disagreed, declining to find the FCA was sufficiently comprehensive to infer congressional intent to displace state law.

In this case, Gierer’s retaliatory discharge claim was based on Rehab Medical’s alleged retaliatory response to her efforts to expose FCA violations, the court observed. Her wrongful discharge claim rested, however, on alleged violations of other federal and state statutes.

Because Gierer’s wrongful termination claim “seeks to remedy a different wrong,” the court found no FCA preemption.


**U.S. Court in Illinois Allows Whistleblower to Pursue Constructive Retaliatory Discharge Claim**

The U.S. District Court for the Southern District of Illinois allowed December 18, 2015 a whistleblower to pursue his federal constructive retaliatory discharge claims against his former employer. In so holding, the court deemed defendants’ statute of limitations argument waived after finding they neglected to acknowledge the limitations period they sought to enforce was enacted after the suit was filed.

Plaintiff Bryan Carnithan worked at Heartland Regional Medical Center as the EMS coordinator in the emergency department. During his employment, Carnithan voiced his concern to the chief executive officer of the hospital about its alleged practice of admitting all Medicare and Medicaid recipients who came to the emergency room regardless of whether it was reasonable or necessary.

Following that conversation, Carnithan alleged he was moved into a much smaller office and believed he was ultimately going to be terminated. He resigned from his position in September 2006.

In April 2011, Carnithan filed a qui tam suit alleging that Heartland and more than 100 other hospitals affiliated with defendant Community Health Systems, Inc. (CHS) submitted false claims or statements to Medicare and various state Medicaid programs. Carnithan also alleged he was constructively discharged from his job at Heartland in retaliation for questioning the fraudulent admission practice.

The United States elected to intervene in part and a settlement was reached. The instant opinion resolves Carnithan’s remaining claims for retaliatory discharge under the federal False Claims Act (FCA) and the Illinois FCA.
The court first dismissed sua sponte Carnihan’s retaliatory discharge claim under the common law of Illinois, finding the state did not recognize a cause of action for retaliatory constructive discharge.

Defendants also argued Carnihan’s federal FCA claim was time-barred under the three-year limitation periods for retaliation claims because his claim accrued in September 2006 but he didn't file suit until April 2011.

The court pointed out that defendants neglected to mention that the federal FCA was amended to add the three-year limitations period in July 2010, and that the Illinois FCA was not amended until August 2012.

At the time Carnihan's claims accrued in September 2006, his claims would have been subject to the five-year catch-all statute of limitations under Illinois law, the court said.

Because defendants “wholly ignored nuances crucial to their statute of limitations argument,” the court deemed the issue waived.

The court next rejected defendants’ argument that Carnihan failed to state a claim for retaliatory discharge.

CHS and defendant Community Health Systems Professional Services Corp. (CHSPSC) argued that they could not be liable to Carnihan for retaliatory discharge because he did not allege he was employed by them; instead; he alleged he was employed by a subsidiary company that ran Heartland.

The court observed that CHS owns more than 100 subsidiary companies that in turn own and operate hospitals around the country. All of the hospitals are managed and operated by subsidiary company CHSPSC.

Carnihan specifically alleged that CHSPSC provided management services and controlled the daily operations of Heartland, and that CHS was the parent company of CHSPSC and directed its operations, the court noted.

According to the court, Carnihan sufficiently alleged “an employment-like relationship” with CHSPSC and CHS Inc. for purposes of his retaliatory discharge claims.


First Circuit Revives FCA Whistleblower Suit Against PharMerica

The First Circuit vacated December 16, 2015 the dismissal of a whistleblower action under the False Claims Act (FCA) against PharMerica Corporation and remanded to the lower court to determine whether the relator should be allowed to supplement his complaint to account for intervening legal developments.

The lower court previously dismissed relator Robert Gadbois' qui tam suit for lack of subject matter jurisdiction, finding the first-to-file bar applied because an earlier action filed in a Wisconsin federal district court asserted essentially the same allegations of fraud.

But since that initial determination, an intervening Supreme Court decision, and the settlement of the action in Wisconsin, removed the jurisdictional impediment to Gadbois' action, the First Circuit noted.
The appeals court agreed to vacate the dismissal, but refused to order that Gadbois could supplement his pleading with those developments, noting a determination to allow supplementation should be left to the lower court’s discretion under Fed. R. Civ. P. 15(d).

Gadbois, who worked as a pharmacist for PharMerica, filed the qui tam action in a Rhode Island federal district court in November 2010. He alleged PharMerica improperly distributed prescription drugs to long term care facilities resulting in FCA violations.

The government declined to intervene, and Gadbois filed a second amended complaint in February 2014. PharMerica moved to dismiss, arguing the instant lawsuit was barred under the FCA’s first-to-file provision because of an earlier-filed qui tam action that was pending in the Eastern District of Wisconsin.

The district court in an October 2014 unpublished opinion agreed with PharMerica that Gadbois’ lawsuit was jurisdictionally barred. Gadbois appealed.

Two key developments happened while the appeal was pending. The Supreme Court issued its decision in *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015), which held the FCA’s first-to-file bar applies only where related claims are still active, not in perpetuity. Shortly thereafter, the Wisconsin action settled, with PharMerica agreeing to pay $31.5 million to resolve the allegations in that case.

Gadbois argued these developments materially altered the landscape of his case, since the Wisconsin action was no longer “pending,” which *Carter* clarified was required for the first-to-file bar to apply. He asked to supplement his complaint pursuant to Rule 15(d).

PharMerica contended, however, that jurisdiction is determined based on whether it existed at the time of the original complaint and therefore Gadbois couldn’t avail himself of supplemental pleading under Rule 15(d).

The First Circuit rejected PharMerica’s approach, saying Rule 15(d) could be used to cure jurisdictional deficiencies.

“[W]e think it manifest that the relator’s case is well suited to a motion for leave to supplement. Developments occurring after the filing of the second amended complaint—the *Carter* decision and the dismissal of the Wisconsin action—have dissolved the jurisdictional bar that the court below found dispositive,” the appeals court observed.

The appeals court refused, however, to bypass the district court in deciding to allow supplementation. The district court should make this initial determination pursuant to its discretion to do so under Rule 15(d).


**U.S. Court in Massachusetts Nixes Whistleblower Suit Against Medical Device Makers**

A federal district court in Massachusetts refused December 30, 2015 to allow a whistleblower to amend his complaint for a fifth time in his action against medical device companies and two executives.

Relator Jeffrey D’Agostino was a former medical device salesman for defendant EV3, Inc., which manufactures the two devices at issue in the qui tam case—Onyx Liquid Embolic System (Onyx)
and Axium Detachable Coil System (Axium). Both were developed by Micro Therapeutics, Inc. (MTI), which later merged with EV3.

The FDA approved Onyx in 2005 for the presurgical treatment of a specific vascular defect. Axium was first marketed in 2007 for embolizing intracranial aneurysms and other neurovascular anomalies.

Relator initiated the qui tam action in October 2010 on behalf of the United States, 26 states, and the District of Columbia, all of which declined to intervene.

Relator alleged MTI misled the Food and Drug Administration (FDA) during the Onyx approval process and later marketed the device to treat other types of vascular disease beyond the single, approved indication. According to relator, after Onyx was approved, MTI, and then EV3, marketed the device for off-label uses. For example, relator alleged defendants conducted a surgical training program at hospitals with no physicians on staff with practices requiring the on-label use of the device.

According to relator, because defendants fraudulently obtained the FDA’s approval for Onyx, all off-label reimbursement claims were tainted.

As to Atrium, relator alleged EV3 hurried the development of the device, resulting in a product that was improperly manufactured and not safe for use. Relator alleged that EV3 was marketing medical devices that were eligible for Medicare reimbursement only because the government was in the dark about their defects.

In September 2014, the U.S. District Court for the District of Massachusetts dismissed the complaint, finding the FCA’s public disclosure provision barred relator’s “fraud-on-the-FDA” allegations that MTI omitted safety information and misrepresented the substance of its training program. The court also found relator’s off-label marketing claims, though not barred under the public disclosure provision, were deficient under Fed. R. Civ. P. (9)(b). United States ex rel. D’Agostino, No. CIV.A. 10-11822-RGS (D. Mass. Sept. 30, 2014).

The court rejected relator’s motion to file a fourth amended complaint. But in September 2015, the First Circuit held the district court applied the wrong standard in refusing to allow relator to amend. United States ex rel. D’Agostino v. EV3, Inc., No. 14-2145 (1st Cir. Sept. 30, 2015).

On remand, the court in the instant opinion found relator’s proposed amended complaint still was deficient and therefore allowing further amendment would be futile.

The court again held the public disclosure bar applied to claims involving the FDA’s approval of Onyx and to the training program.

The court also held the proposed amended complaint didn’t clear the Rule (9)(b) pleading hurdle with respect to the alleged off-label marketing of Onyx or that all claims for Axium were false because the product was defective per se.

According to the court, these claims failed because relator did not show the actual submission of a false claim to the government.


**Seventh Circuit Tosses FCA Action Alleging Medical Supplier Paid Kickbacks to Nursing Homes**
The Seventh Circuit affirmed January 4 the dismissal of a qui tam action alleging Medline Industries, Inc., a national distributor of medical-surgical supplies, violated the False Claims Act (FCA) by using various “kickbacks” and “bribes” to solicit business from nursing homes.

The appeals court agreed with the U.S. District Court for the Northern District of Illinois that the allegations were disclosed publicly in a prior suit against Medline. The fact that the relator named another defendant, the Tutera Group, a chain of nursing homes, in his qui tam action and alleged fraud against other federal health care program wasn’t enough to avoid dismissal.

Relator August Bogina brought the whistleblower action alleging Medline gave bribes and kickbacks—in the form of cash payments and rebates—to the Tutera Group to induce it to purchase from Medline. Tutera then allegedly would submit claims to the government for reimbursement that reflected the full price of the product despite having received a discount or rebate.

According to Bogina, he learned of the alleged fraud through his business associate who was a former member of Tutera’s ownership group.

Four years before Bogina brought his suit, Sean Mason, an employee of Medline, initiated a similar action alleging Medline gave bribes and kickbacks to purchasers—primarily hospitals—of its medical equipment. Medline eventually settled the lawsuit for $85 million.

The court dismissed Bogina’s action, finding it was based on allegations that were publicly disclosed in Mason’s lawsuit.

The Seventh Circuit agreed, rejecting Bogina’s attempt to distinguish his case from the prior lawsuit.

Bogina argued that Mason’s complaint mainly alleged that Medline’s bribery and kickback scheme involved hospitals paid under Medicare Part A, not nursing homes that submitted claims to Medicare Part B and TRICARE.

Calling these differences “unimpressive,” the appeals court said it was common knowledge that Medline supplied both hospitals and nursing homes.

“Bogina is not allowed to proceed independently if he merely ‘adds details’ to what is already known in outline,” the Seventh Circuit noted. Neither the addition of Tutera, nor allegations that the fraud involved Medicare Part B and TRICARE, added “materially” to the publicly disclosed allegations.

Bogina also contended that the alleged fraud continued beyond the settlement of Mason’s lawsuit. Those allegations, the appeals court noted, are based “on information and belief,” which isn’t enough to state a fraud claim.


U.S. Court in Missouri Finds Qui Tam Suit Barred by Public Disclosures

The U.S. District Court for the Eastern District of Missouri dismissed January 20 a qui tam action, finding the basis for the relator’s claims were publicly disclosed and therefore barred under the False Claims Act’s public disclosure provision.

Relator Shane Lager worked for defendant drug manufacturer CSL Behring in sales and sales management. He alleged that CSL Behring, LLC, and its parent corporation CSL Behring Limited (collectively, CSL Behring) conspired with specialty pharmacies Accredo Health, Inc. and Coram LLC to submit false claims for prescription drug reimbursement.
According to the complaint, CSL Behring manufactures durable medical equipment (DME) infusion drugs Vivaglobin and Hizentra. Such drugs are reimbursed based on a percentage of the drug’s average wholesale price (AWP).

Relator alleged that CSL Behring reported inflated wholesale prices and, as a result, the AWPs for Vivaglobin and Hizentra were established at $133 and $151 respectively, while the pharmacies actually paid between $65 and $70.

The suit alleged that CSL Behring uses the "spread" between the actual cost and the AWP-based reimbursement rates to induce their customers, including Accredo and Coram, to buy their products and that Accredo and Coram sought out patients covered by government health programs to take advantage of the spread.

In addition to multiple public disclosures regarding DME infusion drugs generally, specific public disclosures have been made regarding the AWP for Vivaglobin and Hizentra specifically, the court noted.

Relator argued his suit should not be barred because none of the public disclosures contained all of the elements of the alleged fraudulent transactions. The court found, however, that the disclosures only must be sufficient to alert the government to the likelihood of fraud by a particular actor. Relators’ claims only survived if he was an "original source."

Relator argued that he had firsthand knowledge of the "actual sales prices" for Vivaglobin and Hizentra, but such prices were readily available in publicly disclosed information, the court said. "Relator's information does not materially add to the vast amounts of information available in public disclosures," the court added.

The court also found the complaint "void of a single, specific instance of fraud, much less any representative examples," and thus held relator also failed to satisfy Fed. R. of Civ. P. 9(b).

The court denied relator an opportunity to amend his complaint.


U.S. Court in Kentucky Holds Pharmacist's Exclusion from Medicare, Medicaid Didn't Violate Due Process

Although not addressed by the Sixth Circuit, a federal district court in Kentucky agreed with several other federal appeals courts that providers don’t have a property interest federal health care program participation.

The ruling comes in an action brought by pharmacist Leo Parrino, who was excluded from participating in Medicare and Medicaid for five years after he pled guilty to a misdemeanor misbranding offense.

Parrino argued the Department of Health and Human Services Office of Inspector General (OIG) violated his due process rights by exercising its mandatory exclusion authority under 42 U.S.C. § 1320a-7(a) because the underlying conviction for misbranding was a strict liability offense that didn’t require proof he knew the drug was misbranded.

The U.S. Court for the Western District of Kentucky acknowledged some disagreement among the federal courts as to whether a provider has a property interest in participating in federal health care programs.
While the Second and Fourth Circuits ruled providers do have a property interest in continued participation in federal health care programs, the First, Ninth, and Tenth Circuit have held otherwise.

The court here agreed with the First, Ninth, and Tenth Circuit in finding Parrino had no property interest in his Medicare and Medicaid participation.

Parrino also argued he had a liberty interest in maintaining his good name and professional reputation, which the OIG exclusion significantly affected, resulting in the loss of his job as a pharmacist and limiting his ability to work in the health care field.

But the court rejected Parrino’s claim of a constitutionally protected liberty interest, noting no allegations that OIG publicly disclosed his exclusion.

Finally, the court held OIG’s decision to exclude Parrino under the mandatory exclusion provision, rather than the “permissive” exclusion provision, 42 U.S.C. § 1320a-7(b), did “not constitute ‘official egregious conduct’ that is ‘arbitrary in the constitutional sense.’”

In the court’s view, Parrino’s five-year exclusion did not “shock the conscience.”


**U.S. Court in Florida Says Government’s FCA Allegations Against Ambulance Provider Fall Short**

A federal court in Florida dismissed, without prejudice, the government’s complaint in intervention against an ambulance provider that allegedly defrauded Medicare and Medicaid by billing for medically unnecessary transports.

The U.S. District Court for the Middle District of Florida said the government’s allegations of False Claims Act (FCA) violations didn’t satisfy the particularity requirement under Fed. R. Civ. P. 9(b) as they failed to supply “some indicia of reliability” that an actual false claim was submitted to the government for payment.

The federal government in June 2015 intervened in an FCA whistleblower action alleging Liberty Ambulance Services, Inc. in Jacksonville, FL defrauded federal health care programs and engaged in a kickback scheme that involved offering discounts to private payers—such as hospitals and nursing homes—so they would provide the company with exclusive access to their patients with federally subsidized health care.

The qui tam action was filed by Shawn Pelletier, who worked for Liberty Ambulance from 2006-2008. The government settled with the provider defendants. Liberty moved to dismiss the complaint against it.

Granting the motion, the court noted while the government filed sworn statements from several current and former Liberty emergency medical technicians who submitted run reports to the main office, none of those individuals were involved with the actual submission of claims to the government.

And though the government “attached numerous exhibits to its complaint, it did not attach copies of any actual claims (and, unlike a typical qui tam relator, the government presumably has access to all of these records),” the court observed.
While acknowledging that the government wasn’t required to submit any actual claims, the court doubted the complaint could clear the Rule 9(b) hurdle “without such claims or supporting information from anyone ‘with first-hand knowledge’ of Liberty’s internal billing practices.”

The court also questioned the timeframes referenced in the complaint, noting they exceeded the time span that any of the employees who submitted statements worked for Liberty.

The court gave the government until February 1 to submit an amended complaint addressing the pleading deficiencies.


**U.S. Court in California Finds Violation of Medicare Conditions of Participation Sufficient for FCA Claims**

Hospital and physician defendants’ efforts to dismiss claims against them under the False Claims Act (FCA) were rebuffed for a second time January 26 by a federal court in California.

The U.S. District Court for the Eastern District of California upheld its previous ruling that plaintiffs’ claims that defendants violated a Medicare condition of participation were sufficient to state an FCA claim. The court again rejected defendants’ argument that only a condition of payment can trigger FCA liability.

Defendants AmSurg Corporation provides management services to ambulatory surgery centers. Physician defendants (collectively Redding Gastroenterology L.L.C. d/b/a Redding Endoscopy Center (REC) physicians) are surgeons specializing in gastroenterology.

Relators Douglas Dalitz and Randy Gray worked at REC as Certified Registered Nurse Anesthetists.

Under Medicare conditions of participation providers must perform and place in the patient’s record: a medical history and physical assessment (H&P), a pre-surgical assessment, and an anesthetic risk assessment.

During their employment, plaintiffs alleged that REC physicians either did not perform the H&Ps and pre-surgical assessments, or performed them in such a cursory manner that relators did not have adequate information to properly assess whether the patient was fit to receive anesthesia or undergo surgical procedures.

Dalitz and Gray raised their concerns about the REC physicians’ failure to perform pre-surgical assessments and comprehensive H&Ps to the office manager of REC and other responsible parties. But no actions were taken and relators ultimately received letters informing them that REC had terminated their employment.

In a previous order, the court found that relators properly pleaded their claims of false certification under the FCA and related state laws and conspiracy to submit false claims.

Defendants moved for reconsideration, alleging that the court committed a clear error in its analysis of the applicable case law by holding that certification of the condition of participation at issue was sufficient to support plaintiffs’ claims and by holding that they were material and/or conditions of payment under the law.
Denying the motion, the court noted that in its view “Defendants oversubscribe to the payment/participation distinction and fail to present any binding precedent to indicate that the Court's determination on this issue constitutes a clear error of law.”

While acknowledging that only a condition of payment, not a condition of participation, can trigger FCA liability was a viable legal argument, the court said it was not obligated to agree.

“[T]he Ninth Circuit has not adopted the bright line payment/participation distinction that Defendants advocate, nor does the Ninth Circuit require express payment conditions within the underlying regulation,” the court observed.

Instead, the Ninth Circuit has instructed courts to focus on whether the underlying statutes are material, the court explained, emphasizing its finding of materiality here.

The court also denied defendants’ request to certify several questions for interlocutory appeal.


U.S. Court in Florida Refuses to Dismiss FCA Claims Based on Complex Real Estate Transactions

The U.S. District Court for the Southern District of Florida allowed January 28 False Claims Act (FCA) allegations to go forward against HCA, Inc., finding relator Thomas Bingham sufficiently stated claims under the Stark Law and Anti-Kickback Statute (AKS).

Relator alleged a complicated fraud scheme under which HCA “purposefully obscured the remuneration it paid to physicians to induce them to refer patients,” and subsequently submitted claims from those referrals to the government.

Specifically, relator alleged that HCA provided referring physicians with a portion of a medical office building's operating cash flow, as well as profits after its sale, free parking, and other cash flow subsidies designed to funnel money to referring physicians.

HCA moved to dismiss the claim, but the court found relator plausibly alleged that the agreements entered into between physician tenants and Tegra Healthcare Properties, a medical office building development and property management company, took into account the volume or value of patient referrals to HCA.

“It is plausible, after accepting as true all facts alleged by Relator, that HCA (through Tegra) took into account patient referrals when assigning office space to physician tenants, thus compensating those who referred more patients to HCA at a higher rate,” the court found.

The court also said relator sufficiently alleged violations of the AKS in a scheme where Tegra passed on a variety of financial benefits it received from HCA to physician tenants, who in turn, leased office space at an effective rate per square foot that fell well below fair market value.

HCA argued that relator failed to allege that anyone at HCA acted willfully and knowingly in offering remuneration to induce referrals. But the court said relator sufficiently alleged HCA paid remuneration “knowingly and willfully” because it certified compliance with the AKS by submitting “false certifications and representations on claim forms or their electronic equivalents and cost reports.”

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The court also rejected HCA's argument that the complaint failed to satisfy Fed. R. Civ. P. 9(b) because relator did not plead any specific samples of false claims submitted by HCA.

According to the court, relator met the relaxed pleading standard. "While Relator has not provided specific samples of false claims submitted by HCA, the facts alleged provide sufficient ‘indicia of reliability’ that HCA submitted false claims to the government for payment,” the court held.

The court did dismiss, however, claims based on a scheme at another location, finding those claims do not provide sufficient “indicia of reliability” to find that HCA violated the FCA.


**U.S. Court in Michigan Upholds Medicare Fraud Search Warrant**

The U.S. District Court for the Eastern District of Michigan refused February 3 to suppress evidence of health care fraud seized by the government pursuant to a warrant to search defendant's home health care business.

The court found the government's search warrant contained sufficient evidence of fraud and was not overly broad.

Defendant Naseem Minhas was charged with conspiracy to commit health care fraud and conspiracy to pay or receive kickbacks. The search warrant at issue was executed by the Federal Bureau of Investigation at defendant's place of business, Tricounty Home Care Services, Inc.

The warrant sought to seize evidence of the health care fraud scheme for the period from February 1, 2009 until the present. It sought "all records related in any way" to defendant's patients, including, for example, patient charts, files, records, and patient sign-in sheets. It also sought "[a]ll documents constituting, concerning, or relating to bills, invoices and claims for payment or reimbursement for services billed to insurance companies for any patients," as well as all financial and tax-related books, records, and documents.

Defendant moved to suppress all evidence seized on the ground that the affidavit supporting the search warrant was overly broad and contained deliberate or reckless omissions critical to the finding of probable cause.

The court was not persuaded by defendant's arguments, finding he failed to make a substantial preliminary showing that the warrant contained material omissions regarding evidence of "patient cycling."

The information in the warrant related to that part of the scheme "supplements patient interviews, recordings of Defendant paying kickbacks for referrals, and other evidence of fraudulent behavior," the court found.

Moreover, the court said that even if it found omissions, they were not "so fundamentally misleading as to vitiate the showing of probable cause."

Based on the recordings of meetings, interviews of defendant's patients, and statements from a recruiter admitting to having been paid kickbacks by defendant, “there were reasonable grounds to believe that there was a fair probability that evidence of a crime would be located on Tricounty's premises,” the court said.
The court found defendant also failed to establish that the warrant was overly broad. Defendant argued that the search warrant effectively sought "all records" from his business, and the government failed to establish probable cause justifying such a broad search.

But the court said the government was not required to have evidence relating to each and every patient to justify the seizure of all patient files.

The examples in the affidavit of referral fees and billing for services not rendered “may fairly be considered to be representative of more pervasive violations” that established “sufficient probable cause that Defendant was engaging in a wide-scale practice of Medicare fraud,” the court held.


**Fourth Circuit Rules Attorney’s Involvement in Second Whistleblower Action Triggers Public Disclosure Bar**

The Fourth Circuit affirmed January 29 a federal district court’s dismissal of a qui tam action against Purdue Pharma LP and Purdue Pharma, Inc. as barred by the False Claims Act’s (FCA) public disclosure provision.

The appeals court found the allegations in the relators’ whistleblower action were based on facts their attorney learned in the course of pursuing an earlier filed whistleblower action that was dismissed.

**Two Qui Tam Actions**

Steven May and Angela Radcliffe initiated the instant qui tam action against defendant Purdue Pharma, alleging the company marketed its controlled-release pain relief drug OxyContin to physicians as more potent than a cheaper alternative.

Their action followed another whistleblower action, initiated in 2005 and ultimately dismissed with prejudice, which was asserted by Mark Radcliffe, relator Angela Radcliffe’s husband and relator Steven May’s former supervisor at Purdue Pharma. The allegations in Mark Radcliffe’s qui tam action were nearly identical to those in the instant whistleblower suit.

In the 2005 action, the Fourth Circuit ultimately found a release Mark executed after leaving the company prevented him from suing Purdue Pharma. *See United States ex rel. Radcliff v. Purdue Pharma L.P.*, 600 F.3d 319 (4th Cir. 2010).

The district court held that the instant action was barred by res judicata, giving preclusive effect to the Fourth Circuit’s decision dismissing Mark Radcliffe’s qui tam action. *United States ex rel. May v. Purdue Pharma L.P.*, No. 5:10-cv-01423 (S.D.W.V. Sept. 14, 2012).

But the Fourth Circuit, in December 2013, vacated the district court’s dismissal, finding the release did not apply to the relators in the instant action. *United States ex rel. May v. Purdue Pharma L.P.*, No. 12-2287 (4th Cir. Dec. 12, 2013).

On remand, the district court again dismissed, finding the pre-2010 public disclosure bar stripped it of jurisdiction.

**Public Disclosure**

This time, the Fourth Circuit affirmed the district court’s dismissal.
Citing its decision in United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339 (4th Cir. 1994), the appeals court found relators’ allegations were “actually derived from” a public disclosure even if they did not personally review the filings in Mark Radcliffe’s prior action.

In this case, relators did not learn of the alleged fraud independently, instead their knowledge stemmed directly from their attorney’s involvement in Mark Radcliffe’s qui tam action, the appeals court noted.

Purdue Pharma argued, and the appeals court agreed, that relators’ FCA claim was “a quintessential parasitic action” because it didn’t provide any additional, useful information to the government


First Circuit Finds Public University Can’t Be Sued Under FCA

The University of Massachusetts Medical School (UMMS) is an “arm of the state” and therefore isn’t a “person” that can be sued under the False Claims Act (FCA), the First Circuit held January 27.

Relator Michael A. Willette worked in UMMS’ Center for Health Care Financing (CHCF) for 14 years. One of the CHCF’s main responsibilities was recovering funds from third parties to reimburse Medicaid.

Leo Villani also worked at CHCF and when he died, relator was appointed his personal representative. Relator subsequently discovered that Villani allegedly embezzled nearly $4 million in funds that CHCF collected.

Relator said he shared the details of Villani’s alleged fraud with his supervisors at CHCF. According to relator, UMMS officials subsequently retaliated against him for doing so. Relator sued UMMS and Villani’s estate in an FCA qui tam action. The federal government and state of Massachusetts declined to intervene.

The district court dismissed the relator’s claims against UMMS, finding the medical school was an “arm of the state” and therefore could not be sued under the FCA pursuant to Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000), which held that states are not “persons” subject to liability under the statute. The court also denied relator leave to amend.

On an issue of first impression, the appeals court agreed with the other federal circuits to consider the question and held the Eleventh Amendment “arm-of-the-state” analysis applies to determine whether an entity is a “state” for purposes of the FCA.

Applying that test, the appeals court found UMMS was an arm of the state immune from FCA liability.

The appeals court held the structural analysis in this case was conclusive—specifically that public universities generally are considered arms of the state; the university was not separately incorporated; the state had substantial control over the university and UMMS; the state closely supervised the university’s budget and its educational mission; and all university property was considered state property.

The appeals court rejected relator’s arguments that CHCF, which is for-profit, should be carved out of UMMS and treated differently than other parts of the university.
“[T]he mere fact that a governmental agency generates revenue for the state does not deprive the agency of arm-of-the-state status,” the appeals courts said.

Unlike another case where a university-affiliated laboratory was found not to be an arm of the state, UMMS and CHCF were not separately incorporated and did not possess the same level of independence to enter the private sector and compete as a commercial entity.

The First Circuit also held it lacked appellate jurisdiction over relator’s attempt to appeal the district court’s denial of leave to amend.


U.S. Court in Texas Narrows Whistleblower Claims Against Drug Maker in Medicaid Fraud Action

Solvay Pharmaceuticals, Inc. (SPI) continued to winnow down a False Claims Act (FCA) whistleblower action filed against it, obtaining a partial summary judgment ruling in the U.S. District Court for the Southern District of Texas on relators’ allegations the company caused the submission of false claims to the government by trying to persuade members of state Medicaid Pharmaceutical and Therapeutics (P&T) Committees to give preferred status for its drugs on Medicaid preferred drug lists (PDLs).

Relators John King and Tammy Drummond, who formerly worked for SPI as district sales managers brought the FCA action against SPI alleging an extensive off-label marketing scheme involving three of its drugs—Aceon, Luvox, and AdroGel.

SPI moved to dismiss one aspect of the complaint related to allegations that it caused the submission of false claims to Medicaid by “wooing” members of state Medicaid P&T Committees to obtain preferred status for the three drugs on their PDLs or formularies.

According to relators, SPI sales representatives were encouraged to “wine and dine” P&T Committee members so they would listen to off-label details about the drugs.

A drug listed on a PDL can be prescribed without restrictions like prior authorization from Medicaid and, theoretically, may increase the number of prescriptions written for the drug.

The court in a January 2015 decision granted partial summary judgment to SPI on the P&T Committee influence claims for various states. It denied the motion without prejudice, however, for states SPI said didn’t have PDLs, where the drugs at issue were not on the PDLs, or were the PDLs unavailable. According to the court, more information was needed to resolve these claims. United States ex rel. King v. Solvay, No. H-06-2662 (S.D. Tex. Jan. 23, 2015).

SPI then filed a supplemental motion seeking summary judgment on the P&T Committee influence claims in the remaining states.

The court first addressed a statement of interest filed by California asking that the state’s Medi-Cal formulary and advisory committee be treated as a PDL and P&T Committee, respectively, for purposes of the lawsuit.

Declining to do so, and granting summary judgment to SPI on these claims, the court said the complaint specifically referred to P&T Committees, not other groups, and relators, per Fed. R. Civ. P. 9(b), had to plead their fraud claims with particularity.
As to the other states, the court agreed with SPI that, among other things, relators’ evidence of “wooing” was insufficient to support causation. The court this time around granted SPI's motion as to all the P&T Committee claims.


U.S. Court in New Jersey Trims Claims in FCA Action

The U.S. District Court for the District of New Jersey February 22 dismissed with prejudice certain claims from a False Claims Act (FCA) qui tam action against a hospice provider but allowed others to go forward.

Relators in the case are former employees of defendant, Care Alternative, Inc., a provider of hospice care.

Relators' whistleblower action alleged a concerted effort by defendant to bring in patients to its residential facilities who were ineligible for hospice care coverage under Medicare. In addition, relators alleged staff were directed to re-write medical records to meet the Medicare-coverage hospice criteria and re-create "missing" documents.

After the United States elected not to intervene, defendant moved to dismiss.

Defendant contended that relators' claims failed as a matter of law because they failed to allege factually false or legally false claims. According to defendant, the statutory and regulatory provisions and guidelines at issue were "conditions of participation, not "conditions of payment."

The court rejected this argument, noting the Third Circuit holding that compliance with the Anti-Kickback Statute (AKS) is a condition of payment under the Medicare program, see United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004).

The court also found the hospice certification provisions of the Medicare statute and regulations are conditions of payment, although it acknowledged the Third Circuit has not ruled on this specific issue.

The accompanying regulations detail requirements with which certifications "must conform" for the hospice care provider to receive payment, the court noted. In addition, Local Coverage Determinations (LCDs) referenced throughout relators’ complaint impose further requirements on hospice care providers before they receive reimbursement, the court observed.

The court rejected, however, relators claims involving interdisciplinary group meetings, finding they failed to show compliance with applicable regulations are a condition of payment.

Relators could pursue their claims under an implied certification theory for alleged violations of the Medicare statute and regulations, including violation of LCD criteria, but not for violation of the regulations regarding interdisciplinary group meetings, the court concluded.

Defendant also argued that relators' allegations did not satisfy the Fed. R. Civ. P. 9(b) because they failed to describe a "plausible or particular scheme to submit false claims" or that any false claims for Medicare reimbursement were actually presented to the government for payment.

Rejecting this argument, the court found relators alleged “circumstances which allow the strong inference that claims actually were presented”—namely, that “at least certain of the reimbursements
presented on behalf of the 15 identified patients were false because they did not contain the required 'clinical information . . . that support the medical prognosis’ of terminally ill."

The court also found the complaint “plausibly suggest[s] management's reckless disregard for the ‘truth or falsity’ of the information contained in the claims for reimbursement from Medicare.”

Relators’ claims related to altered medical records were, however, “plainly insufficient” under Rule 9(b). “Nowhere in the complaint do details about the ‘who, what, when, where and how of the events at issue appear,” the court said.

The court also found AKS claims that gifts, lunches, dinners, and other perks were offered to physicians, administrators, and others who could supply referrals did not satisfy the Rule 9(b) particularity requirement.


**U.S. Court in Illinois Says FCA Whistleblower Sufficiently Detailed Fraud to Avoid Dismissal**

A federal court in Illinois refused February 11 to dismiss a whistleblower action under the False Claims Act (FCA) even though the complaint didn’t allege any facts regarding an actual claim submission to or payment by Medicare.

According to the U.S. District Court for the Northern District of Illinois, relator provided sufficient details of the alleged scheme to defraud the government to clear the Fed. R. Civ. P. 9(b) pleading hurdle.

Relator Chelsey Schramm worked briefly as a physician assistant (PA) for Fox Valley Physicians Services, SC (FVPS).

She filed a qui tam action against FVPS, individuals who ran or worked for the company, Priority Health Chiropractic of Yorkville, IL, and two of its chiropractors (collectively, defendants).

Schramm alleged that during her three-month period of employment (July 2012-October 2012), defendants submitted claims to Medicare for services she rendered as a PA before her Medicare enrollment application was approved and while she was not duly supervised by an authorized physician; for services rendered by two chiropractors who were not Medicare-enrolled providers; and for services that weren’t actually performed.

The court previously dismissed the complaint, but gave Schramm the opportunity to amend her pleadings to cure the deficiencies.

FVPS and Priority Health both moved to dismiss the second amended complaint, arguing it failed to plead fraud with sufficient particularity under Rule 9(b) because the allegations didn’t include any facts about the submission of an actual false claim to Medicare for payment.

Denying the motion, the court said the complaint sufficiently detailed the alleged fraud to satisfy Rule 9(b).

The second amended complaint alleged a specific timeframe (July through October 2012), identified ten Medicare patients who relator treated before obtaining the Centers for Medicare & Medicaid Service’s (CMS’) approval of her enrollment application and without the legally required physician
supervision, and contended that she entered billing data for patients whom she never treated, but who were seen by the two non-CMS approved chiropractors.

Unlike the precedent relied on by defendants in seeking dismissal, relator “provided representative examples of the services for which the government was billed,” the court said. “That Schramm fails to attach an actual claim submitted to Medicare or proof of payment received by defendants is of no moment.”

In the court’s view, Schramm alleged a concrete scheme, “providing detail regarding the participants, their knowledge of bad acts, the timeframe in which the scheme took place, the content of the alleged fraud, the approximate number of Medicare patients at issue and the type of services claimed, and the date when the allegedly fraudulent claims were submitted to Medicare.”

The court also said the scheme did not require proof at an “individualized transaction level” because the alleged fraud did not depend on the accounting mechanics of any particular Medicare claim, but rather hinged on allegedly unlawful treatment and record-keeping systems.


**Texas Supreme Court Revives Whistleblower Lawsuit Against State Health Department**

A former attorney for The Texas Health and Human Services Commission (Commission) could proceed with his action under the state's Whistleblower Act because he reported an alleged violation of federal Medicaid rules to the Commission’s Office of the Inspector General (OIG), which was an “appropriate law-enforcement authority” for purposes of the statute, the Texas Supreme Court held February 26.

In early 2011, Michael McMillen, who was working as Deputy Counsel for the OIG, was asked to research the legality of the Commission’s practice of obtaining payments from certain Medicaid recipients, according to the per curiam opinion.

He prepared a memorandum concluding the Commission’s actions weren’t legally justified. He gave the memo, which did not cite any specific statutory violations or case law, to the OIG. In early 2012, McMillen was placed on administrative leave and was later terminated.

McMillen sued the Commissioner under the Texas Whistleblower Act, which protects “a public employee who in good faith reports a violation of law by the employing governmental entity or another public employee to an appropriate enforcement authority.”

The Commission argued the Act didn’t apply because the OIG was not an “appropriate law-enforcement authority.” The trial court disagreed with the Commission, but the appeals court reversed.

The Texas Supreme Court held the OIG “is an appropriate law-enforcement authority” for purposes of reporting alleged violations of federal Medicaid rules, in this case 42 U.S.C.§ 1396p(b), which prohibits any “adjustment or recovery of any medical assistance correctly paid on behalf of an individual under a State plan.”

The OIG was charged with investigating fraud and abuse in the provision of health care services, as well as related enforcement authority, the high court noted. It therefore had authority to ensure compliance with Section 1396p(b), the high court said.
The high court did not comment on whether McMillen made a good-faith report of the alleged Section 1396p(b) violation to the OIG, but instead remanded to the appeals court for further proceedings.


**Jury Finds Device Company, CEO Not Guilty in Case Alleging “Off-Label” Promotion**

A federal jury returned February 26 a unanimous not-guilty verdict on all charges against Vascular Solutions Inc. (VSI) and its chief executive officer, Howard Root, in a criminal action alleging they sold medical devices without Food and Drug Administration (FDA) approval and conspired to defraud the United States by concealing the illegal sales activity.

The Department of Justice (DOJ) in November 2014 filed the criminal prosecution in the U.S. District Court for the Western District of Texas against Root and VSI, alleging they engaged in the illegal “off-label” promotion of the Vari-Lase® Short Kit.

According to the indictment, the FDA cleared VSI’s Vari-Lase products only for the treatment of superficial veins, but Root and VSI sold them for the ablation, or removal, of “perforator” veins, which connect the superficial vein system to the deep vein system.

The company said in a statement that the jury’s verdict “concludes the litigation and is not subject to appeal.”

According to the statement, the company spent more than “$25 million to defend against a criminal prosecution that clearly was never warranted by the facts.” VSI and Root expressed “outrage[]” at the “obscene legal process we were forced to endure,” the statement said.

VSI also called on DOJ to issue a “corrective press release” to set the record straight “in the interest of justice.”

FDA’s authority under the Food, Drug, and Cosmetic Act (FDCA) to challenge the promotion of drugs or devices for so-called unapproved “off-label” uses has been subject to growing pushback from the industry.

Last year, drug maker Pacira Pharmaceuticals sued the agency, alleging the FDA was improperly trying to silence its truthful and non-misleading speech about one of its products in violation of the First Amendment. FDA eventually withdrew its objections to the marketing at issue and the case was dismissed.

The U.S. District Court for the Southern District of New York also recently granted preliminary injunctive relief to another drug maker, Amarin Pharma, Inc., allowing the company to disseminate truthful and non-misleading statements about the off-label uses of one of its drugs without the threat of criminal misbranding charges.

The court in that case found a substantial likelihood that Amarin would succeed on the merits of its claim that FDA’s regulation of off-label promotion violated the First Amendment. The court stayed in August 2015 further proceedings in the case after Amarin and the FDA agreed to “explore the possibility of settlement.”
Sixth Circuit Affirms Dismissal of FCA Whistleblower Action Alleging HITECH Violation

The Sixth Circuit affirmed January 6 the dismissal of a qui tam action alleging Kettering Health Network (KHN) fraudulently accepted “meaningful use” incentive payments under the Health Information Technology for Economic and Clinical Health (HITECH) Act triggering False Claims Act (FCA) liability.

The case stemmed from an alleged breach of relator Vicki Sheldon’s and her family's electronic protected health information (e-PHI). According to relator, her husband Duane Sheldon, a former KHN director, accessed and shared her e-PHI with others.

KHN informed relator about the breach in two letters, which stated that an internal investigation revealed Duane Sheldon and others impermissibly accessed her e-PHI on several occasions. The letters indicated that the access violated KHN’s policies and procedures and that KHN would report the breaches to the Department of Health and Human Services.

Relator alleged KHN violated the HITECH Act when it failed to protect her privacy and falsely certified its compliance with statutory requirements so it could collect meaningful use incentive payments from the federal government.

A federal district court in Ohio dismissed the action and denied relator’s motion to amend her complaint. The court found relator failed to plead her claims with sufficient particularity under Fed. R. Civ. P. 9(b) because she did not allege KHN submitted a specific false claim. The court also held that relator failed to plead that KHN did not meet the HITECH Act’s standards. United States Sheldon v. Kettering HealthNetwork, No. 1:14-cv-345 (S.D. Ohio Jan. 6, 2015). The Sixth Circuit affirmed the dismissal.

Individual Breaches Don’t Violate HITECH

The appeals court agreed with the lower court that individual breaches, standing alone, do not violate the HITECH Act.

“Relator’s claim that KHN’s individual breaches each constituted a violation of the HITECH Act is an incorrect conclusion of law,” the appeals court remarked. Compliance is premised on establishing a process to analyze and review security policies and procedures; “attestation of compliance is not rendered false by virtue of individual breaches.”

The regulations implementing the HITECH Act contemplate the potential for security breaches, the appeals court observed. Those regulations do not impose a strict liability standard requiring health care providers to prevent all privacy breaches.

Relator also claimed that the individual breaches, taken together, show KHN lacked adequate policies and procedures to comply with the Act. The appeals court disagreed, however, noting no allegations to support such a claim, and that the letters KHN sent to relator indicated at least some policies and procedures were in place for detecting and investigating unauthorized access of e-PHI.

The complaint also alleged KHN violated the HITECH Act because it failed to run certain reports at regular intervals to detect possible data breaches.

Rejecting this argument, the appeals court pointed out that the HITECH Act doesn’t require covered entities to adhere to a particular schedule for running reports or to use a particular software for doing so.
Personal Knowledge Lacking

The Sixth Circuit said the complaint failed to name a single hospital or professional in KHN’s network that made a “false attestation” because of allegedly deficient security protocols.

The complaint may have raised an “inference” that security flaws affected KHN’s network, but that wasn’t enough to satisfy Rule 9(b).

Relator argued the appeals court should apply a “relaxed” pleading standard because she had personal knowledge of the software that KHN used.

Without deciding whether a “relaxed” pleading standard was available in the Sixth Circuit, the appeals court held relator didn’t have the type of “personal knowledge”—i.e., as someone who worked for KHN’s security or billing departments or who spoke directly with someone responsible for HITECH Act certification—to “support a strong inference—rather than a simple possibility—that a false claim was presented to the government.”

The appeals court also concluded that relator’s action was barred by res judicata because of the dismissal of a nearly identical state court action.


Sixth Circuit Affirms Dismissal of FCA Whistleblower Action Against Lab

The Sixth Circuit affirmed February 23 the dismissal of a qui tam action alleging that Physicians Choice Laboratory Services (PCLS) violated the False Claims Act (FCA) and the Anti-Kickback Statute.

In an unpublished opinion, the appeals court found relator Brian Eberhard, who formerly worked as a sales employee for PCLS, failed to satisfy the Fed. R. Civ. P. 9(b) pleading requirement because the complaint didn’t specify any false claim that was actually submitted to the government.

The appeals court also rejected Eberhard’s argument that a “relaxed” pleading standard should apply, holding his position in PCLS’ salesforce did not give him “personal knowledge” of the lab’s billing practices to support a strong inference that a false claim was presented to the government.

Eberhard alleged that PCLS’ sales force is comprised of independent contractors who are paid a commission based on sales of products and services.

According to Eberhard, the commission structure violates the AKS because it offers payments to the sales force to induce Medicare and Medicaid referrals. Eberhard also alleged that PCLS violated the FCA in submitting claims based on those referrals.

Eberhard contended that more than half of PCLS services are paid for by Medicare and Medicaid. Based on this figure, Eberhad alleged Medicare and Medicaid paid PCLS for 7,000 samples in May 2014 alone that violated the FCA.

The district court granted PCLS’ motion to dismiss under Rule 9(b)’s heightened pleading standard for failure to identify any actual false claim submitted to the government. The Sixth Circuit affirmed.

Citing its case law, the Sixth Circuit noted that it has rejected a relaxed pleading standard based on allegations of a fraudulent scheme and “reliable indicia” leading to a strong inference that claims were submitted.
“[W]e have joined the Fourth, Eighth, and Eleventh Circuits in requiring ‘representative samples of the alleged fraudulent conduct,’” the appeals court said.

The appeals court acknowledged that Rule 9(b) could possibly be relaxed where the relator has personal knowledge that claims were submitted to the government for payment.

But the Sixth Circuit said this was not a case where relator had the required personal knowledge. Eberhard’s alleged personal knowledge only was of the “fraudulent scheme,” not of PCLS' billing practices or contracts with the government.

“Eberhard’s complaint fails to bridge the gap between the alleged false scheme and the submission of false claims for payment, as required to allege an FCA violation,” the Sixth Circuit said.


**Fifth Circuit Says Whistleblower Failed to Show Knowledge of Alleged Improper Billing**

The Fifth Circuit affirmed March 7 the dismissal of a whistleblower action alleging a medical group improperly billed for services performed at one of its clinics without appropriate supervision by a licensed provider.

According to the appeals court, relator Darilyn Johnson, a former employee of Kaner Medical Group, PA (KMG), didn’t raise a genuine dispute of material fact that KMG acted with actual knowledge, deliberate ignorance, or reckless disregard to satisfy the False Claims Act’s (FCA’s) scienter requirement.

Johnson worked in KMG’s billing department and was primarily responsible for collecting outstanding patient accounts.

KMG has an allergy clinic in Texas that administers allergy testing and allergen immunotherapy to patients, including Medicare and Tricare enrollees.

According to Johnson, she sent two emails to her KMG supervisors in 2012 raising concerns that it was improperly billing Medicare patients directly. Johnson said KMG fired her shortly thereafter, citing complaints about her job performance.

Johnson filed a qui tam suit under the FCA against KMG and its owner alleging the group submitted false claims to Medicare and Tricare by using the referring provider’s National Provider Identifier number on the allergy clinic’s bills regardless of which provider actually supervised the services.

Johnson also asserted an FCA retaliation claim, alleging KMG fired her for raising concerns about its billing practices.

The district court sua sponte granted summary judgment to KMG. In an unpublished opinion, the Fifth Circuit affirmed.

Noting the FCA’s scienter requirement was an “elevated standard,” the appeals court said a finding of negligence or gross negligence was insufficient.

Assuming KMG actually submitted false claims to the government, “none of Johnson's arguments raise a genuine dispute of material fact that KMG acted with the requisite mental state required under the statute,” the appeals court said.
At most, the record showed that KMG was negligent in misunderstanding federal requirements, “which is not sufficient to attach liability under the FCA.”

The appeals court also agreed that Johnson’s retaliation claim failed because she didn’t engage in protected activity. Her emails to KMG reported alleged concerns about directly billing Medicare patients, which was unrelated to the alleged billing fraud against the government.


**U.S. Court in Pennsylvania Allows Some Off-Label Promotion Claims Against Pfizer to Proceed**

A federal court in Pennsylvania refused to dismiss a qui tam action alleging Pfizer, Inc. promoted its anti-fungal medication for off-label uses, which resulted in the submission of false claims to Medicare and Medicaid.

The U.S. District Court for the Eastern District of Pennsylvania allowed relators to proceed with the bulk of their action alleging the off-label promotion of Voriconazole, or Vfend, after rejecting Pfizer’s argument that they failed to meet the Fed. R. Civ. P. 9(b) heightened pleading standard.

Relators Catherine A. Brown and Bernard G. Vezeau formerly worked as marketing and product managers for Pfizer.

Relators filed their amended qui tam action in December 2009 on behalf of the federal government and various state and local governments. The federal government declined to intervene.

Relators alleged that Pfizer caused the submission of more than $250 million in false claims to federal and state governments by making fraudulent misrepresentations and statements to the FDA in Vfend’s New Drug Application (NDA) and by promoting the anti-fungal medication for off-label uses.

**First-to-File Dispute**

The court held the first-to-file bar applied to relators’ claims that Pfizer promoted Vfend for pediatric and prophylactic uses, citing a case in the federal district of Massachusetts that included similar allegations and was filed a few months before the amended complaint. *See United States ex rel. Worsfold v. Pfizer, Inc.*, No. 09-11522 (D. Mass).

Relators argued that their original complaint, which was filed in December 2005, pre-dated the *Worsfold* action. In addition, relators contended they provided supplemental disclosures to the Department of Justice (DOJ) raising the off-label promotion claims before the amended complaint in *Worsfold* was filed.

The court found these arguments flawed for two reasons: (1) relators’ original complaint didn’t assert the off-label promotion claims at issue and (2) the “extra-judicial filings” made to DOJ weren’t relevant to resolving a first-to-file dispute—only a comparison of the two complaints mattered.

But the court went on to say that relators could amend the complaint and reassert the claims dismissed under the first-to-file bar because *Worsfold* was no longer “pending.” The court in *Worsfold* dismissed the action in 2013 finding the complaint failed to plead fraud with particularity under Rule 9(b).
The court cited here the Supreme Court’s decision last year in *Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015), which held that the first-to-file bar is lifted once the earlier suit is dismissed.

**Flawed Study**

At the heart of relators’ claims involving misrepresentations to the FDA were allegations that Pfizer knowingly relied on a flawed study in submitting its Vfend NDA for approval.

Pfizer contended it didn’t mislead the FDA because once it realized the study switched endpoints, it disclosed the inadvertent mistake to the agency.

But the court said relators alleged a broader fraud beyond the switched endpoints. According to relators, Pfizer knew the study was “seriously flawed” and nonetheless concealed the adverse results from the FDA and the medical community.

These allegations, the court said, were sufficient to survive dismissal.

**False Claims?**

Pfizer argued that the off-label promotion claims should be dismissed under Rule 9(b) because relators failed to allege with particularity the actual submission of any false claims to the government for reimbursement.

The Third Circuit takes a more relaxed approach to Rule 9(b), allowing relators to meet the pleading requirement by alleging details of a scheme to submit false claims along with “reliable indicia that lead to a strong inference that claims were actually submitted.” *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153 (2014), the court noted.

The court held relators met the standard as articulated in *Foglia*. They alleged sufficient details of a widespread scheme to promote Vfend for off-label uses, including misrepresenting the clinical study and concealing data, creating “speaker programs” to convince others to prescribe Vfend, and making other payments to physicians and pharmacists to promote the anti-fungal medication.

The court also held relators supplied “reliable indicia” leading to a strong inference that Pfizer caused the submission of false claims. Specifically, relators alleged that since 2002, Vfend, beating out competitors, generated $1.9 billion in sales, 40% of which were for an indication not approved by the FDA. According to relators, as of 2009, Pfizer received $950 million in off-label sales of Vfend.

**Medically Accepted Indications**

Pfizer also contended that the prescriptions for off-label uses of Vfend were reimbursable under federal health care programs because they were “medically accepted indications” in the medical compendia.

The court agreed that although the FDA didn’t approve Vfend for “Empiric Therapy in Febrile Neutropenic Patients,” one of the Medicaid-recognized compendia listed this as an approved use. The court therefore dismissed any FCA claims based on Medicaid reimbursement for this use.

The court refused, however, to dismiss the same FCA claims related to Medicare, noting the need to explore whether the two other statutorily recognized compendia listed empiric therapy as an indication for Vfend.
Relators also could proceed with their off-label promotion claims for pediatric use, citing factual disputes that needed to be resolved.

**Kickback Scheme**

The court found relators sufficiently alleged violations of the Anti-Kickback Statute under Rule 9(b), even without identifying the physicians submitting claims.

Relators may be able to establish their claims with the benefit of discovery, the court said.


**U.S. Court in Georgia Takes Middle Ground in Dispute over Amount Qui Tam Relator Is Due**

The U.S. District Court for the Middle District of Georgia resolved March 28 a dispute over a whistleblower's share of settlement proceeds from two qui tam actions. After determining the amount of potential losses for each underlying action, the court awarded the relator 29% of the proceeds of the first action and 20% in the second action.

Relator Richard Barker brought the two qui tam actions alleging that Columbus Regional Healthcare System violated the federal False Claims Act and the Georgia Medicaid False Claims Act.

Columbus Regional settled both actions with the United States and Georgia for $25 million, plus a possible contingent payment in the future.

Barker argued he was entitled to more than $6.7 million plus interest of the settlement proceeds, while the federal government and Georgia pegged the amount substantially lower at roughly $4.5 million plus interest.

The court reached a middle ground, finding that Barker was entitled to approximately $5.3 million plus pro rata interest.

The court found the potential losses associated with *Barker I* were $6 million, and the potential losses associated with *Barker II* were $47.81 million.

Based on those numbers, the court said 11.2% ($2.8 million) of the $25 million settlement should be attributed to *Barker I* and 88.8% ($22.2 million) should be attributed to *Barker II*. “Should there be any future payments by Columbus Regional under the settlement agreement, these percentages should be used to calculate Barker's share,” the court instructed.

As a relator, Barker was entitled to receive “not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement” attributable to *Barker I*, the action where neither the United States nor Georgia intervened.

For *Barker II*, he was entitled to “receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which [he] substantially contributed to the prosecution of the action,” the court noted.

The court found relator contributed significantly to *Barker I*. Not only did he promptly report “the issues in *Barker I* when the government had no knowledge of them,” he also “lost his job as administrative director of the John B. Amos Cancer Center, and he has not been able to find another job in the field despite nearly thirty years of experience managing cancer treatment centers.”
The court held relator should be entitled to 29% percent of the proceeds from *Barker I*, or $812,000.

Although relator's efforts in *Barker I* led to the discovery of the facts underlying *Barker II*, his contribution was more limited in the second action, the court said. The court determined relator was entitled to 20% of the proceeds from *Barker II*, or $4,525,000.


**Government Must Show More Than Difference of Opinion to Prove Falsity, Court Says in Hospice FCA Win**

A federal trial court in Alabama granted March 31 summary judgment to AseraCare Inc. in a False Claims Act (FCA) action alleging the hospice provider knowingly submitted false claims to Medicare for patients who were not terminally ill.

The U.S. District Court for the Northern District of Alabama emphasized that the government couldn’t prove falsity for purposes of the FCA based solely on the opinion of one medical expert who disagreed with the certifying physicians about whether the medical records of the 123 patients at issue supported their eligibility for hospice.

“A mere difference of opinion between physicians, without more, is not enough to show falsity,” said Chief Judge Karon Owen Bowdre in the closely watched case.

The outcome wasn’t unexpected after the court in November 2015 granted AseraCare a new trial when it found reversible error in its jury instructions. At that time, the court said it would consider sua sponte granting AseraCare summary judgment if the government couldn’t point to admissible evidence to prove falsity beyond the opinion of its medical expert. *United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB (N.D. Ala. Nov. 3, 2015).

The FCA action alleged that AseraCare submitted false claims to Medicare by certifying patients as eligible for hospice who did not have a prognosis of “a life expectancy of 6 months or less if the terminal illness runs its normal course,” as specified in Medicare regulations. 42 C.F.R. § 418.22(b)(1).

In May 2015, the court decided to bifurcate the trial into two phases: one on the falsity element of the government’s claims and a second on all other issues, including knowledge and damages.

To show falsity, the government relied on testimony of its medical expert and the patients' medical records. The expert testified that based on his clinical judgment, the sample of 123 patients at issue were ineligible for hospice care.

Following a ten-week trial, the jury found AseraCare submitted false claims for 104 patients during all or some of their hospice stays. But the court threw out the verdict, saying the jury instructions were flawed because they didn’t specify that “the FCA requires ‘proof of an objective falsehood’” and “a mere difference of opinion, without more, is not enough to show falsity.”

In the March 31 opinion, the court said the government failed to point to any admissible objective evidence of falsity to make their case.

“The court is concerned that allowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of the certifying physicians,” Bowdre wrote.
In this case, AseraCare’s medical experts and the government’s medical expert looked at the same medical records and came to different conclusions about the patients’ eligibility for hospice. The government didn’t claim any of the patients lacked a valid certification, that any medical documentation was falsified, or that clinicians withheld information from the certifying physicians.

Accordingly, Bowdre found the government couldn’t prove falsity as a matter of law because it offered only a difference in medical opinion about which reasonable minds could differ.


**U.S. Court in Texas Deals Final Blow to Whistleblower Claims Against Drug Maker in Medicaid Fraud Action**

The U.S. District Court for the Southern District of Texas granted March 31 summary judgment to Solvay Pharmaceuticals, Inc. (SPI) in a False Claims Act (FCA) whistleblower action alleging the company promoted its drugs off-label causing the submission of false claims to state Medicaid programs. The court, which has chipped away at the qui tam action in a series of rulings, found relators failed to provide any claims data that would be admissible at trial. See, *e.g.*, *United States ex rel. King v. Solvay S.A.*, No. H-06-2662 (S.D. Tex. Feb. 8, 2016).

Relators John King and Tammy Drummond, who formerly worked for SPI as district sales managers, brought the FCA action against SPI alleging an extensive off-label marketing scheme involving three of its drugs—Aceon, Luvox, and AdroGel.

Relators sought to rely on Medicaid pharmacy claims data from Texas and New York that was used to create summary charts. But the court found relators failed to show either data set could be presented in a form that would be admissible at trial.

The court also rejected the admissibility of call notes that relators offered as proof of SPI’s alleged off-label promotion scheme.

And in any event, the court said, the call notes were insufficient to raise an issue of material fact that the alleged unlawful marketing caused physicians to write prescriptions for the drugs at issue that were submitted to Medicaid for payment.

Relators’ evidence would require “a jury to draw inference upon inference to find a claim was submitted after a sales representative delivered an off-label message to a particular physician, and if all of these inferences were reasonable, which they are not, then Relators could only show a handful of visits to Texas physicians resulted in a false claim,” the court observed.

The court also said relators’ summary charts were not admissible because they apparently were prepared by their lead counsel, “who cannot serve as the proponent of the charts at trial.”


**U.S. Court in Tennessee Dismisses HCA from Fraud Action**

The U.S. District Court for the Middle District of Tennessee dismissed April 13 a relator’s False Claims Act (FCA) claims against defendant HCA, Inc. and transferred venue to a different district court. All defendants other than HCA, Inc. which is headquartered in Tennessee, are located in and residents of Utah, the court noted. Thus with HCA no longer a party, venue properly belonged to the U.S. District Court for the District of Utah.
Relator Gerald Polukoff worked as a cardiologist at Intermountain Medical Center from 2008 until 2012, at St. Mark's Hospital from 2008 until 2011, and at Sorensen Cardiovascular Group from August to November 2011.

Relator sued defendants St. Mark's, Intermountain Healthcare, Inc., Intermountain Medical Center, Dr. Sherman Sorensen, Sorensen Cardiovascular Group, and HCA, Inc. alleging that Sorensen performed medically unnecessary Patent Foramen Ovale (PFO) closures on cardiovascular patients and conspired with the other defendants to defraud the government by submitting false claims for reimbursement to Medicare and Medicaid.

Defendant HCA moved to dismiss based on relator's failure to plead fraud with particularity under Fed. R. of Civ. P. 9(b).

The court noted relator's only allegation against HCA was that it directly profited from the alleged medically unnecessary PFO closures.

But the court said it's a "well-established principle that parent corporations are not liable for the acts of their subsidiaries, even if they are wholly owned."

"Without any factual allegations that HCA's own conduct violated the FCA, the relationship to St. Mark's does not alone impose liability on HCA," the court held in dismissing relator's claims against HCA.


**Sixth Circuit Vacates Fraud Defendants’ Sentences**

The Sixth Circuit vacated April 7 two fraud defendants' sentences finding the district court's failure to calculate or make factual findings about the sentencing guidelines range made meaningful appellate review impossible. The appeals court also remanded for recalculation of the defendants' restitution amounts, holding the lower court's order "was based on clearly erroneous findings."

A jury convicted defendants, Dr. Carl Fowler and Michael Thoran, of conspiracy to commit health care fraud, conspiracy to distribute controlled substances, and conspiracy to pay or receive health care kickbacks for their roles in a scheme involving doctors writing fraudulent prescriptions and "marketers" filling those fraudulent prescriptions and selling them on the street.

At Fowler's sentencing hearing, the court recommended starting the sentencing inquiry at 108 months, essentially a number in between the requests of the government and defendant.

The court ultimately imposed a sentence of 72 months' imprisonment followed by two years of supervised release without calculating the sentencing guidelines range or making any factual findings about why 108 months was an appropriate starting point.

At Thoran's sentencing hearing, the court similarly made no factual findings in imposing a sentence of 108 months with three years of supervised release.

On appeal, Fowler and Thoran argued their sentences were procedurally unreasonable because the district court failed to calculate the guidelines ranges or make factual findings in imposing the sentences.
The government argued that Fowler waived his objections to the guidelines range because he agreed that 108 months would be the starting point and did not object before the court imposed the sentence.

The appeals court pointed out that the “mere failure to object to a sentencing error, even when the party admits there is no objection, does not constitute waiver.”

“It is difficult to contend, and the Government does not even attempt to argue, that the district court's suggested ‘starting point’ of 108 months was anything other than arbitrary,” the appeals court said.

“Based on the transcript, it seems that the district court did not even acknowledge, much less consider, Fowler's arguments that a lower range was appropriate, leaving us no basis to review the sentence on appeal,” the appeals court held.

The appeals court detailed the same error in Thoran’s sentencing and similarly found his sentence procedurally unreasonable.

The appeals court did find the evidence sufficient to uphold Thoran’s conviction.


**U.S. Court in California Dismisses “Piggybacking” Whistleblower Action Against Device Maker**

A federal court in California dismissed April 20 a whistleblower action under the False Claims Act (FCA) against Biotronik Inc. because the complaint “piggybacked” on an earlier qui tam lawsuit in which the government intervened and settled some, but not all, of the allegations. The U.S. District Court for the Eastern District of California noted no dispute that the instant complaint mirrored the fraud alleged in the previous qui tam action—that Biotronic used medical studies to mask a kickback scheme to physicians.

Even if the government failed to intervene in that aspect of the prior qui tam action, it was a party to the litigation and therefore alerted to the fraud alleged in the instant complaint, triggering the application of the 31 U.S.C. § 3730(e)(3) bar.

Section 3730(e)(3) bars “an action . . . based upon allegations or transactions which are the subject of a civil suit . . . in which the Government is already a party.”

In 2009, relator Brian Sant filed a qui tam action against Biotronik alleging it improperly paid kickbacks to physicians so they would use its cardiac rhythm management devices, such as pacemakers and implantable defibrillators, causing the submission of false claims to Medicare and Medicaid.

Sant alleged the company paid physicians bribes that included paid speaking engagements, sports tickets, expensive meals, and “research payments.” Sant also alleged Biotronik created sham clinical studies that were intended to funnel kickbacks to physicians for using its medical device.

The U.S. government intervened and reached a $4.9 million settlement with the company of the allegations related to providing physicians expensive meals and inflated payments for membership on an “advisory board.” See *United States ex rel. Sant v. Biotronik, Inc.*, No. 2:09-CV-03617 KJM EFB (E.D. Cal.). The case was subsequently dismissed.
Another relator, Max Bennett, initiated the instant qui tam action against Biotronik, his former employer. Bennett’s complaint alleged that Biotronik used clinical studies of questionable scientific value to pay physicians kickbacks. The government declined to intervene.

Biotronik moved to dismiss, arguing Section 3730(e)(3) barred the action because the government was a party to prior litigation that asserted the same allegations.

The court granted the motion to dismiss on the basis of Section 3730(e)(3).

The court found the United States was a party to the Sant lawsuit even if it didn’t intervene as to or settle the specific allegations about the sham clinical studies.

Citing Supreme Court precedent, United States ex rel. Eisenstein v. City of NY, 556 U.S. 928 (2009), the court noted that when the government intervenes it becomes a party to the “action” and not merely to a particular allegation or charge. While some courts have allowed the government to partially intervene in FCA cases, those decisions didn’t consider the impact on Section 3730(e)(3).

The court also rejected Bennett’s argument that the status of the prior lawsuit—which was settled and dismissed—was relevant to Section 3730(e)(3).

The FCA does not use the word “pending” in Section 3730(e)(3), which distinguishes the provision from the first-to-file bar, Section 3730(b)(5). The Supreme Court recently determined that once a prior qui tam action is dismissed, it no longer bars subsequent actions. See Kellogg Brown & Root Servs. Inc. v. United States ex rel. Carter, No. 12-497 (U.S. May 26, 2015).

According to the court, Bennett’s interpretation clashed with the purpose of Section 3730(e)(3)—“discouraging follow-on lawsuits that provide the government with little or no benefit.”

The government learned through Sant’s complaint about the allegedly sham medical studies and had a chance to investigate and prosecute fraud on that basis, but choose not to do so.

“Bennett seeks to remedy fraud the government has already been alerted to, and nothing suggests the government was unable to recover for the alleged sham studies” in the Sant action.


Fifth Circuit Upholds DEA Subpoena for Medical Records

A Drug Enforcement Agency (DEA) subpoena for medical records of 67 patients of a physician who was under investigation for violations of the Controlled Substances Act (CSA) was enforceable, the Fifth Circuit held April 21. In so holding, the appeals court rejected the physician’s assertion that the subpoena lacked probable cause, and would violate the Fourth Amendment and Texas law.

As part of an ongoing investigation, the DEA issued a subpoena to Dr. Joseph Zadeh seeking the medical records of 67 individuals who received prescriptions associated with the doctor’s DEA registration number.

When Zadeh refused to comply with the subpoena, the government petitioned the federal district court for enforcement.
Zadeh moved to dismiss, arguing that probable cause was lacking, that enforcement would violate the Fourth Amendment, and that the Texas Occupations Code barred disclosure of patient medical records.

The district court ultimately granted the government’s petition for enforcement.

On appeal, Zadeh argued among other things, that the Texas Occupations Code bars him from providing the subpoenaed records.

Rejecting this argument, the appeals court found the CSA preempted the Texas Occupations Code.

Zadeh also argued that the district court erred in evaluating the enforceability of the subpoena under a “reasonable relevance” standard. According to Zadeh, the Fourth Amendment, which requires a more stringent standard, should apply because his patients have a reasonable expectation of privacy in their medical records.

Under the “reasonable relevance” standard, courts will enforce an administrative subpoena issued in aid of an investigation if: “(1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome,” the opinion said.

Applying this standard, the district court found, and the appeals court agreed, that “the DEA’s subpoena is consistent with the Fourth Amendment.”

In addition, Zadeh contended that the district court should have declined to enforce the subpoena for abuse of process. According to Zadeh, the affidavit submitted to the court in support of enforcement was signed by one of the DEA agents who had visited Zadeh’s office as part of the investigation.

Zadeh said the DEA agents did not introduce themselves, as the representatives of the Texas Medical Board did, which “undermines the credibility of the enforcement action and suggests that the DEA already has some of the information sought by the subpoena.”

The appeals court noted that Zadeh “put forth no evidence that the DEA agents who joined the Medical Board investigators meant to mislead Dr. Zadeh’s employees by remaining silent during this time.”

Moreover, Zadeh’s contention that but for the allegedly improper access to the records, the DEA would not have subsequently issued the subpoena, was not supported by the evidence, the appeals court held.


**Fourth Circuit Vacates Dismissal of FCA Action, Tells Court to Consider Jurisdictional Defenses First**

The Fourth Circuit vacated April 26 a federal district court’s dismissal of a whistleblower’s second amended complaint against a pharmaceutical manufacturer alleging illegal off-label promotion and the payment of kickbacks to physicians.

The lower court dismissed the complaint under Fed. R. Civ. P. 9(b) for failing to allege the actual submission of a false claim to the government for payment.
In an unpublished opinion, the Fourth Circuit found that defendants asserted jurisdictional defenses—the False Claims Act (FCA) first-to-file and public disclosure bars—that the district court should have considered before assessing the sufficiency of the complaint.

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 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 health care programs. The federal and state governments declined to intervene in the action.


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.

The second time around the court again found the amended complaint still failed to meet the heightened pleading requirements under Fourth Circuit precedent.

The Fourth Circuit said, however, that the lower court should not have dismissed on this basis.

On remand, the appeals court told the district court to determine whether the first-to-file or public disclosure bars deprived it of subject matter jurisdiction.


Fifth Circuit Affirms Civil Monetary Penalties Imposed on Nursing Home

The Fifth Circuit affirmed April 28 civil monetary penalties that the Centers for Medicare & Medicaid Services (CMS) imposed on a Texas nursing facility, finding substantial evidence supported an administrative law judge’s (ALJ’s) order upholding the fines.

The Texas Department of Aging and Disability investigated nursing facility River City’s treatment of a certain resident and found numerous violations of federal regulations.

CMS agreed with the Department’s findings and imposed money penalties against River City totaling $68,950. Specifically, CMS imposed an “immediate jeopardy” penalty of $4,050 per day for each day between April 23, 2013 and May 6, 2013, and also assessed a “less than immediate jeopardy” penalty of $250 per day between May 7, 2013 and June 24, 2013.
River City appealed the findings to an ALJ and the Departmental Appeals Board, which both upheld the penalties.

The Fifth Circuit found substantial evidence supported the ALJ’s decision.

River City argued that the evidence did not support the ALJ’s finding that its treatment of the resident violated nursing home regulations.

But the appeals court said that despite obvious changes in the resident’s condition, River City staff did not immediately notify her family or consult with a physician. Such inaction “did not conform to numerous federal regulations,” the appeals court said.

The appeals court also found the penalties imposed on River City were reasonable.

*River City Care Ctr. v. U.S. Dep’t of Health and Human Servs*, No. 15-60315 (5th Cir. Apr. 28, 2016).

**Third Circuit Upholds Health Care Fraud Conviction**

The Third Circuit in an unpublished opinion affirmed May 2 the conviction of a health care fraud defendant, rejecting her arguments that evidence introduced at trial was improper. The appeals court rejected, among other things, defendant’s argument that the use of certain records violated the Health Insurance Portability and Accountability Act (HIPAA). The appeals court found the disclosure was authorized for a law enforcement purpose, a long-recognized exception to HIPAA.

Defendant Maryam Jafari appealed her conviction on one count of conspiracy to violate the Anti-Kickback Statute and two counts of receiving kickbacks. The charges stemmed from a conspiracy involving high-ranking personnel at Orange Community MRI in which management devised a plan to pay cash payments to doctors, including Jafari, in return for referrals.

The district court sentenced Jafari to 21 months of imprisonment and ordered her to pay a $45,000 fine and forfeit over $40,000. Jafari appealed.

The Third Circuit rejected Jafari’s argument that the evidence presented at trial was not relevant and was unduly prejudicial.

The appeals also rejected Jafari’s contention that the government violated *Brady v. Maryland*, 373 U.S. 83 (1963), finding “no indication that the Government withheld favorable material evidence.”

Jafari also argued the government violated HIPAA’s statutory procedure for using protected medical and health information in litigation.

The appeals court held, however, that the disclosure was authorized for a law enforcement purpose. 45 C.F.R. § 164.512(f)(1)(ii)(A),(5).

The government also sought and was granted a protective order for the medical records at issue, the appeals court noted.


**U.S. Court in Illinois Rejects Counterclaim Against FCA Whistleblower for Contract Breach**
A federal trial court in Illinois rejected May 13 a counterclaim asserted in a False Claims Act (FCA) action against a whistleblower alleging he breached a confidentiality agreement and a privacy policy signed as part of his employment with the company by making certain disclosures to his attorney and the government in the course of pursuing the qui tam lawsuit. Relator Matthew Cieszynski is a certified technician for defendant LifeWatch Services, Inc., which provides remote heart-monitoring services for patients covered by Medicare, Medicaid, TRICARE, and the Veterans Administration Health Care.

In his qui tam action, relator alleged LifeWatch violated the FCA by submitting to the government claims for reimbursement for heart monitoring services that it knew violated federal health care program requirements.


LifeWatch sought to add a counterclaim against relator, alleging he breached a confidentiality agreement he signed as a condition of employment and the company’s privacy policy, which he also agreed to abide by, when he disclosed confidential information, including protected health information (PHI), to his attorney and the government.

The court granted relator’s motion to dismiss the counterclaim, finding LifeWatch failed to create a plausible claim that he should be deprived of the public policy protections afforded to whistleblowers for actions taken in investigating and reporting fraud to the government.

Citing other decisions, the court said the disclosures at issue—including a spreadsheet containing PHI and other information about roughly 52,000 patients—did not go beyond what was necessary to pursue his qui tam action.

LifeWatch did not allege relator took documents for any reason other than to support his FCA claim, or that he gave them to any third party other than the government and his counsel. LifeWatch’s counterclaim also failed to allege any damages resulting from relator’s actions.

The fact that the spreadsheet included information about both publicly and privately insured individuals also did not support a claim of overreaching.

“It is unrealistic to impose on a relator the burden of knowing precisely how much information to provide the government when reporting a claim of fraud, with the penalty for providing what in hindsight the defendant views as more than was needed to be exposure to a claim for damages,” the court wrote.

The court also rejected LifeWatch’s claim based on relator’s alleged breach of the company’s privacy policy.

As a threshold issue, the court found LifeWatch failed to plead that the privacy policy, which relator signed more than three years after his employment began, was part of his employment agreement.

Even assuming a breach of contract action could be based on a violation of the privacy policy, relator’s “limited and narrow disclosure of documents to the government is entitled to public policy protection that bars” the counterclaim.

The court acknowledged that the Health Insurance Portability and Accountability Act could apply to the information on the spreadsheet, but pointed to the regulatory safe harbor for employees who
disclose PHI to a government agency or attorney if they believe, in good faith, that their employer engaged in unlawful conduct. See 45 C.F.R. § 164.502(j).


Second Circuit Rejects Off-Label Marketing Allegations in FCA Action Against Pfizer

The Second Circuit affirmed May 17 a district court’s dismissal of a False Claims Act (FCA) action against Pfizer, Inc. alleging it promoted its blockbuster drug Lipitor for off-label uses.


Relator Dr. Jesse Polansky alleged the pharmaceutical manufacturer engaged in an illegal marketing campaign for its cholesterol-lowering drug Lipitor.

According to relator, Pfizer marketed Lipitor to patients who were outside the National Cholesterol Education Program (NECP) Guidelines, which “improperly induced physicians to prescribe the medication, pharmacists to fill the prescriptions, and Medicare and Medicaid to pay for the drug . . .” Relator alleged the claims submitted as a result of Pfizer’s conduct violated the FCA because Medicare and Medicaid do not reimburse off-label prescriptions.

Polansky, who worked as a medical director for Pfizer until he was fired, also alleged five counts of illegal retaliation.

The lower court dismissed the fraud claims, but on an earlier appeal to the Second Circuit, the appeals court remanded to clarify whether the retaliation claims were dismissed as well. United States ex rel. Polansky v. Pfizer, Inc., No. 12-5008-cv (2d Cir. Aug. 6, 2014). The lower court clarified on remand that the retaliation claims remained pending.

Addressing the merits on appeal, the Second Circuit agreed with the district court that the fraud claims should be dismissed because the NECP Guidelines are intended to be advisory, not mandatory, and were not incorporated into the label for Lipitor approved by the Food and Drug Administration (FDA).

The NECP Guidelines appeared on the pre-2009 label for Lipitor, but not the label approved by the FDA after that point, the appeals court noted.

“Where the label imposes cholesterol-level restrictions, it does so only for pediatric patients,” the Second Circuit said.


OIG Says Patient Assistance Provided by Charitable Organization Would Not Violate Federal Fraud and Abuse Laws

A nonprofit, charitable organization may provide financial assistance to individuals with chronic diseases to assist with the costs of health insurance and drug and device therapies without violating the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted June 4.
The nonprofit, tax-exempt, charitable entity proposed an arrangement whereby it would establish a patient assistance program to provide financial assistance to individuals with cost-sharing obligations for prescription drugs or devices, health insurance premiums, or incidental expenses (e.g., travel expenses, ongoing testing), associated with the treatment of chronic diseases.

According to the opinion, before applying for assistance, a patient must have selected her health care provider, practitioner, or supplier, and have a treatment regimen in place and would remain free to change providers, practitioners, suppliers, drug or device therapies, or insurance plans while receiving financial assistance.

In addition, the requestor would solicit donations from a variety of sources, including pharmaceutical and device companies, specialty pharmacies, distributors, individuals, and corporations.

OIG said the proposed arrangement "entails minimal risk of Donor contributions influencing direct or indirect referrals by Requestor."

The OIG relied on the following factors in making its findings: no donor or affiliate of any donor would exert direct or indirect control over the opinion requestor or its patient assistance program; each patient already would have selected his or her health care provider, practitioner, or supplier, and already would have a treatment regimen in place before applying for assistance; and requestor would not provide donors with any data that would enable them to correlate the amount or frequency of their donations with the amount or frequency of the use of their drugs, devices, or services.

In addition, OIG noted that the "fact that Requestor would permit Donors to earmark donations to particular disease funds generally should not, on the facts presented, significantly raise the risk of abuse."

According to the opinion, the requestor certified that no donor or affiliate of any donor would directly or indirectly influence the identification or delineation of disease funds. "Further limiting the risk that Donors could direct funds to their own products, Requestor certified that: (i) it would define its disease funds in accordance with broadly defined disease states based on widely recognized clinical standards; and (ii) except to the extent that Requestor limits certain disease funds to the metastatic stage of certain cancers, its disease funds would not be defined by reference to specific symptoms, severity of symptoms, the method of administration of drugs, stages of a particular disease, type of drug or device treatment, or any other way of narrowing the definition of widely recognized disease states," the opinion stated.

Based on such certifications and facts, OIG concluded "Requestor’s design and administration of the Proposed Arrangement as described herein would provide sufficient insulation so that Requestor’s assistance to patients should not be attributed to, or influenced by, any of its Donors. In these circumstances . . . we do not believe that the contributions Donors would make to Requestor can reasonably be construed as payments to Requestor to arrange for referrals."

Next, OIG concluded financial assistance provided by the requestor to federal health care program beneficiaries presents a low risk of fraud and abuse and is not likely to influence any beneficiary’s selection of a particular provider, practitioner, supplier, product, or service.

"Eligibility determinations would be made in a consistent, uniform manner and would not be based, in whole or in part, on whether a patient’s provider, practitioner, or supplier has made contributions to Requestor’s patient assistance program," OIG observed.

OIG Says Device Maker May Subsidize Medicare Beneficiaries’ Participation in Clinical Study

A medical device manufacturer that provides subsidies to patients who participate in a clinical research study designed to test the efficacy of a certain spinal treatment with limited Medicare coverage wouldn’t trigger administrative sanctions, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion issued June 4.

The requestor manufacturers a “System” of specialized instruments that are used in a minimally invasive direct decompression of the lumbar spine in patients with lumbar spinal stenosis, a procedure known as percutaneous image-guided lumbar decompression (PILD).

Medicare does not cover PILD for lumbar spinal stenosis except under the Coverage with Evidence Development (CED) Program when the procedure is performed pursuant to a clinical study that meets specific parameters.

The Centers for Medicare & Medicaid Services (CMS) must approve the study, which must be a prospective, randomized, and controlled design, the opinion noted.

The requestor developed a clinical research study to evaluate the effectiveness of PILD using its System compared to a sham procedure in the Medicare population. The requestor designed the study in consultation with CMS and otherwise met the CED criteria, meaning Medicare would provide coverage for beneficiaries who participate in the study.

The requestor wouldn’t charge beneficiaries who receive the sham procedure because no therapeutic treatment would be rendered. But CMS and the requestor noted that the lack of copayments would be a tip off to beneficiaries that they received no treatment and compromise the study’s results.

To address this concern, and with the approval of CMS, the requestor is proposing to pay the applicable copayments for all Medicare beneficiaries enrolled in the study, regardless of whether they receive treatment or the sham procedure.

Requestor also is proposing to fully subsidize the costs of PILD using the System for certain patients in the control group who subsequently elect to have the procedure as a way to encourage enrollment in the study.

While the arrangement implicates the Anti-Kickback Statute, OIG said it would not impose administrative sanctions because of the minimal risk of fraud and abuse.

In reaching this conclusion, OIG noted the requestor designed the study consistent with CMS coverage policies; the subsidies are a reasonable means of achieving the study’s goals by encouraging patient participation and allowing the System’s effectiveness to be tested against a control group; the arrangement is wholly independent of any other agreement among the requestor, participating physician investigators, or any of the patients in the study; and patients must satisfy the Study’s enrollment criteria and execute an informed consent document to be eligible to participate.

“These factors, combined with the fact that the Subsidies may be provided only to the small, predetermined number of patients enrolled in the Study, reduce the risk that the Arrangement will result in overutilization or increased costs to the Federal health care programs,” OIG said.

OIG Allows Use of Preferred Hospital Network for Medigap Policies

The use of a “preferred hospital” network as part of Medicare Supplemental Health Insurance (Medigap) policies, where the insurer would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay, would not run afoul of federal fraud and abuse laws, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted June 19.

The opinion requestor offers Medigap and other insurance policies to subscribers. Under the proposal, the requestor would participate in an arrangement with a preferred hospital organization under which network hospitals would provide discounts of up to 100% on Medicare inpatient deductibles incurred by the requestor’s Medigap plan policyholders that otherwise would be covered by the requestor.

The savings would then be shared with policyholders in the form of a $100 premium credit.

Although the law is clear that prohibited remuneration under the Anti-Kickback Statute may include waivers of Medicare cost-sharing amounts, the proposed arrangement presents a sufficiently low risk of fraud or abuse, OIG said.

The opinion noted that neither the discounts nor the premium credits would increase or affect per-service Medicare payments and the arrangement would be unlikely to increase utilization; should not unfairly affect competition among hospitals; would be unlikely to affect professional medical judgment; and would operate transparently.

According to OIG, the premium credit also would implicate the prohibition on inducements to beneficiaries under the civil monetary penalties law.

OIG noted an exception to the law permits benefit plan designs under which plan enrollees pay different cost-sharing amounts. “Although the premium credit is not technically a differential in a coinsurance or deductible amount, it would have substantially the same purpose and effect as such a differential,” OIG said.

OIG also highlighted that the proposed arrangement has the potential to lower Medigap costs for policyholders who select network hospitals, without increasing costs to those who do not.


OIG Greenlights Medigap Policies’ Use of “Preferred Hospital” Network

In an advisory opinion posted July 23, the Department of Health and Human Services Office of Inspector General (OIG) said a company offering Medicare Supplemental Health Insurance (Medigap) policies could use a “preferred hospital” network without triggering sanctions under federal fraud and abuse laws.

Under the proposed arrangement, the requestor, an offeror of insurance products, including Medigap policies, would participate in a preferred provider organization (PPO) that contracts with hospitals for discounts of up to 100% on otherwise applicable Medicare Part A inpatient deductibles for their policyholders.

The requestor would pay the PPO a fee for administrative services each time it receives a discount from a network hospital and would provide a $100 premium credit to policyholders who use a
network hospital for an inpatient stay. Policyholders would be notified of this feature in an initial notification letter and through a program identification card with an icon indicating the participation of the plan in the network.

OIG said the safe harbor for waivers of beneficiary coinsurance and deductible amounts did not apply where, as here, the waivers are part of an agreement with an insurer. Likewise, the proposed arrangement was not eligible for protection under the safe harbor for reduced premium amounts offered by health plans because the discounts only would be offered to enrollees who choose network hospitals.

OIG noted prohibited remuneration under the Anti-Kickback Statute (AKS) may include waivers of Medicare cost-sharing amounts and relief of a financial obligation—here amounts the requestor would otherwise have to pay—may constitute an illegal kickback.

Moreover, the premium credit implicated both the AKS, as remuneration for selecting a network hospital, and also the civil monetary prohibition on inducements to beneficiaries.

OIG concluded, however, the proposed arrangement presented a sufficiently low risk of fraud or abuse.

According to the opinion, neither the waivers nor the premium credits would increase or affect per service Medicare payments—which mostly are fixed for inpatient services—and should not increase utilization.

The opinion also found the arrangement should not unfairly affect competition among hospitals because membership in the PPO network was open to any accredited, Medicare-certified hospital that meets the requirements of applicable state laws.

In addition, the arrangement "would be unlikely to affect professional medical judgment, because the Policyholders’ physicians and surgeons would receive no remuneration, and the Policyholder would remain free to go to any hospital without incurring any additional out-of-pocket expense," OIG said.

OIG noted the premium credit would implicate the prohibition on inducements to beneficiaries, but added the credit was similar to differentials in coinsurance and deductible amounts as part of a benefit plan design for which a statutory exemption exists.

Moreover, OIG observed, savings from the proposed arrangement would be reported to state insurance rate-setting regulations and therefore had the potential to lower costs for all policyholders.


**OIG Blesses System’s Lease of Employees to Related Psychiatric Hospital**

A nonprofit health system may lease non-clinical employees and provide operational and management services to a related psychiatric hospital without triggering administrative sanctions, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted July 28.

Under the proposed arrangement, the hospital would pay the system for its “fully loaded costs” (i.e. salary plus benefits and overhead expenses) for the leased employees and operational and management services. Unlike an existing arrangement, however, the hospital would not pay an additional 2% administrative fee to the system.
Requestors certified that the arrangements are aimed at integrating the system and hospital to achieve cost efficiencies by eliminating duplicative administrative positions and functions.

Under Medicare’s related-organization rules, the program would not reimburse the hospital for any amount in excess of the system’s cost—i.e., the 2% administrative fee isn’t an allowable cost for the hospital. See 42 C.F.R. § 413.17.

The proposed arrangement implicates the Anti-Kickback Statute because the system would charge the hospital, a possible referral source, a rate that may be below fair market value, which could amount to remuneration in exchange for referrals, OIG noted.

The proposal also doesn’t meet the requirements of the personal services and management contracts safe harbor because compensation may be less than fair market value and isn’t set in advance.

But OIG said it could rule out sanctions because the arrangement presented a low risk of fraud and abuse.

For example, OIG noted the proposal was structured around Medicare cost reporting rules for related parties so the hospital is paying the system only its allowable costs.

Another point in favor of the arrangement: the requestors certified the proposal would achieve cost efficiencies and reduce the hospital’s labor and operational costs. These savings could, at least indirectly, be passed on to federal health care programs.

Finally, OIG noted no evidence suggesting the proposal would increase incentives for referrals or that the arrangement was intended for this purpose.


**OIG Oks Program Providing Limited Supply of Cancer Drug for Free to Certain Patients**

The Department of Health and Human Services Office of Inspector General (OIG) approved in an advisory opinion posted August 12 a program that would provide a free cancer drug for a limited time to patients who experience a delay in the insurance approval process.

Although the arrangement implicated the Anti-Kickback Statute (AKS), the OIG said it presented a low risk of fraud and abuse.

The opinion requestors co-promote the drug, which was approved under the Food and Drug Administration’s breakthrough therapy designation.

The requestors work with a vendor and its affiliated pharmacy to run a “Free Supply Program.” Under the arrangement, the requestors provide one free 30-day supply of the drug to patients who meet the Free Supply Program criteria, including that they have experienced a delay in a coverage determination for the drug of at least five business days.

In finding a low risk of an AKS violation, OIG noted that the arrangement “is distinguishable from problematic ‘seeding’ programs in which a manufacturer might offer a drug for free or at a greatly reduced cost to induce a patient onto that drug and for the patient to obtain subsequent supplies that would be billed to Federal health care programs.”
Here, insurance usually covers the drug so having the arrangement in place “for those rare cases in which insurance approval decisions extend beyond five business days is unlikely to influence patients or prescribers to choose the Drug over alternative therapies, particularly where, as here, the alternatives are limited,” OIG said.

OIG also noted a limited risk of overutilization; prescribers would receive no financial benefits for the arrangement; and the arrangement was unlikely to induce a beneficiary to obtain federally payable prescriptions from the pharmacy.

In addition, OIG said the arrangement would entail no cost to federal health care programs.

OIG also concluded the arrangement would not violate the beneficiary inducements civil monetary penalty.


**Free Introductory Visits by Home Health Provider Not Remuneration, OIG Says**

Free introductory visits by a home health provider for new patients would not generate prohibited remuneration under the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General (OIG) concluded in an advisory opinion posted August 13.

The Anti-Kickback Statute “is not implicated if remuneration is not offered, paid, solicited, or received” and the civil monetary penalties (CMP) law is similarly not implicated if remuneration is not offered or transferred to Medicare or a state health care program beneficiary, OIG said.

Here, the introductory visits do not provide any actual or expected economic benefit to patients and therefore do not constitute remuneration, the opinion concluded.

The opinion requestor is a for-profit entity that provides home health services to patients including those who participate in Medicare, Medicaid, and other federal health care programs.

Once the requestor is notified that a patient has selected the provider, an employee "liaison" contacts the patient by telephone to see if he would like an initial visit. During the introductory visit, the liaison does not provide any type of diagnostic or therapeutic services reimbursed by federal health care programs and does not leave any other items or materials with the patient.

“Although these features of the Arrangement may have some intrinsic value to patients because of the established care relationship they have with the Requestor as their selected home health provider, we believe the intangible worth to patients created by this Arrangement does not implicate the Federal anti-kickback statute or the CMP,” OIG said.


**OIG Clears Health System to Offer Free Van Shuttle to Patients**

An integrated health system’s proposal to provide free van shuttle service to certain component medical facilities would not trigger administrative sanctions under the Anti-Kickback Statute (AKS) or the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted October 21.
While a health care provider offering free transportation potentially implicates the AKS and the CMP, OIG found the proposed arrangement had a number of features that sufficiently minimized the risk of fraud and abuse, including offering the service to patients without taking into account the past or anticipated volume or value of federal health care program business.

Under the proposal, the system would offer patients free van shuttle service to several of its component facilities—a large regional referral tertiary/quaternary care medical center located in a rural area and several surrounding (within 16 miles) facilities (a 72-bed community hospital, a clinic operating a multi-specialty group practice with more than 1,000 physicians, a 55-bed community hospital, and an ambulatory surgical center (ASC)).

All the physicians at the medical center, the ASC, and one of the community hospitals are bona fide system employees, while some physicians working at the other community hospital are in private practice. The shuttle service would be offered between the medical facilities, as well as a stop in the town where the medical center is located, along two designated routes ten times daily Monday through Thursday.

OIG said the free transportation raised concerns because its value could exceed $10 per transport or $50 annually, which was more than nominal.

OIG noted it published a proposed rule in October 2014 that would establish a new safe harbor under the AKS to protect free or discounted local transportation to federal health care program beneficiaries under certain circumstances, but the proposal had not been finalized.

But regardless, OIG found the proposed arrangement carried a minimal risk of fraud and abuse under the AKS or CMP. OIG distinguished the proposed arrangement from “suspect arrangements” where free transportation is “selectively offered to patients based on their diagnoses, conditions, treatments or types of insurance coverage.”

The transportation itself also would be basic—a van shuttle that could accommodate wheelchairs but that wouldn’t include “air, luxury or ambulance-level transportation,” which patients could view as more valuable. And the drivers of the vans would be system employees with salaries and benefits—not paid on a per-person or per-patient-transported basis, which OIG would view as problematic.

Another favorable feature, OIG said, was that the van shuttle service would be offered only locally, with the longest circuit being roughly 18 miles, and not outside the medical facilities’ primary service areas, which could indicate an attempt to “leapfrog competitor facilities and recruit beneficiaries” from outside an offeror’s service area.

The system also wouldn’t market or advertise the free transportation to the general public, which would pose a “greater risk that the arrangement is being offered as an inducement for referrals.” Instead, the system plans to inform existing patients only of the availability of the van shuttle.

OIG also wasn’t concerned that the proposed arrangement would subsidize the practices of the private physicians at the second community hospital, noting any benefit to them likely would be “incidental.” “It does not appear that a purpose of the Proposed Arrangement is to induce referrals to System facilities by these physicians, or that the effect of the Proposed Arrangement would be to influence patients to choose the Private Physicians over other practitioners,” OIG said.

Finally, OIG pointed to the system’s certifications that the availability of local public transportation was limited and that no public transportation was available to the medical center or one of the community hospitals.

OIG Modifies Two Advisory Opinions on Patient Assistance Programs

The Department of Health and Human Services Office of Inspector General (OIG) posted November 2 two modifications to previous advisory opinions on a charity’s operation of patient assistance programs (PAPs) that provide cost-sharing assistance primarily for high-cost medications to patients who have been diagnosed with one of the diseases for which the charity maintains a disease fund and who meet certain financial-need criteria.

In those opinions, OIG said it “approved certain features that we have since determined are problematic.”

OIG said certain aspects of the PAPs now would have to be modified for the charities to retain their favorable advisory opinions.

Each charity that requested the opinion certified to OIG that: it will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states; will not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; will not limit its assistance to high-cost or specialty drugs; and that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.


OIG Allows Nonprofit to Provide Financial Help for MRIs

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted November 23 that a nonprofit organization’s arrangement to help financially needy patients, including Medicare and Medicaid beneficiaries, obtain magnetic resonance imaging (MRI) for the diagnosis or ongoing evaluation of a particular disease by fully subsidizing the costs would not violate federal fraud and abuse laws.

The charitable organization requestor is dedicated to providing resources, services, and support for patients with a single disease, the opinion explained. To be eligible to receive assistance under the arrangement, a patient must have a physician’s order for an MRI for diagnosis of the disease or, if already diagnosed with the disease, have a physician’s order for an MRI for ongoing evaluation.

OIG first examined donors’ contributions to the requestor. “Long-standing OIG guidance makes clear that industry stakeholders can contribute effectively to the health care safety net for financially needy patients, including Federal health care program beneficiaries, by contributing to independent, bona fide charitable assistance programs,” OIG noted.

OIG said the arrangement “entails minimal risk of Donors’ contributions influencing direct or indirect referrals” by the requestor for the following reasons:
• no donor or affiliate of any donor exerts direct or indirect control over requestor or its program;
• while requestor matches patients with contracted MRI providers for MRIs covered under the arrangement, all patients otherwise remain free to change their health care providers, practitioners, suppliers, drugs, and insurance plans;
• requestor does not provide donors with any data that would facilitate a donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its drugs or services;
• and finally, the fact that requestor permits donors to earmark donations to the arrangement should not, on the facts presented, significantly raise the risk of abuse, OIG said.

The opinion also found the requestor’s provision of financial assistance with deductible and cost-sharing obligations presented a low risk of fraud and abuse and was unlikely to influence any beneficiary’s selection of a particular provider, practitioner, or supplier for items or services for which payment may be made by the government.

While the identification of donors may be viewed as problematic in other circumstances, OIG does not see it “as problematic in the instant case because the Arrangement does not support the Donors' products.”


OIG Issues Modified Opinion on Patient Assistance Programs

The Department of Health and Human Services Office of Inspector General (OIG) posted December 7 a modification to a previous advisory opinion on a charity’s operation of a patient assistance program (PAP).

In September 28, 2007 opinion, OIG approved a charity’s operation of a PAP to help financially needy cancer patients pay for their drugs to treat certain types of cancer as well as certain conditions incident to cancer therapy. The arrangement was funded, in part, by donations from manufacturers of drugs used to treat the cancers and conditions incident to cancer therapy and by suppliers of the types of services used by the relevant patient population.

According to OIG, that opinion “approved certain features that we have since determined are problematic.” To that end, OIG informed the requestor that certain aspects of the PAP would have to be modified for the charity to retain its favorable advisory opinion.

To address OIG’s concerns, the requestor made several additional certifications, including: that the charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states; will not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and will not limit its assistance to high-cost or specialty drugs.

The charity also certified that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. OIG also recently modified two other advisory opinions relating to PAPs.
OIG Modifies Another Advisory Opinion on Charity Patient Assistance Program

The Department of Health and Human Services Office of Inspector General (OIG) posted December 16 another modified advisory opinion for a charity’s previously approved patient assistance program (PAP) that provides additional certifications in light of the agency’s Supplemental Special Advisory Bulletin on PAPs, which was issued in May 2014.

According to OIG, the supplemental bulletin expands 2005 guidance “in response to concerns about potential abuses arising from some PAPs’ interactions with their donors.”

OIG sent the supplemental bulletin, as well as targeted letters, to independent charities that previously received advisory opinions to confirm their PAPs operate in compliance with the agency’s guidance and to propose certifications concerning the risks highlighted in the supplement.

The charity in this case received a favorable advisory opinion in September 2006, which was then modified in June 2013, to operate a financial assistance program that pays premiums and cost sharing for individuals with specific blood-related cancers. See Advisory Opinion No. 06-13 and Modification of OIG Advisory Opinion No. 06-13.

The charity responded to OIG’s request and addressed the concerns raised in the supplemental bulletin by making three additional certifications that the charity will not:

- define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states;
- maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and
- limit its assistance to high-cost or specialty drugs.

The charity also certified that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

OIG recently modified several other advisory opinions relating to PAPs.

OIG Posts Favorable Advisory Opinions for Two Patient Assistance Programs

The Department of Health and Human Services Office of Inspector General (OIG) posted January 4 advisory opinions separately approving two charitable organizations’ financial assistance programs for patients with certain diseases. OIG found both patient assistance programs involved a bona fide charity using industry stakeholder contributions in a way that posed minimal risks of generating improper referrals or undue influence of beneficiaries’ selection of providers or suppliers.

In Advisory Opinion 15-16 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 28, 2015), OIG considered a tax-exempt charity’s proposal to provide assistance with out-of-pocket
expenses for outpatient prescription drugs to financially needy insured patients, including Medicare and Medicaid beneficiaries, through two disease funds—one for those with various types of cancer, and one for those with chronic kidney disease (not on dialysis) or iron deficiency anemia.

Advisory Opinion No. 15-17 (Dep’t of Health and Human Servs. Office of Inspector Gen. Dec. 28, 2015) involved another tax-exempt charity’s proposal to provide financial assistance with copayments, health insurance premiums, and insurance deductibles to patients, including Medicare and Medicaid beneficiaries, receiving treatment for the advanced stages of a specified disease.

In both opinions, OIG said it wouldn’t impose administrative sanctions, highlighting similar favorable aspects of the proposals that mitigated fraud and abuse concerns.

OIG said the proposals entailed minimal risk that donors’ contributions would influence referrals by the requesting charities.

For one thing, both organizations were entirely independent from any donor and operated with complete autonomy over how contributions would be used.

Under both programs, patients would be applying for assistance after selecting a health care provider or supplier and already would have a treatment regime in place. Patients at all times could switch providers, suppliers, or drugs without losing the programs’ financial assistance.

The requesting organizations also pledged to provide only aggregate data to any donor, without any individual patient information.

Finally, the organizations certified that no donor would have any direct or indirect say in identifying or delineating the proposed disease funds. Specified disease funds would be for a broadly defined disease states based on widely recognized clinical standards and would cover a broad spectrum of available drugs. The disease funds also would not be defined by reference to any specific symptoms or drugs.

OIG also concluded that neither proposal was likely to influence federal health care program beneficiaries’ selection of a provider or supplier.

Patients would qualify for assistance based solely on financial need under uniform criteria that would be applied consistently.

Both charitable organizations certified that patients determined eligible would be provided assistance on a first-come-first-serve basis to the extent funding was available, regardless of whether the patient’s provider or supplier contributed to the disease fund.

OIG Modifies Four More Advisory Opinions Related to Patient Assistance Programs

The Department of Health and Human Services Office of Inspector General (OIG) posted recently four more modified advisory opinions for charities’ previously approved patient assistance programs (PAPs). The modified opinions provide additional certifications in light of the agency’s Supplemental Special Advisory Bulletin on PAPs, which was issued in May 2014.

In all four opinions, the charities responded to OIG’s requests and addressed the concerns raised in the supplemental bulletin by making three additional certifications that the charities will not:
• define their disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states;
• maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and
• limit their assistance to high-cost or specialty drugs.

OIG has modified several other advisory opinions relating to PAPs following the bulletin's issuance.


**OIG Allows Arrangement Related to Payment for Radiology Transcription**

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted December 29, 2015 that an arrangement under which a hospital would bill a radiology group for transcription of the radiology group’s reports for individuals who are not hospital patients, but rather patients of a third-party clinic that provides the technical component of the radiology exams, would not generate prohibited remuneration under the Anti-Kickback Statute.

A licensed acute care hospital located in a sparsely populated region and a family medicine clinic in a rural community in that region jointly requested the opinion. The clinic physicians are not members of the hospital staff but order certain diagnostic tests from the hospital and sometimes refer patients there, the opinion noted.

The hospital contracts with a radiology practice to supervise all of the hospital's radiology services and to furnish professional interpretations of all radiologic imaging taken at the hospital. The radiology practice is the only one within a 100-mile radius of either the clinic or the hospital.

The clinic electronically transmits images to the radiology practice for interpretation. The radiologists read and interpret the images, dictate reports, and send the dictated reports to the hospital where employees transcribe the reports and return the transcriptions to the radiologists, who provide the final reports of the radiology exams to the clinic. The clinic bills third-party payers, including Medicare and Medicaid, for the technical component of the radiology services, and the radiology practice bills these same payers for the professional component.

Under the proposed arrangement, the hospital would bill the radiology practice for the hospital’s transcription services. The clinic would not pay any portion of the transcription cost through reimbursement of the radiology practice or otherwise, according to the opinion.

The Centers for Medicare & Medicaid Services takes the position that when the technical component and the professional component of radiology services are provided by different entities, the providers
of these separate components may negotiate to determine who will pay for the transcription costs, OIG noted.

OIG addressed the possibility that the radiology practice’s payment of transcription costs would constitute remuneration from the practice to the clinic for the clinic's referrals of the professional component of the radiology exams, since the clinic would not be paying for any transcription costs.

But OIG concluded that under the proposed arrangement no remuneration would pass between the radiology practice and the clinic.

“Because a condition of payment for the professional component of a radiology exam is the preparation of a written report, we conclude that the payment by the Radiology Practice for the transcription of its own reports would not constitute remuneration by the Practice to the Clinic,” OIG said.


OIG OKs Preferred Hospital Network for Medigap Policies

The Department of Health and Human Services Office of Inspector General (OIG) approved a preferred hospital network for Medicare Supplemental Health Insurance (Medigap) policies in an advisory opinion released January 25.

Under the arrangement, the Medigap policies would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for their policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

OIG said it would not impose administrative sanctions under the Anti-Kickback Statute (AKS) or the prohibition on inducements to beneficiaries in connection with the arrangement “given the sufficiently low risk of fraud or abuse and the potential for savings for beneficiaries.”

The opinion requestors, who offer Medigap policies, proposed to participate in an arrangement with a preferred hospital organization, which has contracts with hospitals throughout the country. Under the contracts, Network Hospitals would provide discounts of up to 100% on Medicare inpatient deductibles incurred by policyholders and a portion of the savings resulting from the arrangement would be shared directly with any policyholder who has an inpatient stay at a Network Hospital in the form of a premium credit, the opinion explained.

“The law is clear that prohibited remuneration under the anti-kickback statute may include waivers of Medicare cost-sharing amounts,” OIG noted. In addition, the premium credits implicate not only the AKS (as remuneration for selecting the Network Hospital), but also the civil monetary penalty prohibition on inducements to beneficiaries.

OIG found, however, a sufficiently low risk of fraud or abuse under the AKS because: neither the discounts nor the premium credits would increase or affect per-service Medicare payments; the arrangement would be unlikely to increase utilization; should not unfairly affect competition among hospitals; would be unlikely to affect professional medical judgment; and would operate transparently.

OIG said the premium credits also would implicate the prohibition on inducements to beneficiaries because they would be offered to induce the policyholders to select a particular provider (i.e., a Network Hospital) from a broader group of eligible providers.
But OIG noted that the definition of remuneration in the statute includes an exception for differentials in coinsurance and deductible amounts as part of a benefit plan design, as long as the differentials are properly disclosed to affected parties and meet certain requirements.

“Although the premium credit is not technically a differential in a coinsurance or deductible amount, it would have substantially the same purpose and effect as such a differential,” OIG said.


No Sanctions for AMC That Provides Transportation, Lodging to Women with High-Risk Pregnancies, OIG Says

An academic medical center (AMC) that subsidizes transportation costs and provides free lodging to certain low-income women, including Medicaid beneficiaries, with high-risk pregnancies would not be subject to administrative sanctions, the Department of Health and Human Services Office of Inspector General (OIG) found in an advisory opinion issued March 1. The arrangement implicated the anti-kickback statute (AKS) and Section 1128A(a)(5) of the Social Security Act (the CMP) because the free transportation and short-term lodging could influence the patients' selection of the AMC's hospital as their provider for labor and delivery and postpartum care, OIG noted.

But OIG pledged not to pursue administrative sanctions in connection with the arrangement for a number of reasons—including that it benefited high-risk patients with limited financial means by providing them continuity of care.

The requesting AMC is part of a state university. Its main campus includes a large acute care hospital that includes labor and delivery, as well as a neonatal intensive care unit. The AMC also runs 12 hospital-based clinics that provide prenatal care in certain parts of the state.

The transportation and lodging assistance programs are open only to patients at the 11 clinics located off the hospital's main campus. The aid available under the arrangement isn't advertised, but rather offered to existing clinic patients with high-risk pregnancies under certain circumstances.

OIG said the arrangement wouldn't trigger administration sanctions under the AKS or the CMP because, among other things, it provided a substantial benefit to patients who may otherwise lack the financial means to deliver at the hospital.

OIG also viewed the aid offered under the arrangement as “modest”—paying for public transportation and basic lodging when medically necessary—and limited—only for patients with high-risk pregnancies concerned about being unable to afford travel to the hospital.

“These factors reduce the risk that patients choose to deliver at the Hospital because of the aid offered under the Arrangement, as opposed to other reasons related to continuity and quality of care,” the opinion said.

In addition, the arrangement wasn't advertised, which reduces the likelihood that it was designed as an inducement for patients to select the clinics over other providers, and the decision to provide aid didn't consider whether the patient was a federal health care program beneficiary.

The requesting AMC also certified that none of the costs of the arrangement would be claimed as bad debt or shifted to Medicare or Medicaid.
Finally, the arrangement was part of a program of care established and operated by a state AMC. “We rely, in part, upon the State’s own responsibility, in carrying out the Arrangement, to promote both the well-being of these patients and the integrity of these programs.”

**OIG Allows Use of Preferred Hospital Network for Medigap Policies**

In an advisory opinion posted March 18, the Department of Health and Human Services Office of Inspector General (OIG) said two insurers that planned to begin offering Medicare Supplemental Health Insurance (Medigap) policies could use a "preferred hospital" network without triggering sanctions under federal fraud and abuse laws.

The opinion requesters are licensed insurers owned by the same corporate parent. Although they do not currently offer Medigap policies, they plan to start offering such policies in several states, the opinion said.

In connection with offering Medigap policies, the requestors propose to participate in an arrangement with a preferred hospital organization that contracts with hospitals for discounts of up to 100% on otherwise applicable Medicare Part A inpatient deductibles for their policyholders.

The savings would then be shared with the policyholder in the form of a $100 premium credit.

OIG said the safe harbor for waivers of beneficiary coinsurance and deductible amounts did not apply where, as here, the waivers are part of an agreement with an insurer. Likewise, the proposed arrangement was not eligible for protection under the safe harbor for reduced premium amounts offered by health plans because the discounts only would be offered to enrollees who choose network hospitals.

OIG noted prohibited remuneration under the Anti-Kickback Statute (AKS) may include waivers of Medicare cost-sharing amounts and relief of a financial obligation—here amounts the requestor would otherwise have to pay—may constitute an illegal kickback.

Moreover, the premium credit implicated both the AKS, as remuneration for selecting a network hospital, and also the civil monetary prohibition on inducements to beneficiaries.

OIG concluded, however, the proposed arrangement presented a sufficiently low risk of fraud or abuse.

According to the opinion, neither the waivers nor the premium credits would increase or affect per service Medicare payments and would be unlikely to increase utilization.

OIG also found the arrangement should not unfairly affect competition among hospitals because membership in the network was open to any accredited, Medicare-certified hospital that meets the requirements of applicable state laws.

In addition, OIG said the arrangement was unlikely to affect professional medical judgment and would operate transparently.

OIG noted the premium credit would implicate the prohibition on inducements to beneficiaries, but added the credit was similar to differentials in coinsurance and deductible amounts as part of a benefit plan design for which a statutory exemption exists.

*Advisory Opinion No. 16-03 (Dep't of Health and Human Servs. Office of Inspector Gen. Mar. 11, 2016).*
OIG Allows Use of Preferred Hospital Network for Medigap Policies

Three insurance companies may use a "preferred hospital" network for their Medigap policies without triggering sanctions under federal fraud and abuse laws, the Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted April 19. Similar to other arrangements that OIG has approved, under the proposal the insurers participate in an arrangement with a preferred hospital organization that contracts with hospitals for discounts of up to 100% on otherwise applicable Medicare Part A inpatient deductibles for their policyholders.

The savings would then be shared with policyholders in the form of a $100 premium credit.

OIG said the arrangement would not fall under the safe harbor for waivers of beneficiary coinsurance and deductible amounts or the safe harbor for reduced premium amounts offered by health plans.

Although the arrangement implicated the Anti-Kickback Statute and the civil monetary prohibition on inducements to beneficiaries, OIG said the proposal presented a sufficiently low risk of fraud or abuse.

According to the opinion, neither the waivers nor the premium credits would increase or affect per service Medicare payments and would be unlikely to increase utilization.

OIG also found the arrangement would not unfairly affect competition among hospitals, was unlikely to affect professional medical judgment, and would operate transparently.

The opinion said the premium credit would implicate the prohibition on inducements to beneficiaries, but found the credit was similar to differentials in coinsurance and deductible amounts as part of a benefit plan design for which a statutory exemption exists.


OIG Says Preferred Hospital Network for Medigap Policies Won’t Trigger Sanctions

As it has with similar proposals, the Department of Health and Human Services Office of Inspector General (OIG) approved the use of a preferred hospital network by another set of Medicare Supplemental Health Insurance (Medigap) policies in an advisory opinion released May 3.

Under the arrangement, the Medigap policies would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for their policyholders and, in turn, would provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay.

OIG said it would not impose administrative sanctions under the Anti-Kickback Statute (AKS) or the prohibition on inducements to beneficiaries in connection with the arrangement given the “sufficiently low risk of fraud or abuse.”

The opinion requestors, who offer Medigap policies, proposed to participate in an arrangement with a preferred hospital organization, which has contracts with hospitals throughout the country. Under the contracts, Network Hospitals would provide discounts of up to 100% on Medicare inpatient deductibles incurred by policyholders and a portion of the savings resulting from the arrangement would be shared directly with any policyholder who has an inpatient stay at a Network Hospital in the form of a premium credit, the opinion explained.
“The law is clear that prohibited remuneration under the anti-kickback statute may include waivers of Medicare cost-sharing amounts,” OIG noted. In addition, the premium credits implicate not only the AKS (as remuneration for selecting the Network Hospital), but also the civil monetary penalty prohibition on inducements to beneficiaries.

OIG found, however, a sufficiently low risk of fraud or abuse under the AKS because: neither the discounts nor the premium credits would increase or affect per-service Medicare payments and the arrangement would be unlikely to increase utilization, should not unfairly affect competition among hospitals, would be unlikely to affect professional medical judgment, and would operate transparently.

OIG said the premium credits also would implicate the prohibition on inducements to beneficiaries because they would be offered to induce the policyholders to select a particular provider (i.e., a Network Hospital) from a broader group of eligible providers.

But OIG noted that the definition of remuneration in the statute includes an exception for differentials in coinsurance and deductible amounts as part of a benefit plan design, as long as the differentials are properly disclosed to affected parties and meet certain requirements. “Although the premium credit is not technically a differential in a coinsurance or deductible amount, it would have substantially the same purpose and effect as such a differential,” OIG said.


OIG Says GPO Ownership Change Would Not Trigger Sanctions

A health system’s proposed purchase of the remaining shares in a group purchasing organization (GPO) would not trigger sanctions under the Anti-Kickback Statute (AKS) even though the GPO would no longer qualify for safe harbor protection, according to a Department of Health and Human Services Office of Inspector General (OIG) advisory opinion issued May 9.

Under the proposal, the health system, which currently owns 95% of the GPO, would purchase the remaining 5% to become the GPO’s sole owner.

The requestors certified that the GPO currently satisfies the AKS discount safe harbor, 42 C.F.R. § 1001.952(h), and the GPO safe harbor, 42 C.F.R. § 1001.952(j).

The discount safe harbor excludes from the definition of “remuneration” for purposes of the AKS a discount, including a “rebate,” on an item or service that is payable by federal health care programs. The safe harbor protects discounts offered by a seller to a GPO, by a seller through a GPO to a buyer, and by a GPO to a buyer.

The safe harbor for GPOs excludes from the definition of “remuneration” certain fees paid by vendors to GPOs.

After the purchase, the requestors also certified that the GPO would continue to satisfy the discount safe harbor—members would continue to receive the records necessary to disclose discounts, and the GPO would not impede members from meeting reporting requirements.

OIG noted, however, that even if the discounts and rebates to members qualified for protection under the discount safe harbor, the administrative fees obtained by the GPO from its vendors would not and would need to be analyzed under the GPO safe harbor.
After the purchase, the GPO would no longer satisfy the requirement for safe harbor protection that the GPO is not wholly owned by an entity that owns any of its members. Specifically, the health system owns or operates roughly 1% of the GPO’s pool of members (800 of 84,000 members).

In other words, OIG said, the proposed ownership change “would cause the GPO Requestor to fall outside the definition of a ‘GPO’ that would be protected by the GPO safe harbor.”

Despite the lack of safe harbor protection, OIG found the proposal would not increase the risk of fraud and abuse to federal health care programs.

OIG took into account the health system's minimal ownership of the GPO's total membership--only 1%--and the requestors certifications that all members would continue to be subject to the same GPO contract terms and conditions regardless of their affiliation with the health system.

“We therefore do not view the Health System’s acquisition of the remaining five percent of the GPO Requestor as increasing the risk to Federal health care programs,” OIG concluded.


OIG Issues Modified Advisory Opinion on Charity Patient Assistance Program

The Department of Health and Human Services Office of Inspector General (OIG) posted May 12 another modified advisory opinion for a charity’s previously approved patient assistance program (PAP) that provides additional certifications in light of the agency’s Supplemental Special Advisory Bulletin on PAPs, which was issued in May 2014.According to OIG, the supplemental bulletin expands 2005 guidance “in response to concerns about potential abuses arising from some PAPs' interactions with their donors.”

OIG sent the supplemental bulletin, as well as targeted letters, to independent charities that previously received advisory opinions to confirm their PAPs operate in compliance with the agency’s guidance and to propose certifications concerning the risks highlighted in the supplement.

The charity in this case received a favorable advisory opinion in May 2010, which previously was modified in May 2011, to operate a PAP to provide cost-sharing assistance for specialty medications to patients who are diagnosed with one of three specific disease states and to maintain a separate fund for genetic testing. See Advisory Opinion No. 10-07. The modified opinion permitted the charity to add new disease funds to its PAP so long as they provided the same safeguards as the original proposal.

The charity responded to the concerns raised in the OIG’s supplemental bulletin by making three additional certifications that it will not:

- define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states;
- maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and
- limit its assistance to high-cost or specialty drugs.

The charity additionally certified that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.
The charity also sought, and the OIG approved, several other modifications to its current operations, including establishing funds that would serve only federal health care program beneficiaries; establishing new funds that cover multiple disease states; and providing additional assistance beyond copayment and premium help in some funds.

OIG recently has modified several other advisory opinions relating to PAPs.

Supreme Court Upholds Federal Exchange Subsidies in ACA Ruling

The U.S. Supreme Court in a 6-3 ruling upheld June 25 the availability of subsidies under the Affordable Care Act (ACA) to federal exchange purchasers of insurance coverage. The majority opinion, written by Chief Justice Roberts and joined by Justices Kennedy, Ginsburg, Breyer, Sotomayor, and Kagan, preserves federal subsidies for some 6.4 million individuals with household incomes between 100% and 400% of the federal poverty line in the 34 states that opted not to establish their own exchanges.

Speculation about how the Court would resolve the challenge—which centers on the ACA provision that establishes federal premium tax credits through "an Exchange established by the State"—has been mounting since it agreed last November to review the Fourth Circuit's decision upholding an Internal Revenue Service (IRS) final rule that allows individuals to qualify for subsidies in the federally facilitated exchanges as a reasonable interpretation of ambiguous statutory text. See King v. Burwell, 759 F.3d 358 (4th Cir. 2014).

In recent weeks, lawmakers and other stakeholders have been scrambling to devise contingency plans if the Court decided to jettison the subsidies in the federal exchanges, but no clear path forward seemed to emerge from those efforts.

The ruling is a decisive win for the government—the majority didn't reach the issue of Chevron deference and instead found reading the statute to foreclose subsidies through the federal exchanges was untenable in the context of the law and its underlying purpose. As a number of commentators have pointed out, because the Court did not rely on Chevron, future administrations won't be able to change the interpretation of the law.

"King is a big win for the government not only in the outcome but in the reasoning," said Abbe Gluck, a Professor at Yale Law School, in emailed comments on the decision. "The Court could have given the government victory in a lot of other ways—such as relying on interpretive presumptions or deferring to the agency to fill in statutory gaps—but instead it essentially held that there was no other reasonable way to read the ACA than the reading the government advanced," she noted.

"It's too soon to tell the impact of the opinion on other pending ACA challenges, but the strong, united 6-3 ruling sends a signal that frivolous litigation won't be easily welcomed," Gluck added.

President, Lawmakers React

Following the decision, President Obama, in remarks delivered from the White House, declared the ACA "here to stay" and lauded the decision as a "victory for hardworking Americans all across this country."

"For all the repeal attempts, this law is now helping tens of millions of Americans," Obama said.

Republican lawmakers were quick to turn the focus back to efforts for repealing the now five-year old law.

Senate Finance Committee Chairman Orrin Hatch (R-UT) said in a statement that the "ruling failed to hold the Obama Administration responsible for its reckless execution of its own poorly-crafted law."
Hatch pledged to continue efforts to repeal the ACA and “seek input” on his replacement legislation, the Patient Choice, Affordability, Responsibility, and Empowerment (CARE) Act.

The Patient CARE Act would retain some of the ACA’s popular reforms, such as prohibiting insurance companies from imposing lifetime limits and requiring health plans to offer dependent coverage up to age 26, but would largely strip most of the ACA’s core requirements, including the individual mandate.

House Speaker John Boehner (R-OH) echoed Hatch’s sentiments, vowing to “continue our efforts to repeal the law and replace it with patient-centered solutions that meet the needs of seniors, small business owners, and middle-class families.”

“Interlocking” Reforms

Plaintiffs in the case argued that Congress limited the subsidies to state-run exchanges as a way to incentivize states to establish their own marketplaces rather than default to the federally facilitated model.

Chief Justice Roberts noted repeatedly, however, that the ACA was designed as a series of interlocking reforms—guaranteed issue and community rating requirements, the individual mandate to obtain coverage or pay a penalty, and federal subsidies to help individuals buy coverage who otherwise couldn’t afford it.

The statutory scheme was devised to avoid adverse selection—the so-called “death spiral” of rising coverage costs when the insured population lacks sufficient young and healthy individuals to spread risk—which played out in states that enacted insurance market reforms without adopting a mandate or the extra help to make coverage affordable. Roberts said.

Taking subsidies out of the equation, and also likely eliminating the mandate to buy insurance for the large share of the population who no longer would have access to affordable coverage, while leaving the insurance market reforms in place in all the states would trigger the very scenario the ACA was designed to avoid, Roberts concluded.

“It is implausible that Congress meant the Act to operate in this manner,” he wrote.

Inartful Drafting

While acknowledging the merits of plaintiffs’ plain-meaning reading of the “Exchange established by the State” language, Roberts said a fundamental canon of statutory construction dictates that a single provision not be considered in isolation, but in the context of the statutory scheme.

Roberts noted that giving the language its most natural reading—i.e., that federal subsidies only are available on state-run exchanges—would mean that a host of other ACA provisions—which refer to the federal and state-run exchanges interchangeably—wouldn’t make sense.

The majority refused to attach additional significance to the “established by the State” language, instead chalking it up to “inartful drafting,” something Roberts suggested was commonplace in the ACA.

Statutory Scheme Resolves Ambiguity

While suggesting at oral arguments that the case may be resolved through a Chevron analysis, see Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), Roberts said
it was highly unlikely that Congress would leave the momentous subsidy determination in the hands of the IRS.

Instead, Roberts found the statutory scheme “compels us to reject [plaintiffs’] interpretation because it would destabilize the individual insurance market in a State with a Federal Exchange, and likely create the very ‘death spirals’ that Congress designed the Act to avoid.” He cited several studies projecting a steep rise in premiums and a precipitous decline in those maintaining coverage without the subsidies.

“Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them,” Roberts commented. “A fair reading of the legislation demands a fair understanding of the legislative plan.” And that legislative plan requires that the subsidies be available through the federal exchanges, he concluded.

Dissent

Justice Scalia authored a blistering dissent, in which Justices Thomas and Alito joined, accusing the Court of “rewriting” the legislation in order to “save” the ACA.

“We should start calling this law SCOTUScare,” Scalia said in his withering discourse on what he viewed as the Court’s judicial activism.

According to the dissent, the Court’s decision is “quite absurd” in its finding that the phrase “Exchange established by the State” means “Exchange established by the State or the Federal Government.”

In contrast, the only relevant definition provides that “State” means “each of the 50 States and the District of Columbia,” the dissent argued; accordingly, because “the Secretary is neither one of the 50 States nor the District of Columbia, that definition positively contradicts the eccentric theory that an Exchange established by the Secretary has been established by the State.”

Scalia countered the majority’s reasoning that other parts of the ACA use the terms interchangeably, instead saying the law clearly distinguishes between exchanges established by a state and exchanges established by the federal government.

The dissent also took issue with the Court’s finding that other parts of the ACA appear to assume the availability of tax credits on both federal and state exchanges. According to the dissent, those provisions are “perfectly consistent with limiting tax credits to state Exchanges.”

Even if other parts of law seem incongruous with allowing tax credits on only state exchanges, Scalia admonished that the Court “does not revise legislation . . . just because the text as written creates an apparent anomaly.”

The dissent disagreed with the Court’s decision to look at statutory design and purpose in the first place, arguing the plain meaning of the statute was not ambiguous.

Although the Court reasoned that “without a broadly applicable individual mandate the guaranteed-issue and community-rating requirements ‘would destabilize the individual insurance market,’” Scalia countered that, if true, such predictions “would show only that the statutory scheme contains a flaw; they would not show that the statute means the opposite of what it says.”
In fact, Scalia argued, plaintiffs’ interpretation makes even more sense because although having tax credits available on all exchanges would advance the goal of improving health care markets, it also frustrates the goal of encouraging state involvement in the ACA’s implementation.

According to the dissent, if the Court’s predictions about disastrous economic consequences were true, states would react by setting up their own exchanges—an outcome that would satisfy two of the ACA’s goals: enabling the ACA’s reforms to work and promoting state involvement in its implementation, Scalia contended.

Lastly, Scalia argued that the Court has “no authority to dismiss the terms of the law as a drafting fumble.”

“Let us not forget that the term ‘Exchange established by the State’ appears twice in section 36B and five more times in other parts of the Act that mention tax credits,” Scalia said. “What are the odds, do you think, that the same slip of the pen occurred in seven separate places?” the dissent mused.

“Rather than rewriting the law under the pretense of interpreting it,” the Court should have left it to Congress to clarify its intent regarding the limitation of tax credits to state exchanges, Scalia reasoned.


Second Circuit Upholds Connecticut Restriction on Teeth Whitening Procedure by Non-Dentists

A Connecticut rule restricting the use of certain teeth-whitening procedures to licensed dentist does not violate constitutional due process or equal protection, the Second Circuit held July 17. The appeals court said the state had a legitimate interest in protecting the public’s oral health and the rule, which barred non-dentists from shining a light emitting diode (LED) lamp at a consumer’s mouth for teeth-whitening purposes, was rationally related to that objective, regardless if the restriction was economically motivated.

The Second Circuit noted it wasn’t resolving whether the restriction violated the antitrust laws under the Supreme Court’s decision in North Carolina State Bd. of Dental Examiners v. FTC, 135 S. Ct. 1101 (2015), which held that the North Carolina State Board of Dental Examiners was not entitled to immunity from antitrust scrutiny under the state action doctrine because it was controlled by “active market participants” and its decision to block non-dentists from providing teeth-whitening services was not “actively supervised” by the state.

According to the appeals court, the antitrust issue “is a separate and distinct inquiry that was not argued and is not before us.”

Sensational Smiles, LLC challenged as unconstitutional a declaratory ruling by the Connecticut State Dental Commission restricting the use of LED lights during teeth-whitening procedures to licensed dentists. A federal district court in Connecticut upheld the rule.

The Second Circuit affirmed, finding the rule passed muster under a rational-basis review.

The parties agreed that protecting the public’s oral health is a legitimate governmental interest, but disputed whether the rule was rationally related to that interest.

The appeals court said it was rational for the Commission to conclude that LED lights posed health risks to consumers and that dentists would be better equipped to handle any adverse side effects
from the treatment, or to determine whether the consumer was a good candidate for the procedure in the first place.

“[G]iven at least some evidence exists that LED lights may cause some harm to consumers, and given that there is some relationship (however imperfect) between the Commission’s rule and the harm it seeks to prevent, we conclude that the rule does not violate either due process or equal protection,” the Second Circuit wrote.

Sensational Smiles also argued that the true purpose of the LED restriction was “to protect the monopoly on dental services enjoyed by licensed dentists.”

The Second Circuit acknowledged that some federal appeals courts have held that laws and regulations that are solely motivated by economic protectionism cannot survive rational basis review.

But the appeals court agreed instead with the approach of the Tenth Circuit and held “economic favoritisms is rational for purposes” of reviewing state action.

“Even if, . . . the Commission was in fact motivated purely by rent-seeking, the rational reasons we have already discussed in support of the regulation would be enough to uphold it,” the Second Circuit said.

The appeals court emphasized, however, that it took no position on any potential antitrust issue.

A concurring opinion agreed with the result but would not have concluded that pure economic protectionism is a legitimate state interest for rational basis review.


Federal Court Tosses Ohio’s Challenge to ACA Reinsurance Tax

A federal district court rejected January 5 Ohio’s lawsuit against the federal government over what the state contended was an illegal “tax” on state and local governments under the Affordable Care Act’s (ACA’s) transitional reinsurance program. Granting the federal government’s motion to dismiss, the U.S. District Court for the Southern District of Ohio held that Congress intended all group health plans, including those operated by state and local governments for their employees, to contribute to the three-year transitional reinsurance program.

The court also found the ACA provision did not violate the Tenth Amendment or the Intergovernmental Tax Immunity Doctrine.

Transitional Reinsurance

The ACA transitional reinsurance program authorized tax assessments against health insurance companies and certain employers offering self-insured group health plans for a three-year period beginning in 2014.

The 2015 lawsuit, which was filed by Ohio Attorney General Mike DeWine, four public universities, and Warren County, alleged that the ACA did not authorize an assessment on public employee health plans as part of the transitional reinsurance program, and that even if it did, the imposition of such a tax on state and local governments was unconstitutional.

The state indicated it contributed about $5.3 million to the program in January 2015. DeWine said the state decided to initiate the lawsuit after letters to the Department of Health and Human Services objecting to the mandatory payments went unanswered.
According to the lawsuit, HHS improperly decided to extend the tax assessment on state and local governments for their public employee health plans and collect the mandatory contributions through 2017.

The lawsuit argued HHS’ position was not supported by the statutory language and violated “important federalism protections” of the U.S. Constitution.

The state sought to recoup the monies already paid to the federal government and to invalidate any future assessments.

**Group Health Plan Dispute**

According to the state, Congress didn’t intend to include non-federal governmental health plans in the requirement that group health plans contribute to the reinsurance program.

Although the ACA doesn’t specifically define “group health plan,” the statute references the Public Health Service Act (PHSA), which the court said considers non-federal governmental health plans a subset of group health plans.

“Congress plainly understands the term ‘group health plan’ to encompass ‘non-Federal governmental plans’ (including state and local governmental health plans) under the PHSA, and thus, the ACA,” the court said.

**Constitutional Challenge**

The court also held the transitional reinsurance program as applied to state and local government employers wasn’t unconstitutional.

Citing Supreme Court authority, the court said the Tenth Amendment doesn’t prevent Congress from applying the same regulatory standards to state employers that it does to private-sector employers.

In addition, the court found the reinsurance program didn’t run afoul of the Intergovernmental Tax Immunity Doctrine, which protects against discriminatory taxes levied directly on the states.

“Here, the Transitional Reinsurance Program imposes reinsurance contributions on private-sector employers and state and local government employers equally—i.e., non-discriminatorily. That is all the Constitution requires,” the court wrote.

Health Information Technology

U.S. Court in California Narrows Anthem Data Breach Lawsuit, But Allows Certain State Law Consumer Claims

A federal district court judge in California issued February 14 a ruling dismissing some, but allowing other, claims in a putative class action against Anthem, Inc., its affiliates, and various Blue Cross Blue Shield companies stemming from a massive data breach last year involving the personal information of roughly 80 million former and current customers. Consumers filed numerous lawsuits in courts across the country after Anthem announced the breach, which compromised personal information including names, dates of birth, Social Security numbers, and other identifying data, in February 2015.

The actions, which were brought under various state and federal consumer protection laws, later were consolidated in multi-district litigation before the U.S. District Court for the Northern District of California.

Plaintiff consumers generally alleged Anthem and the other defendants didn’t do enough to safeguard their personal data, misrepresented the adequacy of their security measures, and failed to timely notify customers of the data breach, which occurred between December 2014 and January 2015.

Action Trimmed

In a lengthy opinion, U.S. District Court Judge Lucy H. Koh agreed to dismiss, without prejudice, claims against certain non-Anthem defendants with whom plaintiffs failed to allege a sufficient connection.

Koh also rejected a negligence claim under Indiana law against all defendants, finding that only the state's attorney general could bring data breach actions. Breach of contract claims under California, New Jersey, and New York law also were shelved, albeit with leave to amend, on a finding that plaintiffs didn’t point to any specific contract language pledging to keep their personal data secure.

In addition, Koh dismissed claims under the Kentucky Consumer Protection Act (KCPA), noting no authority for allowing a KCPA claim to be brought as a class action, and under the Georgia Insurance Information and Privacy Protection Act, finding plaintiffs failed to allege a “disclosure” of their personal information by Anthem.

New York, California Consumer Claims

Significantly, however, Koh ruled plaintiffs had standing to bring their claims under California’s unfair competition law (UCL) for unlawful or unfair business practices, holding consumers’ so-called “benefit-of-the-bargain losses” amounted to a cognizable economic injury under the statute. Koh also held plaintiffs alleged causation to support standing.

Plaintiffs contended they paid premiums to defendants that in part were intended to fund adequate security measures to protect their personal information. But according to plaintiffs, they didn’t get what they bargained for because defendants actually failed to take sufficient steps to safeguard their data.

Consumers essentially were arguing that defendants “profited from their lax security measures,” Koh said. She held that, at least at this stage of the litigation, plaintiffs stated a claim to recover restitution for these benefit-of-the-bargain losses under the UCL.
On the issue of causation, defendants argued that other security breaches in the marketplace could be to blame for the misuse of plaintiffs’ personal information, citing, as an example, recent data breaches at eBay, Target, Home Depot, Neiman Marcus, and other major companies.

Rejecting this argument, Koh noted that defendants’ theory would “create a perverse incentive for companies: so long as enough data breaches take place, individual companies will never be found liable.”

Koh did dismiss, with leave to amend, plaintiffs’ fraud claim under the UCL, saying they failed to specify the timing of alleged misrepresentations about the adequacy of defendants’ security measures.

Similar to her UCL analysis, Koh also allowed plaintiffs’ claims under the New York General Business Law (GBL) provision prohibiting deceptive business practices.

Koh agreed with defendants that costs associated with credit monitoring and the potential for future identity theft were not cognizable injuries under the statute. But Koh found plaintiffs stated cognizable economic harm under the GBL for a loss of privacy and value in personal information, as well as for benefit-of-the-bargain losses.


**U.S. Court in Maryland Finds Data Breach Victim Lacked Standing**

A federal trial court in Maryland found May 18 it lacked subject matter jurisdiction to consider a putative class action alleging Children’s National Health System (CNHS) violated state consumer protection laws by allowing a data breach to occur. According to the decision, the named plaintiff did not have standing in federal court because she failed to show an increased risk of identity theft, under the facts of her case, was a concrete injury.

The court declined to dismiss the case, instead remanding to the Maryland state court where the action was initiated.

Plaintiff Fardoes Khan received treatment at a CNHS-operated hospital and provided her personal identifiable information such as date of birth, Social Security number, address, and telephone number. CNHS also kept records of Khan’s private health information.

In 2014, hackers, as part of a “phishing” scam, gained access to certain CNHS employees’ email accounts, which contained personal and health care-related information of approximately 18,000 patients. CNHS notified each patient of the data breach, but noted “no evidence that the information has been misused.”

As an affected patient, Khan sued CNHS in Maryland state court alleging its failure to take sufficient measures to safeguard patients’ confidential information violated Maryland and District of Columbia consumer protection laws. She did not allege, however, any actual misuse of the data. CNHS removed the action to federal court.

The U.S. District Court for the District of Maryland held Khan failed to show an injury in fact to support Article III standing.

Khan asserted that the data breach made her a more likely target of identity theft, but the court said those allegations were not enough for a data breach victim to show standing.
Instead, the court explained, a plaintiff must allege either “actual examples of the use of the fruits of the data breach for identity theft,” including against other affected individuals, or “a clear indication that the data breach was for the purpose of using the plaintiffs’ personal data to engage in identity fraud.”

According to the court, the case law, both at the federal appeals court and district court levels, was consistent with this standard for assessing whether a data breach victim sufficiently alleged an injury in fact arising from an increased risk of identity theft.

In this case, Kahn did not allege the hackers actually misused any of the patient data compromised in the breach. She also did not show that the hackers’ purpose through the phishing emails was to use patients’ personal data to engage in identity fraud.

The court declined, however, to fully grant CNHS’ motion to dismiss, noting its discretion under federal law was limited to remanding a case if it lacks subject-matter jurisdiction, not to dismissing the case.

Health Insurance and Regulation

Eleventh Circuit Upholds Finding That ERISA Plan Participant Was Due Benefits

The Eleventh Circuit affirmed May 26 a lower court’s denial of relief from judgment under the Employee Retirement Income Security Act of 1974 (ERISA) that a plan administrator was liable for payment of benefits to a plan participant. The administrator’s motion contended that newly discovered evidence entitled it to relief, but the appeals court found the administrator failed to show "material evidence that would probably produce a new result if the final judgment were reconsidered."

After a motorcycle accident that was the result of Cornelius Faison's attempt to elude police, Faison was treated at Tallahassee Memorial Hospital. Faison eventually amassed $481,783.48 in medical bills.

Paragon Benefits, Inc., the third-party administrator of Faison's employee benefit plan, denied benefits on the basis that the medical care related to his accident was not covered under the terms of the plan.

Faison appealed the denial to Donalsonville Hospital, Inc., the named fiduciary and administrator of the plan (Hospital) and was sent a letter explaining that Paragon denied coverage based on the plan's "Illegal Acts" exclusion.

Faison sued the Hospital under ERISA, alleging the denial of benefits was improper. The district court found for Faison in the amount of $481,783.48. The Hospital then filed a Fed. R. Civ. P. 60(b) motion for relief from judgment.

According to the Hospital, newly discovered evidence showed that Tallahassee Memorial "wrote off" Faison's entire medical bill, $420,631.55, to charity.

Faison argued that although he participated in Tallahassee Memorial's financial assistance program and received a charitable credit for the charges he incurred, under the terms of that program, the charitable credit would become null and void if Faison recovered payment for the charges from the Hospital.

But the Hospital contended that Faison's declaration failed to prove he was under any legal obligation to reimburse Tallahassee Memorial for the charitable credit pursuant to the terms of the financial assistance program.

The district court denied the Hospital's Rule 60(b) motion, finding Faison "may be liable to Tallahassee Memorial Hospital for his expenses initially covered by a charitable credit should they be paid by an insurance provider."

The appeals court agreed. "Put simply, the Hospital did not show that Faison was not still liable to Tallahassee Memorial for his full medical bill of $420,631.55," the appeals court concluded.

With regard to the evidence of the charitable credit, the court found "the Hospital proffered no evidence of when that version of the application was in effect, whether that version of the application contained identical terms as the application signed by Faison, or whether the form constituted the entire application for the program or contained an exclusive list of the program's terms."

U.S. Court in New Jersey Certifies Class Challenging Insurer’s Payment Policy for Chiropractic Services

The U.S. District Court for the District of New Jersey certified June 1 a class of plaintiffs objecting to an insurer’s policy of automatically denying certain claims for chiropractic services. The court found a class action was the "superior method" for addressing the issues presented in the case because it would allow one court to resolve whether the insurer’s policy was illegal. The putative class action was brought by three chiropractors who treated patients insured by Horizon Blue Cross Blue Shield of New Jersey and Horizon HMO (Horizon).

The chiropractors regularly provided three types of treatment: (1) chiropractic manipulative therapy (CMT); (2) evaluation and management services; and (3) ancillary physical therapy. During the class period, Horizon paid plaintiffs for CMT but denied the claims for the other services.

According to Horizon, it uses a practice called "bundling" to incorporate payments for all chiropractic treatments into a "global fee" for CMT.

Horizon plan policyholders receive covered services either from a network of participating providers (Par providers), or through out-of-network, non-participating providers (Non Par providers).

Most of the plans operated or administered by Horizon are private employer welfare benefit plans governed by the Employee Retirement Income Security Act of 1974 (ERISA), but certain plans are exempt from ERISA.

The New Jersey Department of Banking and Insurance determined that Horizon's bundling practice violated New Jersey's Unfair Claim Settlement Practices Act and issued a cease and desist order. Plaintiffs sought relief for Horizon's denial of their claims before the cease and desist order.

Plaintiffs brought federal ERISA claims (Counts I-II) and state law claims (Counts III-VI) on behalf of themselves and other chiropractors who were denied benefits under Horizon plans during the Class Period. They sought certification of two classes, and two sub-classes—ERISA or non-ERISA providers with subclasses of Par providers and Non Par providers.

The court found that class certification was appropriate because it would be able to determine, on a class-wide basis, whether the bundling policy violated ERISA or breached all the non-ERISA contracts in this case.

To keep the class manageable, however, the court said "the available relief must be limited to an order that Horizon reprocess the class members' claims."

Horizon's defenses to its bundling policy are simple and apply to all allegations that the bundling policy violated ERISA and New Jersey contract law, the court noted.

Horizon argued that a class should not be certified because "individualized issues" predominate over the central question of the bundling policy's legality.

Finding Horizon’s claims "unpersuasive," the court noted that "[w]hile it is true that Horizon’s ultimate responsibility on each claim will require individual attention, the fairest and most efficient way for the court to address the class members' claims is to consider the legality of the bundling policy on a class-wide basis and, if illegal, to order reprocessing of the claims."

Horizon further argued that the class concerns did not predominate because claims might be denied for reasons other than the bundling policy
According to the court, "[a]ny reason for denial other than the bundling policy is subordinate to the question of the bundling policy's legality because the claims were automatically denied under the bundling policy, without any consideration of whether other legitimate reasons for denial might exist."


**Fifth Circuit Rejects Religious Nonprofits’ Bid for Injunction in Contraceptive Coverage Challenge**

The Fifth Circuit has joined the growing ranks of federal appeals court that have refused to enjoin the contraceptive coverage requirement of the Affordable Care Act (ACA) and its implementing regulations as to religious nonprofits.

In a unanimous panel decision issued June 22, the appeals court found the opt out process provided by the administration as a regulatory “accommodation” for religious nonprofits was unlikely to amount to a substantial burden on the free exercise of religion under the Religious Freedom Restoration Act (RFRA).


The ACA regulations provide a “religious employer” exemption as well as an “accommodation” for certain nonprofits that do not qualify for the exemption but object to contraceptive coverage on religious grounds.

To be eligible for the accommodation, an organization must fill out a self-certification form—the EBSA Form 700—or provide notice of their objections to the contraceptive mandate to the Department of Health and Human Services (HHS) directly, in writing. HHS would then notify insurers and third-party administrators of the need to arrange separate coverage for enrollees of the organization, with no additional cost to the enrollee or the employer.

As with similar lawsuits, plaintiffs in the consolidated Fifth Circuit action that the opt process, including the alternative pathway, impermissibly “triggers” the provision of the contraceptive coverage to their employees by the insurance issuer or their third-party administrator contrary to their sincerely held religious beliefs.

While the district courts held the requirement violates the RFRA, the appeals court disagreed and reversed. “Although the plaintiffs have identified several acts that offend their religious beliefs, the acts they are required to perform do not include providing or facilitating access to contraceptives. Instead, the acts that violate their faith are those of third parties. Because RFRA confers no right to challenge the independent conduct of third parties, we join our sister circuits in concluding that the plaintiffs have not shown a substantial burden on their religious exercise,” the Fifth Circuit wrote.


**U.S. Court in New Jersey Tosses Most Claims Against Aetna Related to Reliance on Flawed Ingenix Database**
The U.S. District Court for the District of New Jersey dismissed June 30 most of the claims brought in a consolidated action against defendants Aetna Health Inc., UnitedHealth Group, Inc., and Ingenix, Inc. alleging that Aetna failed to reimburse insurance subscribers and health care providers properly for out-of-network medical services based on its reliance on flawed data from the Ingenix database. The case is one of many civil actions challenging the widespread reliance on databases owned and operated by Ingenix Inc. The cases generally allege that insurers orchestrated a scheme to artificially reduce and fix “usual, customary, and reasonable” (UCR) schedules for out-of-network reimbursements using information from a flawed database that was maintained by Ingenix.

Most suits were filed after an investigation by the New York Attorney General determined that health insurers who participated in the Ingenix data collection maintained an incentive to provide artificially low claims information, and Aetna and UnitedHealth Group agreed to settlements of $20 million and $50 million, respectively.

The current action was filed by plaintiffs representing three putative classes: (1) subscriber plaintiffs, individually named and representative of a class that contracted for health insurance plans affected by the alleged under-reimbursement scheme; (2) provider plaintiffs, individually named and representative of a class of out-of-network medical providers that treated members of the subscriber class; and (3) association plaintiffs.

A third amended complaint in the long-running case sought to add 15 causes of action under the Employee Retirement Income Security Act (ERISA), the Racketeer Influenced and Corrupt Organizations Act (RICO), the Sherman Act, and state law claims.

Of those claims, only two survived defendants’ motion to dismiss. In an unpublished opinion, the court allowed a breach of contract claim to go forward against Aetna, and allowed only one ERISA claim for unpaid benefits.

Among the ERISA claims dismissed by the court was a claim under Section 503 that Aetna failed to provide a “full and fair review” of denied claims by making benefit reductions there were inconsistent with the terms of the plans. However, the court found plaintiffs failed to “identify any specific aspect of the statute that they claim Aetna violated.”

The court also rejected claims based on Aetna’s alleged breach of its fiduciary duties under section 404 as administrator under the plan.

On these claims the court cited its prior holding in Franco v. Connecticut General Life Insurance, Co., No. 07-6039 (D.N.J.) which found that “[p]laintiffs have not cited, nor has the Court’s independent research uncovered, any binding authority holding that the fiduciary duty of disclosure under ERISA requires that a plan fiduciary disclose the data the plan uses to determine what constitutes the UCR or prevailing fee for a service.”


Second Circuit: Doctors Are Not “Beneficiaries” Under ERISA

Health care providers are not “beneficiaries” of an employee benefit plan under the Employee Retirement Income Security Act (ERISA) by virtue of their in-network status or their entitlement to payment, the Second Circuit ruled July 15. The physician practice in the case was assigned only the
right to collect payment from their patients’ plan, not to assert anti-retaliation protections under ERISA, the appeals court added.


Following an investigation, Cigna concluded that plaintiff was ordering medically unnecessary blood tests for allergies amounting to more than $844,000 in overpayments. Cigna asked plaintiff to return the alleged overpayments and, when plaintiff objected, threatened to terminate the practice from Cigna’s network.

Plaintiff sued in federal court, alleging Cigna violated ERISA’s anti-retaliation provision, which makes it unlawful to “discriminate against a participant or beneficiary for exercising any right . . . under the provisions of an employee benefit plan.” 29 U.S.C. § 1140. Plaintiff sought reinstatement as an in-network provider.

The district court denied plaintiff injunctive relief, finding it lacked standing under ERISA to bring a civil anti-retaliation action as it was not a “participant, beneficiary, or fiduciary” of an ERISA plan.

The court held health care providers aren’t beneficiaries solely because they receive payment directly from a plan, nor do patient assignments for reimbursement purposes convey the right to assert ERISA anti-retaliation claims.

The Second Circuit affirmed, suggesting that plaintiff should have sued under its provider agreement, not ERISA.

Although not defined in ERISA, “we are persuaded that Congress did not intend to include doctors in the category of ‘beneficiaries,’” the appeals court said.

Benefits in the context of ERISA involve bargained-for medical goods and services, not the right to payment, the appeals court explained, noting every other federal circuit court to consider the issue has reached the same conclusion.

Plaintiff also didn’t have standing as its patients’ assignee. The patient assignments were for reimbursement for the medical services rendered, not for other categories of ERISA claims.


**Eighth Circuit Revives State Employee’s Challenge to Contraceptive Coverage**

The Eighth Circuit reversed July 20 the dismissal of a Missouri lawmaker’s lawsuit challenging the contraceptive coverage requirement under the Affordable Care Act (ACA) and its implementing regulations. The lower court found Paul Wieland and his wife, who are devout Roman Catholics and have three daughters, lacked standing because they were seeking an injunction prohibiting enforcement of the mandate against the state, which was not a party to the case.

But the Eighth Circuit disagreed, finding the Wielands established a causal connection between the mandate and their injury, which was “fairly traceable” to the enforcement of the mandate because the state likely would have continued to offer the option of “contraceptive-free” coverage as it previously had under a statutory provision that a district court ruled the ACA preempted. Missouri Ins. Coalition v. Huff, 947 F. Supp. 2d 1014 (E.D. Mo. 2013).
Wieland is a member of the Missouri House of Representative who obtains health coverage for himself and his family through the Missouri Consolidated Health Plan (MCHCP), made available by his employer, the state of Missouri.

Before August 1, 2013, MCHCP offered state employers an opportunity to opt out of contraceptive coverage based on religious objections under a provision of state law. In Huff, however, a federal district court held the ACA preempted the state’s opt out provision. The state did not appeal the decision in Huff.

In their lawsuit, the Wielands contended that, as a result of the ACA mandate, MCHCP placed them in a health care plan that includes coverage for contraceptives in violation of their sincerely held religious beliefs.

On the standing issue, the Wielands argued that absent the mandate they would have a contraceptive-free health care plan.

The Eighth Circuit agreed, noting the mandate caused the state and MCHCP to eliminate contraceptive-free health care plans and therefore caused the Wielands’ alleged injury.

The government argued that it was the state’s independent and discretionary decision not to challenge Huff that triggered the elimination of contraceptive-free plans.

The appeals court, however, viewed Huff as merely clarifying how the ACA would be applied; the mandate itself was the “but-for cause of the change in the Wielands’ healthcare plans.”

The appeals court also found the Wielands’ alleged injury could be redressed by an injunction prohibiting the enforcement of the mandate against MCHCP, which could again offer a contraceptive-free coverage option as it did before under state law.

The Eighth Circuit also questioned Huff’s viability in light of the subsequently decided Supreme Court ruling in Hobby Lobby v. Burwell, 134 S. Ct. 2751 (2014), which found requiring closely held for-profit businesses to provide contraceptive coverage to their employees or pay a penalty violated the Religious Freedom Restoration Act.

The appeals court remanded to the district court for further proceedings, including considering whether Hobby Lobby overruled Huff.


Second Circuit Latest to Reject Religious Nonprofits’ Contraceptive Coverage Challenge

The Second Circuit upheld August 7 the administration’s regulations implementing the Affordable Care Act (ACA) provisions that allow religious nonprofits to opt out of providing contraceptive coverage.

In a unanimous panel decision reversing a lower court ruling, the appeals court found the opt-out process provided by the administration as a regulatory “accommodation” for religious nonprofits was not a substantial burden on their religious exercise and therefore did not violate the Religious Freedom Restoration Act (RFRA).

The ACA regulations provide a “religious employer” exemption as well as an “accommodation” for certain nonprofits that do not qualify for the exemption but object to contraceptive coverage on religious grounds. To be eligible for the accommodation, an organization must fill out a self-certification form or provide notice of their objections to the contraceptive mandate to the Department of Health and Human Services (HHS). HHS then notifies insurers and third-party administrators of the need to arrange separate coverage for enrollees of the organization, with no additional cost to the enrollee or the employer.

As with similar lawsuits, plaintiffs in the action argued that the opt-out process, including the alternative pathway, impermissibly “triggers” the provision of the contraceptive coverage to their employees by the insurance issuer or their third-party administrator contrary to their sincerely held religious beliefs.

While the district court held the requirement violates the RFRA, the appeals court disagreed and reversed, noting the “challenged accommodation for religious objectors relieves, rather than imposes, any substantial burden on Plaintiffs’ religious exercise.”


D.C. Circuit Rejects Challenge Alleging ACA Religious Exemption Violated Establishment Clause

The D.C. Circuit said August 14 an individual’s challenge to the religious exemption in the Affordable Care Act (ACA) as an unconstitutional establishment of religion failed on the merits. While disagreeing with a lower court decision dismissing the action for lack of standing, the appeals court found long-standing precedent upheld similar religious accommodations for Social Security and Medicare taxes.

As did the lower court, the D.C. Circuit ruled the individual did not have standing to assert a claim that the administration’s “transitional policy” to allow temporarily ACA non-compliant plans violated his equal protection rights because his inability to maintain his old insurance plan resulted from the independent choice of his insurer.

The ACA includes a “religious conscience exemption” to the requirement that individuals buy insurance coverage or face a penalty. The exemption is modeled on existing provisions in the Social Security Act allowing individuals to opt out of the Social Security and Medicare programs.

Jeffrey Cutler, a resident of Pennsylvania, is non-observant in his religion and does not qualify for the ACA religious exemption. He alleged that he had insurance, but it was cancelled as a result of the ACA.

Cutler challenged the ACA as unconstitutional in the U.S. District Court for the District of Columbia, alleging the religious exemption violates the First Amendment’s guarantee of religious freedom. He also alleged the transitional policy—allowing insurers to offer ACA non-compliant policies until
October 1, 2016—violated the Equal Protection Clause because the statute could be enforced differently in different states. The district court held Cutler lacked standing to assert either claim.

The D.C. Circuit held Cutler had standing to bring his Establishment Clause challenge to the religious exemption.

Cutler argued that allowing religious objectors to avoid paying for insurance or the penalty while not extending the same exemption to individuals who don’t want to buy insurance for secular reasons was unconstitutional because it favored faith over non-belief.

“Cutler has adequately alleged an injury in fact to his constitutional right not to be treated differently—not to be penalized for lacking insurance—just because he is not religiously motivated,” the appeals court reasoned. The appeals court also found the injury was redressable because granting him the relief he sought would end the differential treatment.

The Establishment Clause challenge failed, however, under “[s]ettled precedent,” which has long upheld a similar exemption in the Social Security Act.

The exemptions in the ACA and Social Security Act are “narrow[ly]” drawn—they are limited to those with sincerely held religious beliefs, and they require the faith system to have a proven track record of providing an alternative safety net for its members so that those individuals don’t later have to avail themselves of the public services to which they have not contributed, the appeals court explained.

Finally, the appeals court held Cutler lacked standing to assert his equal protection claim.

The appeals court was dubious that Cutler “even colorably alleged” differential treatment as he provided no evidence that some states required insurers to maintain ACA non-compliant plans while other states, like Pennsylvania, allowed, but did not require, them to do so.

In any event, the D.C. Circuit concluded that Cutler’s alleged injury was not fairly traceable to the transitional policy—which applied “evenhandedly across the United States.” His own insurer cancelled the policy and therefore any injury stemmed from the decision of a private actor.


**Tenth Circuit Stays Compliance with Contraceptive Mandate Accommodation Pending Supreme Court Consideration**

The Tenth Circuit in an August 21 order provided relief to religious objectors from complying with a regulatory accommodation from the so-called contraceptive mandate in the Affordable Care Act (ACA). In a July 14 decision, the Tenth Circuit joined the Third, Sixth, DC, Seventh, and Fifth Circuits in rejecting religious nonprofits’ efforts to enjoin the contraceptive coverage mandate. In that opinion, the Tenth Circuit ruled that the administration’s regulatory accommodation “relieves Plaintiffs of their obligations under the Mandate and does not substantially burden their religious exercise” under the Religious Freedom Restoration Act (RFRA). _Little Sisters of the Poor Home for the Aged, Denver, CO v. Burwell_, No. 13-1540 (10th Cir. July 14, 2015).

In its latest order, however, the appeals court stayed the mandate pending the Supreme Court’s consideration of plaintiffs’ petition for certiorari. “If the petitions are granted, the stay of the mandate shall continue until the Supreme Court’s final disposition,” the order said.

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The ACA regulations provide a “religious employer” exemption as well as an “accommodation” for certain nonprofits that do not qualify for the exemption but object to contraceptive coverage on religious grounds. To be eligible for the accommodation, an organization must fill out a self-certification form or provide notice of their objections to the contraceptive mandate to the Department of Health and Human Services (HHS). HHS then notifies insurers and third-party administrators of the need to arrange separate coverage for enrollees of the organization, with no additional cost to the enrollee or the employer.

As with similar lawsuits, plaintiffs in the consolidated Tenth Circuit action argued that the opt out process, including the alternative pathway, impermissibly “triggers” the provision of contraceptive coverage to their employees by the insurance issuer or their third-party administrator contrary to their sincerely held religious beliefs.

Meanwhile, the Sixth Circuit on August 21 held the administration's accommodation does not violate RFRA. The case was considered on remand from the Supreme Court after the High Court vacated the Sixth Circuit's original finding that neither the religious exemption from the contraceptive coverage requirements or the accommodation violated plaintiffs' right to free exercise of religion.

In re-examining the case in light of *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), which found closely held, for-profit companies with sincerely held religious beliefs could not be compelled to provide contraceptive coverage to their employees, the appeals court noted the Court discussed the accommodation favorably and nothing in that case changed the Sixth Circuit's opinion that the accommodation does not violate RFRA.


**U.S. Court in DC Says Contraceptive Coverage Mandate Unconstitutional as to Secular Nonprofit**

A federal court in the District of Columbia sided with pro-life group March for Life Education and Defense Fund, which opposes abortion but isn’t a religious organization, in its challenge to the Affordable Care Act (ACA) contraceptive coverage mandate. According to U.S. District Court for the District of Columbia judge Richard J. Leon, the mandate as to March for Life violates equal protection under the Fifth Amendment because it treats the secular nonprofit group differently from similarly situated religious employers like churches that oppose abortion on religious grounds.

The court also ruled that the mandate runs afoul of the Religious Freedom Restoration Act (RFRA) as to March for Life employees, who do oppose the mandate on religious grounds.

The court permanently enjoined the government from enforcing the contraceptive coverage mandate against March for Life, its employees, and its insurers.

**Novel Lawsuit**

Unlike many of the legal challenges to the ACA contraceptive coverage mandate, March for Life, whose foundational tenet is that life begins at conception, argued that the statute and its implementing regulations treat the nonprofit, pro-life group differently than similarly situated religious employers in violation of equal protection.

The ACA regulations provide a “religious employer” exemption as well as an “accommodation” for certain nonprofits that do not qualify for the exemption but object to contraceptive coverage on religious grounds.
Secular nonprofit organizations, like March for Life, which offers health insurance to its employees, are excluded from the exemption and the accommodation.

The U.S. Supreme Court held in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), that closely held, for-profit companies with sincerely held religious beliefs could not be compelled to provide contraceptive coverage to their employees.

Religious nonprofits, which are eligible for the accommodation, have met with little success in challenging the mandate. All federal appeals court to consider their challenges so far have ruled that the accommodation isn’t a substantial burden on their religious exercise.

“Identically Situated”

In finding an equal protection violation in this case, the court focused on the Department of Health and Human Services’ (HHS’) stated reason for implementing the “religious employer” exemption to the mandate—namely, that “houses of worship” were more likely to employ individuals who would be less likely to use contraceptive services.

“[W]hat HHS claims to be protecting is religious beliefs, when it actually is protecting a moral philosophy about the sanctity of human life. HHS may be correct that this objection is common among religiously-affiliated employers. Where HHS has erred, however, is in assuming that this trait is unique to such organizations,” the court noted.

According to the court, March for Life proves this point because its employees are hired to advocate the organization’s pro-life views and are “to put it mildly, ‘unlikely’ to use contraceptives.”

“In this respect,” the court said, “March for Life and exempted religious organizations are not just ‘similarly situated,’ they are identically situated.”

The court therefore held the mandate violated equal protection in this case and “must be struck down as unconstitutional” as to March for Life.

**RFRA Violation**

The court also held that the individual employee plaintiffs stated a violation of the RFRA.

Plaintiff employees argued that participating in a health insurance plan that covers contraceptives goes against their sincerely held religious beliefs. The mandate forces them to make a choice between violating those beliefs or foregoing coverage and facing the penalty for not having insurance. In the court’s view, this “proverbial rock and a hard place” constitutes a substantial burden on the employees’ exercise of religion.

March for Life’s insurer indicated that it would offer employee plaintiffs a plan that excluded contraceptive coverage if doing so was legally permissible. The court said this type of remedy would be sufficiently limited.

“Prohibiting the government from punishing a company that offers a modified plan to an employee plaintiff who certifies that she objects on religious grounds to otherwise-required contraceptive coverage does not enable that company to refuse to provide such coverage to others who do not share those religious objections,” the court concluded.

Second Circuit Reverses Dismissal of Lawsuit Alleging Mental Health Parity Violations Against Claims Administrator

The Second Circuit reversed August 20 in part the dismissal of an action alleging a third-party claims administrator violated the Mental Health Parity and Addiction Equity Act (Parity Act) by improperly imposing financial requirements and treatment limitations on mental health benefits. In so holding, the appeals court issued two critical holdings—that the New York State Psychiatric Association, Inc. (NYSPA) had associational standing at this stage of the litigation and that the third-party claims administrator could be sued for alleged parity violations under the Employee Retirement Income Security Act (ERISA).

NYSPA said in a statement that it was pleased the court found it had associational standing “to represent the interests of our members and their patients.” The group also said the decision “regarding the ability to sue plan administrators is particularly important because it removes a technicality that plan administrators might raise to avoid being responsible when they make determinations that run afoul of federal parity laws.”

Alleged Parity Violations

Plaintiffs, including NYSPA and Jonathan Denbo, sued UnitedHealth Group and various affiliated companies (collectively, United) alleging it violated its fiduciary duties under ERISA, the terms of ERISA-governed health insurance plans that it administered, and the Parity Act, which requires group health plans to ensure financial requirements and treatment limitations applied to mental health benefits aren’t more restrictive than those applied to medical and surgical benefits covered by the plan.

Denbo alleged United, as the third-party administrator of a self-funded plan, treated medical claims more favorably than mental health claims. Specifically, he alleged United subjected mental health claims, but not medical claims, of plan participants to preauthorization requirements or concurrent review and also applied more restrictive review standards. According to Denbo, United violated not only the Parity Act, but in some cases, the terms of the plan it was administering.

The district court granted United’s motion to dismiss, finding NYSPA lacked associational standing to sue on its members’ behalf and that as a claims administrator, United could not be sued for federal parity violations under ERISA.

Associational Standing

The appeals court found NYSPA met the requirements of associational standing.

Specifically, the Second Circuit noted that NYSPA members had standing to sue United in their own right, both as assignees of ERISA benefits and to prevent interference with their provision of mental health treatment; that the action implicated interests germane to NYSPA’s purpose; and that NYSPA’s claims did not require individualized proof, at least as alleged at this point in the litigation.

The appeals court said the district court could revisit the standing issue if at summary judgment or trial the need for individual participation or proof arose.

Parity Claims
The appeals court next held United could be liable under Section 502(a) of ERISA for the alleged parity violations in its capacity as an ERISA claims administrator because it exercised “total control over claims for benefits under the terms of the plan.”

According to the appeals court, United had “sole and absolute discretion” to deny benefits and make “final and binding” decisions as to appeals of those denials. Because of this total control over claims for benefits, United was “an appropriate defendant in a § 502(a)(1)(B) action for benefits,” the appeals court held.

The Second Circuit noted its holding on this issue was in accord with six other federal circuits and followed from Supreme Court precedent.

United also argued that it couldn’t be held liable for Parity Act violations under Section 502(a)(3) of ERISA because it was the claims administrator of a self-funded plan. According to United, the Parity Act only applies to group health plans and it did not offer health insurance coverage to Denbo.

But the appeals court held Section 502(a)(3) “may impose a fiduciary duty arising indirectly from the Parity act even if the Parity Act does not directly impose such a duty.”

United also argued the Section 502(a)(3) claim should be dismissed because adequate relief was available under Section 502(a)(1)(B).

The Second Circuit thought the district court’s dismissal of the Section 502(a)(3) claim on this basis was premature because it wasn’t clear whether monetary benefits alone would provide Denbo with a sufficient remedy.


**U.S. Court in DC Says House Has Standing to Pursue ACA Lawsuit Against Administration**

The U.S. District Court for the District of Columbia held September 9 that the House of Representatives may pursue its lawsuit against the administration over its use of allegedly unappropriated funds to implement the Affordable Care Act (ACA). The court dismissed, however, the lawmakers’ claims that Treasury Secretary Jacob Lew exceeded his constitutional powers by delaying enforcement of the ACA’s employer mandate without seeking an amendment. According to the court, those claims “concern only the implementation of a statute, not adherence to any specific constitutional requirement.”

The lawsuit, which was filed in November 2014, alleged the Secretaries of the Departments of Health and Human Services and Treasury exceeded their constitutional powers by delaying enforcement of the employer mandate without seeking an amendment to the ACA and expending public funds without obtaining congressional appropriations.

Republican lawmakers praised the court’s decision. “Republicans will continue to fight the White House’s unworkable and unaffordable health care law,” House Ways and Means Health Subcommittee Chairman Kevin Brady (R-TX) said in a September 9 statement.

“This lawsuit confirms that the Obama administration cannot usurp congressional authority and spend money that has never been approved,” Brady said.

** Appropriation Claims**
The Secretaries moved to dismiss the action arguing that the House lacked standing to sue. The court dismissed some claims for lack of standing but allowed two to go forward.

The House alleged that the Executive branch has spent billions of dollars without a valid appropriation, in direct contravention of the constitutional provision that “No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . .” U.S. Const. art. I, § 9, cl. 7.

According to the complaint, the Secretaries, despite Congress’ refusal to fund Section 1402 of the ACA, which requires insurance companies that offer qualified health plans to reduce the out-of-pocket cost of insurance coverage for policyholders who qualify, through a current appropriation, nonetheless drew and spent public monies on that program beginning in January 2014.

After examining related precedent, the court concluded that no prior case directly addressed the question of whether Congress has standing to bring a suit against the President.

But the court found the “constitutional trespass alleged in this case would inflict a concrete, particular harm upon the House for which it has standing to seek redress in this Court.”

The court rejected the Secretaries’ argument that the House lacked standing to “maintain an action against the Executive Branch concerning its implementation of a statute,” pointing out the critically important distinction between alleging a constitutional violation and alleging a statutory violation.

The House’s theory here, the court said, “is not about the implementation, interpretation, or execution of any federal statute,” instead it “alleges a specific, constitutional violation that is wholly irrespective of the ACA’s implementation.”

After analyzing the complaint in that manner, it “becomes clear that the House has suffered a concrete, particularized injury that gives it standing to sue,” the court held.

“Congress cannot fulfill its constitutional role if it specifically denies funding and the Executive simply finds money elsewhere without consequence,” the court explained.

“Indeed, the harm alleged in this case is particularly insidious because, if proved, it would eliminate Congress’s role via-a-vis the Executive. The political tug of war anticipated by the Constitution depends upon Article I, § 9, cl. 7 having some force; otherwise the purse strings would be cut,” according to the opinion.

The court dismissed, however, a claim alleging a violation of 31 U.S.C. § 1324 that was based on an alleged violation of the ACA’s “statutory scheme,” and also limited in scope the House’s claims under the Administrative Procedure Act (APA).

Under the APA, the court found the House only had standing to pursue its claim to redress agency action that is “contrary to constitutional right, power, privilege, or immunity.”

The court also dismissed a count citing a violation of Article I § 1 as “insufficient to allege a particularized harm to the House.”

**Employer Mandate Claims**

The House also alleged that Secretary Lew effectively “legislate[d] changes” to Section 1513 of the ACA by delaying the employer mandate beyond December 31, 2013 and by reducing the
percentage of employees or full-time equivalents who must be offered insurance, thereby decreasing the burden on employers.

In dismissing these claims, the court distinguished them from the House’s constitutional claims, finding that the theory of these claims was “fundamentally a statutory argument.”

If the House were allowed to pursue such a theory, “every instance of an extrastatutory action by an Executive officer might constitute a cognizable constitutional violation, redressable by Congress through a lawsuit,” the court said.

The court concluded the complaint as to the employer mandate harms was “too general to state a concrete, particularized harm to the House.”

**Cause of Action**

The Secretaries also argued that the House had no cause of action even if it had standing to sue.

Rejecting that argument, the court held the House alleged a proper cause of action under the Declaratory Judgment Act for each count it had standing to assert.

To state a cause of action under the Declaratory Judgment Act, a court “need only assure itself that the case is ‘within its jurisdiction’ and that the House has filed ‘an appropriate pleading,’” the court said.

The court also denied the Secretaries’ motion to dismiss the APA claim for lack of a cause of action, finding the House had standing because it alleged a legal wrong that was traceable and remediable.

In addition, the court noted the House had an implied cause of action under the Constitution itself.

**Separation-of-Powers**

The court also found the Secretaries’ separation-of-powers argument unavailing. The court refused to be swayed by the Secretaries’ slippery slope argument, finding “prudential considerations do not counsel avoidance of this dispute.”

Acknowledging the novelty of the suit, the court nonetheless said “[t]he refrain by either branch from exercising one of its options does not mean that the option was unavailable; there will never be a history of litigation until the first lawsuit is filed.”

The court also noted its confidence that “this decision will open no floodgates, as it is inherently limited by the extraordinary facts of which it was born.”


**U.S. Court in DC Enjoins HHS from Enforcing Fixed Indemnity Plan Rule Under ACA**

The U.S. District Court for the District of Columbia permanently enjoined September 11 the government from enforcing a rule that bars sellers of fixed indemnity plans from selling to individual consumers unless those consumers certify they have "minimum essential coverage" under the Affordable Care Act (ACA). In so holding, the court found the Department of Health and Human Services exceeded its statutory authority in promulgating the rule.
The final rule was issued May 27, 2014, and provided that fixed indemnity plans will not be treated as excepted benefits unless sold to people "who attest, in their fixed indemnity insurance application, that they have other health coverage that is minimum essential coverage within the meaning of [the ACA]."

Plaintiffs Central United Life Insurance Co. and Gaylan Hendricks, sellers of fixed indemnity plans, sought to enjoin the government from enforcing the rule on the grounds that it exceeded the defendants' statutory authority, violated the Constitution, and was arbitrary and capricious under the Administrative Procedure Act.

Standing

The court found plaintiffs had standing because the old version of the rule did not require an attestation, therefore there was a "concrete harm."

In addition, the court rejected the government's argument that the challenge was unripe because the new rule had not yet been enforced. According to the court, the law of the D.C. Circuit is that "an agency rule . . . is typically reviewable without waiting for enforcement."

Merits

According to the court, the government's new reading of the phrase "fixed indemnity insurance" failed at Chevron's first step because it had no basis in the Public Health Service Act, the statutory text it purported to interpret, and plainly exceeded the scope of that statute.

The relevant statutory language defines the set of "excepted benefits" to include, among other things, "fixed indemnity insurance," 42 U.S.C. § 300gg-91(c)(3), but the phrase "fixed indemnity insurance" is undefined, the court said.

The court found the government's proposed definition unreasonable.

According to the court, the "only reasonable interpretation" of the relevant statutory text "is that the statute looks to the seller's conduct—are they offering the ostensibly excepted benefits in tandem with other benefits—and not the buyer's."

Injunctive Relief

In deciding that injunctive relief was appropriate, the court rejected the government's arguments that (1) plaintiffs' delay in filing the suit "weighs against" a claim of irreparable harm and that they therefore weren't unentitled to injunctive relief, (2) the equitable defense of "unclean hands" barred plaintiffs' request, and (3) that the balance of equities tipped in favor of denying the requested injunction.

Specifically, the court found the government cited no evidence or argument that plaintiffs' six-month delay in filing suit was either unjustified and prejudicial; moreover, plaintiffs offered "both a reasonable explanation for the delay and ample (and unrebutted) reasons to believe that they would suffer irreparable harm if the new fixed indemnity rule remains in force."

The court also found the doctrine of unclean hands inapplicable as "plaintiffs' history of violating the old rule appears to have no causal relationship to this challenge against the new one, and defendants have not even tried to show otherwise," the court said.
Lastly, the court found the public interest weighed in plaintiffs' favor. “Forcing federal agencies to comply with the law is undoubtedly in the public interest, and defendants have not shown to the Court's satisfaction that this clear benefit would be outweighed by the harms putatively caused by plaintiffs' policies," the court held.


**Third Circuit Finds Assignment of Benefits Sufficient to Confer Standing on Health Care Provider Under ERISA**

The Third Circuit held September 11 that a patient's explicit assignment of benefits to her health care provider, without direct reference to the right to file suit, was sufficient to confer standing to the provider to sue for those benefits under the Employee Retirement Income Security Act of 1974 (ERISA). The appeals court noted that in reaching this holding it joined "[e]very United States Court of Appeals to have considered this question."

Plaintiff North Jersey Brain & Spine Center (NJBSC) is a neurosurgical medical practice that treated three patients who were members of ERISA-governed health care plans administered by defendant Aetna, Inc.

Before surgery, each patient executed an assignment that provided: “I authorize [NJBSC] to appeal to my insurance company on my behalf. . . . I hereby assign to [NJBSC] all payments for medical services rendered to myself or my dependents."

Following treatment, Aetna allegedly underpaid or refused to pay claims for each of the patients. NJBSC sued Aetna for non-payment of benefits pursuant to Section 502(a) of ERISA.

The district court dismissed NJBSC’s complaint, holding that the assigned rights to payment did not give NJBSC standing to sue under ERISA.

The Third Circuit reversed.

Under ERISA, health care providers that are neither participants nor beneficiaries in their own right may obtain derivative standing by assignment from a plan participant or beneficiary.

Aetna argued that such an assignment must explicitly include not just the right to payment but also the patient’s legal claim to that payment if a provider is to file suit.

Rejecting this argument, the Third Circuit held that when a patient assigns payment of insurance benefits to a health care provider, that provider gained standing to sue for that payment under ERISA Section 502(a).

“An assignment of the right to payment logically entails the right to sue for non-payment," the appeals court commented.


**Eighth Circuit Enjoins Contraceptive Coverage Requirement Against Religious Groups**

In a departure from the seven other federal appeals courts to consider the issue, an Eighth Circuit panel held September 17 that the accommodation process for religious nonprofits that object to
providing contraceptive coverage pursuant to the Affordable Care Act (ACA) and its implementing regulations amounts to a substantial burden on their exercise of religion. Affirming a lower court decision granting the plaintiffs in the case a preliminary injunction, the appeals court also found in a pair of decisions that the government failed to show the accommodation process was the least restrictive means of achieving its asserted compelling interest in offering women no-cost contraceptive coverage.

The Eighth Circuit ruled plaintiffs were likely to succeed on the merits of their challenge that the contraceptive coverage mandate and accommodation process violated the Religious Freedom Restoration Act (RFRA).

The ACA regulations provide a “religious employer” exemption as well as an “accommodation” for certain nonprofits that do not qualify for the exemption but object to contraceptive coverage on religious grounds.

To be eligible for the accommodation, an organization must fill out a self-certification form or provide notice of their objections to the contraceptive mandate to the Department of Health and Human Services (HHS). HHS then notifies insurers and third-party administrators of the need to arrange separate coverage for enrollees of the organization, with no additional cost to the enrollee or the employer.

As with similar lawsuits, plaintiffs in the action argued that the opt-out process, including the alternative pathway, impermissibly “triggers” the provision of the contraceptive coverage to their employees by the insurance issuer or their third-party administrator contrary to their sincerely held religious beliefs.

Breaking from other federal appeals courts to consider the issue, the Eighth Circuit found the threat of “significant monetary penalties” if plaintiffs failed to comply with the accommodation process imposed a substantial burden on their exercise of religion.

“The question here is not whether [plaintiffs] have correctly interpreted the law, but whether they have a sincere religious belief that their participation in the accommodation process makes them morally and spiritually complicit in providing abortifacient coverage,” the appeals court said.

Assuming a compelling interest in the mandate, the appeals court went on to find that the government failed to prove the accommodation process was the least restrictive alternative for ensuring women have access to cost-free contraceptive coverage.

For example, the appeals court noted a number of potentially viable alternatives suggested by plaintiffs, including that the government assume the cost or that it offer contraceptive coverage through the health insurance exchanges.

New York Court Rejects Insurer’s Lawsuit Against Out-of-Network Physicians

A New York trial court dismissed September 16 a lawsuit brought by United Healthcare Services, Inc. (United) alleging an out-of-network physician practice charged excessive fees for treating the health insurer’s plan participants.

In the lawsuit, United sought to recover more than $1.7 million in alleged damages against Long Island Laparoscopic Doctors (defendants) for tortious interference with contractual relations, conspiracy, and fraud, among other claims. Physicians affiliated with Long Island Laparoscopic don’t participate in United’s network.

United reimbursed defendants for the services provided to its plan participants, largely in the context of medical emergencies, but argued in its subsequent action that the fees were excessive.

The New York Supreme Court, Commercial Division, pointed out that patients in an emergency medical situation aren’t in a position to consider a physician’s in-network or out-of-network status or to negotiate the terms for providing care.

While the fees at issue undoubtedly exceeded “FAIR Health Standards” and Medicare guidelines, these standards were not legally binding on defendants when the charges were submitted, the court said.

The court noted recent legislation, which went into effect March 31, sets forth guidelines for patients, physicians, and health insurers when a non-participating physician provides emergency medical care. This law was not in effect, however, when defendants submitted the bills, and the statute does not address retroactive fee adjustments or clawback of fees that were already paid in full, the court said.

“In the absence of a contractually or statutory mandated fee-cap, physicians are at liberty to set their own fees,” the court concluded in granting defendants’ motion to dismiss.

Seventh Circuit Says Preferred Providers Not “Beneficiaries” Under ERISA

The Seventh Circuit reversed October 1 a lower court’s holding that an insurer improperly failed to follow certain procedures under the Employee Retirement Income Security Act (ERISA). The appeals court found plaintiff preferred providers were not "beneficiaries" under ERISA and were not entitled to the procedures at issue. Two chiropractors and an association of chiropractors sued Independence Hospital Indemnity Plan, Inc., an insurance company. Plaintiff chiropractors are preferred providers under contract with the insurer.

The dispute concerned the amounts providers received under their participating-provider contracts. After reimbursing some services on a fee-for-service basis, the insurer found it made payments in error and recouped the amounts by reducing future payments for other services that the insurer acknowledged were compensable.
Plaintiffs argued that the insurer had to offer hearings under ERISA Section 1133 and the implementing regulations, while the insurer contended that its procedures were governed by contract.

According to the insurer, ERISA requirements did not apply because plaintiffs were neither participants in nor beneficiaries of welfare-benefit plans.

On appeal, plaintiffs conceded they were not participants, but argued they were beneficiaries under ERISA.

The appeals court disagreed, however, noting that a "beneficiary" is a person designated "by a participant" or "by the terms of an employee benefit plan," and plaintiffs were neither.

The appeals court also found that plaintiffs did not rely on a valid assignment from any patient nor on a designation in a plan. Instead, they relied on their contracts with "an insurer in its role as insurer, not any employer or plan sponsor."

The Second Circuit also recently held that a network contract between a medical provider and an insurer does not make that provider a "beneficiary" under ERISA, the appeals court noted. See Rojas v. CIGNA Health & Life Insurance Co., 793 F.3d 253 (2d Cir. 2015).


**High Court Denies Review of Case Finding Provider Lacked Standing to Challenge Delay of ACA Employer Mandate**

The Supreme Court declined October 5 to review a Florida district court’s finding that a provider lacked standing to challenge the government’s planned delay in implementing the Affordable Care Act’s (ACA’s) employer mandate. Under the ACA, employers who have more than 50 full-time employees face tax penalties if they do not offer health insurance coverage that meets statutorily specified minimum requirements.

On July 2, 2013, the government announced that the tax penalties and reporting requirements would not begin until 2015. Plaintiff Kawa Orthodontics, LLP sued defendants Jack Lew, Secretary of the Department of the Treasury; Daniel I. Werfel, Acting Commissioner of the Internal Revenue Service; and the Internal Revenue Service alleging the employer mandate delay exceeded defendants’ statutory authority, was arbitrary and capricious, and was contrary to law under the Administrative Procedure Act.

According to plaintiff, before the government’s delay of the requirements, plaintiff expended substantial time and resources preparing for complying with the mandate. Plaintiff alleged it would not have expended its time and resources on these issues if it had known the employer mandate would not take effect until January 1, 2015.

The court found no concrete injury in fact and, even if there was, plaintiff failed to show a favorable decision would redress that injury.


**U.S. Court in Missouri Says ERISA Preempted State Law Claims for Nonpayment**

The U.S. District Court for the Eastern District of Missouri held November 5 a provider's state law claims against an insurer for nonpayment of care were preempted by the Employee Retirement Income Security Act (ERISA). Plaintiff Chesterfield Spine Center, LLC d/b/a St. Louis Spine and Orthopedic Surgery Center sought preauthorization from defendants Cigna Healthcare, Inc. and Connecticut General Life Insurance Company to provide medical care for patient RN.

On or about October 31, 2012, defendants preauthorized the medical care and told plaintiff that RN was covered by their health insurance policy.

On November 5, 2012, plaintiff provided medical care to RN and then invoiced defendants in the amount of $95,099.

Defendants refused to pay plaintiff, claiming that RN's health insurance policy was not in effect when plaintiff provided the medical care as it was terminated in August 2012.

Plaintiff alleged claims for negligent misrepresentation (Count I), Promissory Estoppel (Count II), Equitable Estoppel (Count III) under state law. Plaintiffs also alleged a claim under ERISA (Count IV).

Defendants moved to dismiss Counts I, II, and III on the grounds that ERISA preempted them.

The court agreed, finding ERISA completely preempted Counts I-III. "For all of these claims, the Court must determine whether Defendants are required to pay benefits under the ERISA plan," the court said. "Although Plaintiff attempts to frame its argument in the alternative, the essence of its state law claims remains that Defendants ‘should have [] paid medical benefits under an ERISA-regulated plan and failed to do so.'"

Under Eighth Circuit precedent, plaintiff's state law causes of action were preempted because plaintiff could have brought them under Section 502(a)(1)(B), (a)(2), and (a)(3) of ERISA and because they arose from a duty created by ERISA or the ERISA health plan.

Defendants would have no independent basis for paying RN's claim, absent an ERISA plan, the court noted.

The court also held that ERISA expressly preempted the state law claims because they related to an ERISA plan.

*Chesterfield Spine Center, LLC v. Cigna HealthCare, Inc., No. 4:14-CV-2067 (E.D. Mo. Nov. 5, 2015).*

**U.S. Court in DC Says West Virginia Lacks Standing to Challenge ACA “Administration Fix”**
The U.S. District Court for the District of Columbia dismissed October 30 for lack of standing West Virginia’s action challenging an administration transitional policy allowing health insurers to continue to offer policies in the individual and small group markets that are not compliant with the Affordable Care Act’s (ACA’s) requirements. The Department of Health and Human Services (HHS) first announced the transitional policy—or “administrative fix”—in November 2013 after a flurry of policy cancellations undermined previous assertions that consumers would not lose coverage they liked as a result of the ACA. At that time, the policy, which is optional for the states and insurers, extended through October 1, 2014. HHS later extended the policy until October 1, 2016.

The ACA requires health insurance plans that went into effect or were renewed after January 1, 2014 to comply with eight market requirements. But the administration’s transitional policy indicated that HHS would refrain from enforcing the requirements. States were encouraged, but not required, to refrain from enforcing the requirements as well.

Plaintiff, the state of West Virginia, challenged the administrative fix in court on a number of grounds. But the court found, without reaching the merits, that the state failed to make the threshold showing of standing, and therefore granted HHS’ motion to dismiss the action.

West Virginia argued it had standing because HHS’ policy “shifted enforcement responsibility to the State” and “made the federal government less politically accountable for the non-enforcement of the ACA at the expense of the States.”

But the court found the state’s asserted injuries were “not the kind of concrete and particularized injury-in-fact that is actual or imminent—and not conjectural or hypothetical—that is required to establish standing.”

The state indicated in a November 6 filing that it was appealing the dismissal to the D.C. Circuit.


Eighth Circuit Denies ERISA Injunctive Relief to Compounding Pharmacies

The Eighth Circuit January 11 denied several compounding pharmacies’ request for injunctive relief under the Employee Retirement Income Security Act (ERISA) after a pharmacy benefit manager began rejecting claims for compounded drugs, finding the pharmacies were unable to show irreparable harm. Plaintiffs Grasso Enterprises, NERxD, and Wiley’s Pharmacy and Compounding Services are compounding pharmacies. Express Scripts, Inc. (ESI), a pharmacy benefits manager, announced in 2014 a program to reduce the increasing costs being incurred by health plans for compound drugs. ESI began denying compound drug claims in July 2014 and fully implemented the program on January 1, 2015.

Plaintiffs sued alleging that ESI was systematically denying payment of compound drug claims without adhering to the procedural requirements of ERISA’s “Claims Regulation,” 29 C.F.R. § 2560.503-1.

Plaintiffs moved for a preliminary injunction requiring ESI to pay all claims for compound medications until it complies with the Claims Regulation, ordering ESI to issue explanation-of-benefit forms complying with the Claims Regulation, and declaring that ESI must provide a procedure for patients to request access to compound medications to comply with the Affordable Care Act.

The district court denied the preliminary injunction, and plaintiffs appealed.
Plaintiffs sought injunctive relief as assignees of patients who claim coverage of their compound drug prescriptions as participants or beneficiaries of health care plans, the opinion noted.

But the appeals court found plaintiffs could not show irreparable harm because plan beneficiaries had an adequate remedy at law. According to the appeals court, a suit under ERISA Section 502(a)(1)(B) would overturn the initial denial of a compound drug pharmacy benefit if that medication was in fact covered under the plan.

“Indeed, the grant of equitable relief declaring what procedures are needed to substantially comply with the Claims Regulation would disrupt efficient plan administration and in some cases would conflict with the ERISA policy that reviewing courts should review final decisions to deny claims for benefits, rather than the initial denials,” the appeals court said.

The appeals court also rejected plaintiffs’ alternative argument that they had standing to bring a civil action under ERISA Section 502(a)(1) or (3) in their own right, as “plan-designated beneficiaries,” based on summary plan descriptions describing how pharmacy benefit programs administered by ESI would be implemented.

The appeals court said the district court, “consistent with every circuit that has considered the question,” correctly concluded that “the Pharmacies do not have standing under ERISA to assert harm to themselves” because they are not ERISA beneficiaries.


Eleventh Circuit Dismisses Physician’s ERISA Claims for Lack of Standing

The Eleventh Circuit affirmed February 2 the dismissal of a physician’s claims for unpaid benefits under an Employee Retirement Income Security Act (ERISA) plan for lack of standing.

Although a provider may acquire derivative standing by obtaining a written assignment from a beneficiary, the plan had an unambiguous anti-assignment clause that rendered any assignment void, the appeals court held.

Dr. W. A. Griffin, a dermatologist, treated a patient insured under a Habitat for Humanity International, Inc. health plan (Plan) as an out-of-network provider.

Blue Cross Blue Shield of Georgia (BCBSGA) serves as the Plan’s claims administrator. Griffin submitted a claim to BCBSGA for services she provided to the insured, which she alleged BCBSGA underpaid.

BCBSGA denied her first appeal and failed to respond to her level two appeal. Griffin then sued Habitat in federal court, bringing ERISA claims for unpaid benefits, breach of fiduciary duty, failure to provide Plan documents, and breach of contract.

The district court granted Habitat’s motion to dismiss, concluding that Griffin lacked standing under ERISA based on the Plan’s anti-assignment provision. The Eleventh Circuit agreed.

Section 502(a) of ERISA provides that only plan participants and plan beneficiaries may bring a private civil action to recover benefits due under the terms of a plan, to enforce rights under a plan, or to recover penalties for a plan administrator’s failure to provide documents.
A health care provider may sue under ERISA pursuant to a valid assignment, but a plan participant or beneficiary may not assign benefits to a provider when the plan includes an unambiguous anti-assignment provision.

Although the insured's assignment purported to transfer to Griffin the right to payment of benefits, Habitat's Plan documents included an anti-assignment provision, which unambiguously prohibited assignment except as required by law.

Griffin argued that Habitat could not rely on the anti-assignment provision because BCBSGA failed to notify her of the provision even after she asked whether the Plan contained such a term.

But the court said equitable estoppel under ERISA applies only when "the plaintiff can show that (1) the relevant provisions of the plan at issue are ambiguous, and (2) the plan provider or administrator has made representations to the plaintiff that constitute an informal interpretation of the ambiguity."

Because the anti-assignment provision was unambiguous, equitable estoppel did not apply, the appeals court found.

The appeals court also rejected Griffin's waiver argument. Although she alleged that BCBSGA failed to inform her of the anti-assignment provision during the administrative process, “even liberally construing her pleadings and accepting her allegations as true, we find these allegations insufficient to establish a ‘clear case’ that Habitat intentionally and voluntarily relinquished its rights under the anti-assignment provision,” the appeals court held.

*Griffin v. Habitat for Humanity Int'l., No. 15-13516 (11th Cir. Feb. 2, 2016).*

**Fifth Circuit Holds Texas Prompt Pay Law Doesn’t Apply to Administrator of Self-Funded Plans**

The Fifth Circuit held February 10 that the Texas prompt pay law doesn’t apply to a third-party administrator of employer self-funded and state government plans. The appeals court also held the Federal Employee Health Benefits Act of 1959 (FEHBA) preempted the statute’s application to the administration of claims under the FEHBP.

Under the Texas Insurance Code, ch. 1301, insurers receiving “clean claims” must determine whether a claim is payable in 45 days for non-electronic claims and 30 days for electronic claims or face a range of late-payment penalties. The statute extends to administrators under contract with an insurer.

Plaintiff Health Care Service Corporation (HCSC), which operates in Texas as Blue Cross and Blue Shield of Texas (BCBSTX), sought a declaratory judgment in federal court that it wasn't subject to the Texas prompt pay law in its capacity as administrator to self-funded and state government plans, or to its administration of claims under the FEHBP.

The action was in anticipation of Methodist Hospitals of Dallas, which has a preferred provider agreement with HCSC, seeking penalties, interest, and attorneys’ fees under ch. 1301 for alleged late payments by BCBSTX.

The district court granted summary judgment to HSCS, finding ch. 1301 didn’t apply to BCBSTX’s administration of the plans at issue and that FEHBA preempted the application of the prompt pay law to Methodist’s claims related to FEHBA-governed plans. The Fifth Circuit affirmed.
The appeals court agreed that the prompt pay law didn’t apply to the administration of self-funded or state government plans because “BCBSTX neither provides for coverage through its ‘health insurance policy’” regarding the plans at issue, “nor is a ‘person’ with whom an ‘insurer’ contracts to perform administrative services.”

BCBSTX was not an “insurer” under ch. 1301 when it acted only as an administrator, but even if it was, it did not provide payments through its “health insurance policy” because it had no financial burden of payment, the appeals court said.

“Simply put, BCBSTX, as an administrator, does not confer any benefits for medical expenses on beneficiaries and therefore does not provide for payment through its ‘health insurance policy,’” the appeals court explained. BCBSTX merely distributes claim payments from plans to providers, it does not provide benefits as the plan administrator.

The appeals court acknowledged that the prompt pay law extends to administrators that contract with “insurers.” The appeals court pointed out, however, that the self-funded and state government plans at issue do not operate as “insurers” under ch. 1301.

The appeals court also held that FEHBA preempted ch. 1301’s application to claims arising under FEHBP plans that BCBSTX processes, citing the federal law’s underlying policy “to ensure nationwide uniformity” in the administration of FEHBA benefits.

Methodist argued that ch. 1301 did not “relate to” FEHBP plans, and therefore was not preempted, because the statute permits a claim for statutory penalties only after an affirmative coverage decision.

In the Fifth Circuit’s view, however, by imposing late-payment penalties, ch. 1301 also imposes claims-processing deadlines on FEHBP that may not synch with federal requirements.


**Eleventh Circuit Rejects Religious Groups’ Challenge to Contraceptive Coverage Accommodation**


The Eighth Circuit stands alone in ruling that the contraceptive coverage mandate and accommodation process likely violate the Religious Freedom Restoration Act (RFRA).
The Supreme Court agreed in November 2015 to review seven challenges brought by religious nonprofits to the contraceptive coverage mandate. The High Court is scheduled to hear oral arguments on March 23.

The ACA regulations provide a “religious employer” exemption as well as an “accommodation” for certain nonprofits that do not qualify for the exemption but object to contraceptive coverage on religious grounds.

To be eligible for the accommodation, an organization must fill out a self-certification form or provide notice of their objections to the contraceptive mandate to the Department of Health and Human Services (HHS). HHS then notifies insurers and third-party administrators of the need to arrange separate coverage for enrollees of the organization, with no additional cost to the enrollee or the employer.

Religious nonprofits argue that the opt-out process, including the alternative pathway, impermissibly “triggers” the provision of the contraceptive coverage to their employees by the insurance issuer or their third-party administrator contrary to their sincerely held religious beliefs.

A divided Eleventh Circuit panel concluded that the regulations do not substantially burden plaintiffs’ religious exercise. Alternatively, the appeals court said the government has a compelling interest in mandating contraceptive coverage and the accommodation is the least restrictive means of furthering that interest.

The Eleventh Circuit stayed enforcement of the mandate and accommodation against plaintiffs pending the High Court’s decision.


**U.S. Court in California Remands Provider's Claim for Payment Finding No ERISA Preemption**

A federal court in California agreed February 24 to remand a medical provider’s action alleging an insurer failed to adequately pay for services provided to its insureds, finding the Employee Retirement Income Security Act (ERISA) did not preempt the claims. The U.S. District Court for the Eastern District of California also denied the insurer’s motion to dismiss.

Plaintiff operates Shasta Regional Medical Center where it provided emergency medical services to enrollees of defendant, which sponsors a self-insured health benefits plan.

According to plaintiff, defendant failed to fully reimburse for the reasonable and customary value of emergency medical services provided to its enrollees between November 4, 2008, and March 28, 2015. Plaintiff did not have any written contract with defendant.

Plaintiff asserted state common law claims, but defendant removed the case to federal court on ERISA preemption grounds. Defendant also argued that the complaint failed to state a claim for relief under ERISA.

The court noted that a third-party medical provider may bring a claim under Section 1132(a) of ERISA if the provider is suing as an assignee of a beneficiary’s rights to the benefits under an ERISA plan. See *Blue Cross of Cal. v. Anesthesia Care Assocs. Med. Group, Inc.*, 187 F.3d 1045 (9th Cir. 1999).
Plaintiff argued that the complaint did not allege it was an assignee for purposes of ERISA's enforcement scheme.

The court agreed, finding defendant’s purported evidence of assignment “does not appear to necessarily show an assignment such that the court could be satisfied that plaintiff could have brought its claims consistent with ERISA's civil enforcement scheme.”

In addition, the court said, the Ninth Circuit recognized in Blue Cross a distinction between the right to payment, which would depend on an enrollee’s assignment to a provider, and the level of payment, which would not.

“In this case, plaintiff's complaint alleges that defendant failed to fully pay claims,” the court reasoned. “Given this allegation, plaintiff's claims relate more closely to the level of payment and do not depend logically on an assignment.”


Supreme Court Says ERISA Preempts State Efforts to Collect Data from Insurers

The U.S. Supreme Court rejected March 1 the state of Vermont’s attempt to require insurers to submit data to an all-inclusive health care database. In a 6-2 decision, the Court held the statutory scheme was preempted by the Employee Retirement Income Security Act (ERISA). According to the Court’s majority opinion, which was authored by Justice Kennedy and joined by Justices Roberts, Thomas, Breyer, Alito, and Kagan, the state statute at issue impermissibly intruded on fundamental components of ERISA’s regulation of plan administration.

“The state statute imposes duties that are inconsistent with the central design of ERISA, which is to provide a single uniform national scheme for the administration of ERISA plans without interference from laws of the several States even when those laws, to a large extent, impose parallel requirements,” Kennedy wrote.

The Vermont law requires disclosure of payments relating to health care claims and other information relating to health care services for the purpose of maintaining an all-inclusive health care database. See Vt. Stat. Ann., tit. 18, § 9410(a)(1).

Liberty Mutual Insurance Company maintains an ERISA-covered health plan that provides benefits in all 50 states. The plan’s third-party administrator, Blue Cross Blue Shield of Massachusetts, Inc., which is subject to Vermont’s disclosure statute, was ordered to transmit its files on eligibility, medical claims, and pharmacy claims for the plan’s Vermont members.

Liberty Mutual was concerned that the disclosure of such information might violate its fiduciary duties and instructed Blue Cross not to comply. Liberty Mutual then filed suit, seeking a declaration that ERISA preempted the Vermont statute.

The U.S. District Court for the District of Vermont granted summary judgment to Vermont, but the Second Circuit reversed, concluding that ERISA preempted Vermont’s reporting scheme.

The High Court agreed that ERISA’s express preemption provision applied to the statute.

ERISA preempts a state law if it has a “reference to” ERISA plans or has an impermissible “connection with” ERISA plans, the Court explained.
The Vermont law governs, or interferes with the uniformity of, plan administration and therefore has an impermissible “connection with” ERISA plans, according to the opinion.

The Court noted that welfare benefit plans governed by ERISA already must file an annual report with the Secretary of Labor. This and other reporting requirements are fundamental to the administration of an ERISA plan, the Court said.

The state law and regulation also govern plan reporting, disclosure, and—by necessary implication—recordkeeping, the opinion said. Because these matters are fundamental components of ERISA’s regulation of plan administration, “differing, or even parallel, regulations from multiple jurisdictions could create wasteful administrative costs and threaten to subject plans to wide-ranging liability,” the Court said.

Vermont’s reporting regime, which compels plans to report detailed information about claims and plan members, both intrudes upon “a central matter of plan administration” and “interferes with nationally uniform plan administration.”

The Court rejected Vermont’s argument that the law fell within its traditional power to regulate in the area of public health. “ERISA pre-empts a state law that regulates a key facet of plan administration even if the state law exercises a traditional state power,” the Court observed.

Justices Thomas and Breyer each filed separate concurring opinions and Justice Ginsburg filed a dissent, which was joined by Justice Sotomayor.

In her dissent, Ginsburg argued that Vermont’s effort to track health care services provided to its residents and the cost of those services did not impermissibly intrude on ERISA’s dominion over employee benefit plans.

According to Ginsburg, the Vermont law and ERISA serve different purposes. ERISA’s reporting requirements ensure that the plans provide covered benefits whereas Vermont’s data-collection statute “aims to improve the quality and utilization, and reduce the cost, of health care in Vermont by providing consumers, government officials, and researchers with comprehensive data about the health care delivery system,” Ginsburg said.

Vermont’s law also does not “impose burdens on ERISA plans of the kind this Court has found sufficient to warrant preemption,” she argued.


**Supreme Court Declines to Review Origination Clause Challenge to ACA Employer Mandate**

The U.S. Supreme Court declined February 29 to review a Fifth Circuit decision that a physician and his employer lacked standing to challenge the individual and employer mandates of the Affordable Care Act (ACA) under the Origination Clause of the U.S. Constitution. Plaintiffs argued the ACA’s individual and employer mandates violated the Origination Clause because all revenue-raising bills must originate in the House of Representatives. The Senate amended wholesale a bill that originated in the House and replaced it with the ACA, which plaintiffs argued included the revenue-raising provisions that are referred to as the individual and employer mandates.

The U.S. District Court for the Southern District of Texas rejected plaintiffs’ Origination Clause challenge noting the ACA was not designed primarily to raise revenue, but instead to expand health care coverage. According to the court, the individual and employer mandates were incidental to the

While the federal district court dismissed the action on the merits, the Fifth Circuit said the court lacked subject matter jurisdiction to consider the constitutional challenge to the ACA.

According to the appeals court, plaintiffs in the case—Steven F. Hotze, MD and his employer Braidwood Management, Inc.—did not have standing and therefore the lower court should never have reached the merits.

In this case, Hotze had a high-deductible health plan through his employer, which he did not show fell short of the “minimum essential coverage” requirement of the ACA’s individual mandate, the appeals court said. Because he failed to show he was subject to the individual mandate penalty, he lacked the required “injury-in-fact” to establish constitutional standing.

The Fifth Circuit also found Braidwood lacked standing to challenge the employer mandate under the Anti-Injunction Act (AIA), which bars pre-enforcement challenges to a “tax.”

With respect to the AIA, the appeals court distinguished the employer mandate from the individual mandate. In *National Federation of Independent Bus. v. Sebelius*, 132 S. Ct. 2566 (2012) (*NFIB*), the Supreme Court held the AIA did not bar a challenge to the individual mandate. According to the Court, Congress labeled the individual mandate payment as a “penalty” not a “tax” and therefore did not intend for the AIA to apply. By contrast, Congress specifically labeled payments pursuant to the employer mandate as a “tax,” triggering the AIA’s application.

The appeals court interpreted the Court’s decision in *NFIB* as requiring strict adherence to the label assigned by Congress. The Fifth Circuit specifically rejected the Fourth Circuit’s reasoning in another case that both the individual and employer mandates should be treated the same under *NFIB* for purposes of the AIA.


**Fifth Circuit Again Holds Texas Prompt Pay Law Doesn’t Apply to Self-Funded Plans Administrator**

In a per curiam opinion, a Fifth Circuit panel held February 18 that the Texas prompt pay law doesn’t apply to a third-party administrator of employer self-funded plans. A week earlier, the Fifth Circuit reached the same conclusion in a case involving the same provider—Methodist Hospitals of Dallas. *Health Care Serv. Corp. v. Methodist Hosps. of Dallas*, No. 15-10154 (5th Cir. Feb. 10, 2016). In that case, the appeals court also found the Federal Employee Health Benefits Act of 1959 (FEHBA) preempted the statute’s application to the administration of claims under the FEHBP.

Under the Texas Insurance Code, ch. 1301, insurers receiving “clean claims” must determine whether a claim is payable in 45 days for non-electronic claims and 30 days for electronic claims or face a range of late-payment penalties. The statute extends to administrators under contract with an insurer.

Plaintiff Aetna Life Insurance Company, which administers preferred provider plans, sought a declaratory judgment in federal court that it wasn’t subject to the Texas prompt pay law in its capacity as administrator to self-funded plans.
Methodist Hospitals of Dallas, which provided health care to enrollees of the plans that Aetna Life administers, sought penalties against Aetna in state court under ch. 1301 for alleged late payments.

The state court concluded that the prompt pay law applied to Aetna Life, and the federal district court deferred to that decision. The federal court also found the Employee Retirement Income Security Act (ERISA) preempted the statute's application to self-funded ERISA plans.

In an unpublished decision, the Fifth Circuit panel reversed, holding the district court erred in deferring to the state trial court’s decision.

Citing its decision in Health Care Serv. Corp., the appeals court ruled that Section 1301 does not apply to a third-party administrator of self-funded employer plans.

According to the appeals court, Aetna Life neither provides payment of benefits through its “health insurance policy” nor is it an administrator with whom an “insurer” contracts because self-funded ERISA plans are not “insurers” under Section 1301.


U.S. Court in Illinois Allows Out-of-Network Emergency Providers' Prompt Pay Claims

A federal court in Illinois refused March 14 to dismiss the bulk of the claims asserted by out-of-network providers of emergency services against an insurer for alleged violations of the Texas prompt pay law. The U.S. District Court for the Northern District of Illinois rejected the argument advanced by defendant Health Care Service Corporation, which operates in Texas as Blue Cross and Blue Shield of Texas, that penalties under the Texas Prompt Pay Act aren’t available where an insurer denies a claim as not payable. The court held that an insurer’s determination of whether a claim is payable isn’t dispositive of whether prompt pay penalties are available. Under the Texas Insurance Code, ch. 1301, insurers must determine whether a “clean claim” is payable in 45 days if received in non-electronic form and 30 days if received electronically or face a range of late-payment penalties. Plaintiffs in this case are out-of-network health care providers and physicians who provided emergency services to defendant’s insureds. Plaintiffs allege that from November 2009 to the present defendant improperly underpaid, late paid, or wholly failed to pay their clean claims. Defendant argued that plaintiffs’ claims should be dismissed because the prompt pay law didn’t apply to denied claims. According to defendant, prompt pay penalties are only available when an insurer determines a claim is payable and then underpays or pays late. The court acknowledged that penalties under the statute are contingent on the claim being payable, but held “it is not the insurer’s determination of whether a claim is payable that is controlling.” In making their argument, defendant relied on a footnote in a recent Fifth Circuit decision, which said that the prompt pay statute “imposes penalties only for late payment of approved claims.” Health Care Serv. Corp. v. Methodist Hosps. of Dallas, No. 15-10154 (5th Cir. Feb. 10, 2016).

According to the court, however, the “Fifth Circuit merely acknowledged the settled principle that a claim must be ‘payable’ for [prompt payment] penalties to apply.”

Plaintiffs could seek penalties for claims that defendant deemed not payable, and thus went unpaid during the statutory timeframe, but that later were determined to be payable, the court said.

U.S. Court in DC Says ACA Insurer Payments Unconstitutional

The U.S. District Court for the District of Columbia held May 12 that the administration can’t provide payments to insurers under the Affordable Care Act’s (ACA) cost-sharing reduction (CSR) program without a congressional appropriation. The lawsuit, brought by the House of Representatives, challenged the administration’s interpretation of Section 1402 of the ACA, which requires insurance companies to reduce copayments, deductibles, and other out-of-pocket costs for certain beneficiaries.

Section 1402 authorizes the government to make direct payments to insurance companies to offset estimated costs incurred from providing the cost-sharing reductions, but Congress has never appropriated any funds for these payments.

Judge Rosemary M. Collyer of the U.S. District Court for the District of Columbia said unlike Section 1401, which provides premium tax credits to low-income individuals, Section 1402 was not funded through a permanent appropriation.

“Such an appropriation cannot be inferred,” she wrote. “Congress authorized reduced cost sharing but did not appropriate monies for it, in the FY 2014 budget or since.”

Collyer agreed, however, to stay an injunction blocking further reimbursements to insurers under Section 1402 pending appeal.


House Energy and Commerce Committee Chairman Fred Upton (R-MI), who along with House Ways and Means Committee Chairman Kevin Brady (R-TX) are spearheading an investigation into the insurer payments, called the decision a “victory for the rule of law and the American taxpayer.”

“We received vindication of what we have known for quite some time—that the administration does not have the authority to spend over $150 billion for payments to insurance companies without an appropriation from Congress,” said Upton.

In a May 12 briefing, White House Press Secretary Josh Earnest said the lawsuit "represents the first time in our nation's history that Congress has been permitted to sue the executive branch over a disagreement about how to interpret a statute."

"[I]t is unfortunate that Republicans have resorted to a taxpayer-funded lawsuit to refight a political fight that they keep losing," Earnest added.


Supreme Court Vacates, Remands Contraceptive Cases, Citing Potential for Compromise
The Supreme Court, in a widely reported per curiam opinion issued May 16, sent back to the lower courts various nonprofit religious organizations’ challenges to the contraceptive coverage requirement of the Affordable Care Act without expressing any “view on the merits of the cases.” The High Court vacated and remanded the cases, telling the federal appeals courts that based on supplemental briefings the parties may be able to fashion a compromise making the Court’s involvement unnecessary.

Commenters seemed to agree that the Court’s move likely was to avoid a 4-4 split decision that would result in different rules in different states.

At issue in the cases was whether the accommodation process for religious nonprofits that object to providing contraceptive coverage to their employees violates the Religious Freedom Restoration Act (RFRA). The nonprofits argue that submitting notice to their insurers, or to the government, of their religious objections triggers the contraceptive coverage in violation of their sincerely held beliefs.

A majority of federal appeals courts—eight in total—have rejected these arguments, however, finding no substantial burden on religious exercise through the accommodation process. The Eighth Circuit stands alone in ruling that the contraceptive coverage mandate runs afoul of the RFRA.

The Court heard oral arguments March 23 in seven cases challenging the mandate. The Court then took the unusual step of asking the government and the religious groups to file supplemental briefs addressing “whether contraceptive coverage could be provided to petitioners’ employees, through petitioners’ insurance companies, without any such notice from petitioners.”

The Court suggested one alternative could be for the religious objectors to inform their insurance companies that they do not want their health plans to include contraceptive coverage, eliminating the need for the groups to submit separate notice to their insurers or the government.

In April, both sides submitted two rounds of briefs, which at first made a compromise seem possible, but later moved further apart on the potential alternative floated by the Court.

The government argued in its briefs that the RFRA doesn’t give the nonprofits the right to insist “that the coverage must consist of contraceptive-only insurance policies” and that women “take affirmative steps to enroll,” while the religious nonprofits contended the government conceded its existing regulatory scheme could be modified without jeopardizing its stated objective of seamless contraceptive coverage.

In its May 13 order, the Court signaled that in its view the parties’ briefs essentially conceded that a compromise was possible.

“[T]he parties on remand should be afforded an opportunity to arrive at an approach going forward that accommodates petitioners religious exercise while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’”

The order made clear—as did a concurring opinion by Justices Sotomayor and Ginsburg—that the Court was leaving the essential questions of the challenges—whether the nonprofits’ religious exercise has been substantially burdened, whether the government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest—unanswered.

At the same time, the Court said the government could continue to ensure that women covered by the challengers’ health plans have access to no-cost contraceptives, but also should not impose penalties on the nonprofits for failing to provide the relevant notice.
Mark Rienzi, senior counsel at the Becket Fund for Religious Liberty, which represents some of the challengers including the Little Sisters of the Poor, called the Court’s order “a game-changer.”

“The Court has accepted the government’s concession that it could deliver these services without the Little Sisters. The Court has eliminated all of the wrong decisions from the lower courts and protected the Little Sisters from government fines,” he said.

In a press briefing May 16, White House Press Secretary Josh Earnest said the administration was pleased with the Court’s decision.

"It will allow millions of women across the country to continue to get the health care coverage that they need,” Earnest said.


Second Circuit Finds Psychiatrists, Associations Lack Standing to Challenge Insurers’ Mental Health Coverage

The Second Circuit affirmed May 13 the dismissal of an action claiming various insurers violated the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and the Employee Retirement Income Security Act (ERISA) by reimbursing mental health providers at a less favorable rate than for other health care services. The appeals court affirmed the lower court’s finding that the individual psychiatrist plaintiffs lacked a cause of action under ERISA and the psychiatric association plaintiffs lacked constitutional standing.

Plaintiffs, two individual psychiatrists, Susan Savulak, MD and Theodore Zanker, MD and three professional associations of psychiatrists, the American Psychiatric Association, the Connecticut Psychiatric Society, Inc., and the Connecticut Council of Child and Adolescent Psychiatry, sued four health insurance companies: AnthemHealth Plans, Inc. (doing business as Anthem Blue Cross & Blue Shield of Connecticut); Anthem Insurance Companies, Inc. (doing business as Anthem Blue Cross and Blue Shield); Wellpoint, Inc.; and Wellpoint Companies, Inc.

The plaintiffs alleged the insurers’ reimbursement practices discriminate against patients with mental health and substance use disorders in violation of MHPAEA and ERISA and also alleged state law claims.

The psychiatrist plaintiffs argued standing to assert their ERISA Section 502(a)(3) claims as third parties bringing suit on behalf of their patients.

However, the appeals court found that argument “conflates the prudential third-party standing doctrine with the requirement that the plaintiff have a cause of action under the statute.”

Because Congress specified in the ERISA statute who may sue, prudential standing principles do not apply, the appeals court explained.

Section 502(a)(3) provides that a civil action under ERISA may be brought “by a participant, beneficiary, or fiduciary.” 29 U.S.C. § 1132(a)(3).

The psychiatrists, as well as the American Medical Association and Connecticut State Medical Society as amici curiae, argued that the psychiatrists may stand in the shoes of their patients and have their patients’ cause of action under the statute.
But the appeals court rejected that argument, finding that because the psychiatrists are not among those expressly authorized to sue, they lacked a cause of action under ERISA.

The appeals court also agreed with the district court that the association plaintiffs did not have constitutional standing under Article III because their members lack standing.


D.C. Circuit Affirms Dismissal of Challenge to ACA Transitional Policy

The D.C. Circuit agreed May 13 with a lower court decision that a challenge to the administration’s “transitional policy” for plans not compliant with the Affordable Care Act’s (ACA) market reforms failed because the plaintiffs lacked standing to assert their claims.

Plaintiffs, the American Freedom Law Center and its Co-Founder and Senior Counsel Robert Muise, sued the government alleging its transitional policy—which allowed insurance companies to temporarily continue offering coverage through non-ACA compliant plans—and hardship exemption—which permitted certain individuals whose policies were cancelled to avoid paying the individual mandate penalty—violated the Administrative Procedure Act and equal protection under the Fifth Amendment.

According to plaintiffs, the administration’s actions caused fewer individuals to purchase ACA-compliant plans, driving up premium costs by narrowing the insurance risk pool.

Specifically, plaintiffs alleged their insurer, Blue Cross Blue Shield of Michigan, informed them that their policy would transition to an ACA-compliant plan. Under the new plan, plaintiffs claimed their monthly premiums increased by 57% at the end of 2014.

The government implemented the transitional policy—which is optional for insurers—and extended it through October 2017 after a number of individuals saw their existing policies cancelled because the plans weren’t ACA compliant.


The D.C. Circuit affirmed the dismissal on that basis.

Even assuming plaintiffs demonstrated an injury in fact, they failed to show that the transitional policy, as opposed to other factors, caused the alleged increase in their premiums.

The appeals court also found plaintiffs could not maintain their equal protection claim, citing its previous decision in Cutler v. United States Dep’t of Health and Human Servs., No. 14-5183 (D.C. Cir. Aug. 14, 2015).

As it found in Cutler, the D.C. Circuit held that plaintiffs’ inability to benefit from the transitional policy stemmed from its insurer’s independent decision to discontinue their previous policy, not from any specific action on the administration’s part.

Healthcare Delivery Systems

Washington Supreme Court Finds Certificate of Need Rule Overly Broad

The Washington Supreme Court invalidated July 9 a state Department of Health rule related to the hospital certificate of need program as inconsistent with the statute. The state high court found the health department exceeded its authority in promulgating the overly expansive interpretation of the statute.

The underlying statute, which the legislature adopted in 1984 (Wash. Rev. Code (RCW) 70.38.105(4)(b)), provides that certificate of need review can be triggered by "[t]he sale, purchase, or lease of part or all of any existing hospital as defined in RCW 70.38.025 including, but not limited to, a hospital sold, purchased, or leased by a health maintenance organization or by a combination of health maintenance organizations except as provided in subsection (7)(b) of this section."

The provision was not being applied consistently so the health department proposed a rule defining "sale, purchase, or lease" of part or all of any existing hospital as "any transaction in which the control, either directly or indirectly, of part or all of any existing hospital changes to a different person including, but not limited to, by contract, affiliation, corporate membership restructuring, or any other transaction."

The Washington State Hospital Association challenged the rule arguing, among other things, that the department exceeded its statutory authority. The trial court agreed.

Affirming, the state high court found the new rule "invalid because it interprets terms in RCW 70.38.105(4)(b) in a manner that is too broad to be consistent with the statute."

According to the high court, the overriding purpose of the certificate of need program is to "promote, maintain, and assure the health of all citizens in the state, [and] provide accessible health services, health manpower, [and] health facilities." See Overlake Hasp. Ass’n v. Dep’t of Health, 239 P.3d 1095 (2010).

The department’s rule goes beyond this purpose as applied to the "sale, purchase, or lease" of any hospital and instead applies to any change of control, the high court said.

For example, the new rule would require that any change in the board of directors of a hospital be subject to certificate of need review, "which is not consistent with RCW 70.38.105(4)(b)’s requirement that a ‘sale, purchase, or lease’ of part or all of a hospital is subject to certificate of need review."


Florida Appeals Court Revives Hospital’s CON Challenge

The Florida District Court of Appeal reversed October 15 the dismissal of a hospital’s action challenging the duration of a Certificate of Need (CON) issued by a state agency to a competing hospital. The appeals court found the agency exceeded its statutory authority in extending the duration of the CON and therefore the plaintiff hospital could resort directly to a court action without exhaustion of remedies.

West Jacksonville Medical Center, Inc. sought a CON from Florida's Agency for Health Care Administration (AHCA), which administers the state's CON program, for construction of a new
hospital within the sub-district encompassing a number of existing hospitals, including St. Vincent’s Hospital and Ed Fraser Memorial Hospital.

Litigation ensued, initiated by St. Vincent’s Hospital, which protested the need for the certificate. Within the year, West Jacksonville and St. Vincent’s entered into a settlement agreement.

Under the settlement agreement, the certificate, which was issued in 2010, would not become effective until mid-2013 with licensure to follow no earlier than December 2016.

After a downturn in the economy, Fraser Hospital, which was not a party in the administrative forum, filed a legal challenge in the circuit court, alleging AHCA had no statutory authority to delay the validity period of the certificate, and that none of the statutory grounds for extensions had been sought.

The court dismissed the action with prejudice as an impermissible collateral attack on the certificate’s issuance.

On appeal, Fraser Hospital argued existing statutory law provided that the validity period for a CON expires 18 months after issuance, and could be extended only in limited circumstances. The practical effect of the settlement agreement, however, was a six-year period from certificate issuance to hospital licensure, Fraser said.

The appeals court agreed with Fraser that the AHCA lacked statutory authority to extend the time for when the certificate’s validity period commenced.

“[W]e find no principle of law allowing an agency, even one with the gravity of AHCA’s charge, to exceed its delegated statutory authority simply because private parties to a settlement agreement deem it mutually beneficial,” the appeals court said.

Although the court “searched for the existence of colorable statutory authority for AHCA’s action in this case,” the appeals court said it could not find any; thus, Frasier Hospital's claim “falls into the limited category of cases allowing for direct resort to a circuit court without exhaustion of remedies.”


**Texas Appeals Court Finds Practice Management Company Didn’t Circumvent Corporate Practice of Medicine Prohibition**

The Texas 14th Court of Appeals, on an issue of first impression, upheld a trial court’s judgment that FemPartners, a physician practice management company, did not exercise sufficient control over a medical practice to be held accountable for the negligence of one of the practice’s physicians. Appellant Andre McCoy alleged that FemPartners and certain defendant entities used a corporate fiction, a medical practice, to circumvent the statutory prohibition against the corporate practice of medicine (CPOM) within the Texas Medical Practice Act (Act).

No prior case has considered the Act in a veil-piercing context. Previous CPOM cases generally have addressed whether a particular agreement or relationship between a physician/medical group and a non-physician individual/entity was void or improper because it permitted the non-physician to practice medicine in violation of the Act—yielding a test as to whether the non-physician in effect employed the physician.

However, in a veil-piercing context, the court here had to determine whether FemPartners and the other entities exercised sufficient control over the medical practice of Obstetrical and Gynecological
Associates, P.A. (OGA) so that the FemPartners entities were able to circumvent CPOM, and thus be held accountable for any underlying medical negligence of an OGA physician. (The underlying case was a medical malpractice action in which the jury found in McCoy’s favor and which was severed from this veil-piercing case.)

The court ruled that FemPartners and the other entities’ summary judgment evidence established that they did not exercise sufficient control over the medical practice such that they were using it as a means to circumvent the Act. Their relationship to the medical practice was a business arrangement related to the administration of nonmedical operations, the court held.


AHLA thanks Lew Lefko, Law Office of Lewis A. Lefko, for bringing this case to our attention and authoring this summary.

**Fourth Circuit Upholds Virginia's CON Law**

The Fourth Circuit found January 21 that a Virginia law requiring medical providers to obtain a “certificate of public need” (CON) before establishing new or expanding existing operations in the state passed constitutional muster. The appeals court affirmed a district court decision finding the CON program didn’t violate the dormant Commerce Clause by discriminating against, or unduly burdening, interstate commerce.

Plaintiffs Colon Health Centers and Progressive Radiology, out-of-state medical providers that wanted to offer MRI and CT services in Virginia, challenged the CON program as discriminatory. Virginia is one of 36 states with CON laws on the books, the Fourth Circuit noted.

The district court dismissed the action in September 2012 for failure to state a claim, but the Fourth Circuit reversed that decision for further consideration of the dormant Commerce Clause issue, noting the case was one of “heightened importance.”

After extensive discovery, the district court granted summary judgment to the state. This time on appeal, the Fourth Circuit affirmed.

The parties agreed that Virginia’s CON law wasn’t facially discriminatory in that it applies equally to in-state and out-of-state providers that want to establish or expand health care operations in the state.

Plaintiffs argued, however, that the CON program was discriminatory in purpose—because its primary goal allegedly was to shelter existing, in-state providers from competition from out-of-state businesses—and in effect—because it negatively impacted interstate commerce to a greater degree that intrastate commerce.

The appeals court rejected both arguments.

In the Fourth Circuit's view, CON regimes “are designed in the most general sense to prevent overinvestment in and maldistribution of health care facilities.” The appeals court said Virginia’s program served a number of legitimate public aims, including improving health care quality, providing access to needed medical services for underserved and indigent populations, and encouraging cost-effective consumer spending.

The appeals court also found plaintiffs failed to show the CON program had a discriminatory effect—i.e., favoring in-state providers over out-of-state ones.
The appeals court pointed to a state expert’s testimony that the application process and the approval rate showed no appreciable difference in treatment between in-state and out-of-state businesses.

In so holding, the appeals court said it was reasonable for the state’s expert to consider the state of incorporation in comparing in-state and out-of-state providers.

Plaintiffs’ expert argued that the certificate requirement discriminated in favor of incumbent health care providers at the expense of new, mostly out-of-state firms.

But the appeals court wasn’t willing to focus on incumbency as the appropriate measure in a dormant Commerce Clause analysis. “Allowing incumbency to serve as the proxy for in-state status would be a risky proposition,” the Fourth Circuit said.

Finally, the appeals court considered whether the CON law unduly burdened interstate commerce.

Applying rational basis review, the appeals court enumerated a number of legitimate interests that Virginia had for its CON program, including improving quality by reducing excess medical capacity (i.e., by increasing the skills of those performing procedures and using equipment with greater frequency); requiring successful CON applicants to provide a certain level of indigent care or in underserved areas; and providing additional revenue to hospitals to cross-subsidize unprofitable service lines.

Plaintiffs pointed to Federal Trade Commission and Department of Justice findings that CON programs aren’t successful in containing health care costs and may pose anticompetitive risks.

While finding plaintiffs’ argument legitimate, the appeals court said “[l]egislators, not jurists, are best able to compare competing economic theories and sets of data and then weigh the result against their own political valuations of the public interests at stake.”

The appeals court also noted that the “idiosyncrasies” of the health care market counseled against courts dismantling “regulatory efforts to counter perceived gaps and inefficiencies."

Labor and Employment

Washington Appeals Court Upholds Physician Noncompete Covenant

The Washington Court of Appeals upheld August 24 a noncompete agreement between a physician and his former practice as reformed for reasonableness by the trial court. The appeals court also upheld the trial court’s award of attorney’s fees to the practice group as the substantially prevailing party in the suit. Doctor Robert Emerick began working at Cardiac Study Center, Inc., P.S. (CSC) in 2002. After Emerick practiced with CSC for two years as a general employee, he became a shareholder in the practice and signed a shareholder employment agreement.

Emerick agreed that during his employment and for five years after termination for any reason, he would not directly or indirectly "engage in the practice of cardiac medicine in any manner which is directly competitive with any aspect of the business of" CSC within Pierce County or Federal Way.

In 2009, CSC sent Emerick a letter informing him that the agreement and Emerick's employment with CSC would terminate on September 30, 2009.

On September 24, 2009, Emerick filed a lawsuit against CSC seeking injunctive and declaratory relief to invalidate the noncompete provisions in the agreement.

The trial court initially found the agreement unenforceable, and CSC appealed. Relying on the trial court's favorable judgment while the appeal was pending, Emerick opened a new practice about a quarter of a mile from one of CSC's Pierce County offices in June 2011.

The trial court's order granting summary judgment was reversed on appeal. The trial court, on remand, found that the geographic and temporal restraints in the noncompete covenant were unreasonable and reformed the restraints accordingly.

Emerick appealed, arguing that the covenant, even as reformed, was unreasonable and unenforceable.

After a lengthy examination of the agreement, the appeals court affirmed the trial court’s holding.

Emerick also argued that the trial court had no basis to toll the running of the noncompete covenant during the pendency of the case. But the appeals court rejected this argument as well, noting that “Emerick is effectively asking this court to credit Emerick with two years of compliance with the noncompete covenant when he has been practicing cardiology in violation of the covenant.”

If the tolling was in error “[t]hat would mean that Emerick used the litigation to his advantage--the covenant would have expired before resolution of the dispute and Emerick would have violated the restrictive covenant without consequence,” the appeals court held.

The appeals court found the trial court was within its equitable authority and did not abuse its discretion when it tolled the running of the noncompete covenant until Emerick is in compliance.

The appeals court also affirmed the trial court’s finding that CSC was the substantially prevailing party and approved of its award of attorney’s fees.


D.C. Circuit Upholds DOL Wage, Overtime Rules for In-Home Care
The D.C. Circuit upheld August 21 Department of Labor (DOL) regulations interpreting the Fair Labor Standards Act (FLSA) exemptions from minimum wage and overtime pay requirements as no longer applicable to workers who provide companionship services and live-in help through third-party agencies. Reversing a lower court ruling, which blocked the regulations from taking effect on January 1, the appeals court pointed to Supreme Court precedent, *Long Island Care at Home, Ltd. v. Coker*, 551 U.S. 158 (2007), holding FLSA did not address whether the companionship-services exemption applied in the third-party employment context, as opposed to caregivers employed directly by recipients or their families.

Instead, the Court in *Coker* found the statute vested DOL with broad discretion to determine how the exemptions should be implemented, the D.C. Circuit said.

Although DOL until recently interpreted the statutory exemptions to include employees of third-party agencies providing companionship and live-in help, the appeals court said it was reasonable for the agency to reverse course in light of “dramatic” changes in the provision of home care services since the original 1975 regulations.

The 1974 amendments to FLSA exempted certain categories of workers from the statute’s wage and overtime protections, including workers providing “companionship services” and “live-in domestic services.”

Under the 1975 implementing regulations, DOL said the two exemptions included workers employed by third parties other than the family or household using the services.

In 2013, however, DOL finalized regulations that reversed the agency’s previous interpretation of the third-party employment issue, citing changes to the home care industry, including the shift away from providing care in institutional settings. The new rules also narrowed DOL’s definition of “companionship services.”

Plaintiff Home Care Association challenged the regulations under the Administrative Procedure Act. In December 2014, the U.S. District Court for the District of Columbia found the regulations invalid under step-one of *Chevron*, finding the FLSA exemptions applied to “any employee” under the unambiguous statutory language. See *Home Care Ass’n of Am. v. Weil*, No. 14-cv-967 (RJL) (D.D.C. Dec. 22, 2014). In a separate opinion, the court also vacated DOL’s narrowed definition of companionship services. *Home Care Ass’n of Weil*, No. 14-cv-967 (D.D.C. Jan. 14, 2015).

On appeal, the D.C. Circuit said the lower court wrongly invalidated the DOL regulations, holding *Coker* foreclosed a finding that the FLSA unambiguously addressed the third-party employment issue.

*Coker*, instead, held that the statute gave DOL broad authority to implement the 1974 amendments, the appeals court said.

Moving to the second step of *Chevron*, the appeals court found DOL’s new interpretation of the amendments was reasonable.

Although the agency reversed its previous stance, the appeals court said the decision only required a “reasoned explanation,” which DOL provided.

“In addition to reasoning that its original regulation misapplied congressional intent, the Department justified its shift in policy based on the dramatic transformation of the home care industry since [the third-party-employer] regulation was promulgated in 1975,” the appeals court noted.
The appeals court also reversed the district court’s decision as to the narrowed definition of companionship services. In light of the disposition of the third-party employer issue, plaintiff could no longer demonstrate their member companies suffered an injury in fact.


**U.S. Court in Massachusetts Tosses Action Against Hospital That Fired Worker Who Refused Mandatory Vaccine**

The U.S. District Court for the District of Massachusetts said April 5 that a hospital did not violate an employee’s civil rights by terminating her after she refused to receive a mandatory flu vaccine because of her religious beliefs. The court granted the hospital summary judgment, agreeing that it reasonably accommodated the employee and any further accommodation would have been an undue hardship.

Plaintiff Leontine K. Robinson worked at Children's Hospital Boston as an administrative associate in the emergency department. In her position, Robinson typically was one of the first hospital employees to interact with patients and their family members when they arrived in the emergency department as she handled intake and registration and affixed patient identification bracelets.

The hospital decided in 2011 to require all people who work in or access patient-care areas to be vaccinated against the influenza virus to achieve the safest possible environment and to ensure the highest possible care for its patients.

Under the hospital's policy, an exemption from vaccination was available when the influenza vaccine posed a serious health risk. The hospital did not, however, exempt those who objected to vaccination on religious grounds, citing concerns about the increased risk of transmission to patients. The hospital did accommodate individual requests based on religious concerns to receive a gelatin-free vaccine.

Robinson informed her supervisor that she would not take the vaccine because she was Muslim and her beliefs prohibited it. Robinson was told that the vaccine was mandatory but that she could avoid taking it if she found a position outside of patient care.

Robinson asked to interview for a medical records clerk position that she had applied for and also sought to use her two months of accrued earned time to find employment outside the hospital.

The hospital agreed to the two requests. It instructed another employee to help Robinson with her job search and also gave her the opportunity to interview for the medical records clerk position. She didn't get the job and didn't apply for any other positions at the hospital.

After Robinson was terminated, she sued the hospital for violating Title VII and state law. The hospital moved for summary judgment, arguing it reasonably accommodated Robinson; any other accommodation would have been an undue hardship; and no reasonable jury could find that she had a bona fide religious belief that precluded vaccination.

Because the court agreed that the hospital was entitled to summary judgment on the first two grounds, it declined to address the third issue, instead assuming that Robinson’s refusal to take the influenza vaccination was based on a sincerely held, bona fide religious belief.

**Reasonable Accommodation**
The court found the hospital reasonably accommodated Robinson, noting it encouraged her to transfer to another position within the hospital and offered her assistance toward that effort.

Robinson argued that the hospital should have done more to help her find a new position, but the court disagreed. Employers “are not obligated to create a position to accommodate an employee’s religious beliefs,” the court noted.

**Undue Hardship**

The court also agreed with the hospital that granting Robinson's request would have been an undue hardship because it would have increased the risk of transmitting influenza to its already vulnerable patient population.

“Had the Hospital permitted her to forgo the vaccine but keep her patient-care job, the Hospital could have put the health of vulnerable patients at risk,” the court said.


**Tenth Circuit Says Physician Had Property Interest in Employment, Owed Due Process Upon Termination**

The Tenth Circuit held May 12 that a terminated physician had a property interest under Kansas law in continued employment for the period specified in his employment contract even though he was terminated for “good cause.”

Finding the record unclear as to whether the physician was given due process after termination, the appeals court remanded to the lower court for further proceedings.

Dr. Raymond Winger began working at Meade District Hospital pursuant to an employment agreement that provided for an initial term of one year and allowed for termination without cause on 60 days’ notice or immediately for “good cause.”

After receiving complaints about Winger, the hospital’s risk management committee conducted an investigation, which found Winger failed to practice with the expected standard of care.

The hospital terminated Winger’s clinical privileges and employment “with cause” for failing to meet the “standards of care required of physicians in the community.”

Winger sued the hospital under 42 U.S.C. § 1983 alleging due process violations related to his termination.

Specifically, Winger alleged that the hospital fired him without due process, and infringed his liberty interest in his professional reputation by reporting his termination to the National Practitioner Data Bank.

The district court granted summary judgment to the hospital. On appeal, Winger argued he had a constitutionally protected property interest in continued employment at the hospital because his employment agreement imposed a substantive restriction on the hospital's ability to terminate him.

According to the appeals court, Winger’s contract included both “with cause” and “without cause” provisions. Such a “hybrid” contract gives rise to a property interest, the appeals court said.

Because Winger’s employment was terminated with cause, Winger’s employment agreement gave him a property interest in 60 days of continued employment, the appeals court found.

The appeals court remanded to the lower court to determine whether the hospital afforded Winger due process.

The appeals court affirmed summary judgement to the hospital, however, on Winger’s claims regarding the National Practitioner Data Bank report.

Hospitals must report the termination of a physician’s clinical privileges and may not be held liable for such reports, the appeals court said.

Liability and Litigation

Florida Appeals Court Holds Malpractice Damages Caps Unconstitutional

A Florida appeals court held July 1 that state law caps on noneconomic damage awards in medical malpractice actions violated the equal protection clause of the Florida Constitution. According to the court’s analysis, the statute was unconstitutional because individuals with noneconomic damages below the caps are fully compensated under Florida Statutes Section 766.118, but injured parties with noneconomic damages above the caps are not fully compensated.

Plaintiff Susan Kalitan underwent surgery in 2007 at North Broward Hospital District to treat carpal tunnel syndrome in her wrist. During intubation for the anesthesia for surgery, one of the tubes perforated plaintiff’s esophagus.

Plaintiff was discharged from the hospital without anyone being aware of the perforated esophagus. At home, plaintiff became unresponsive and was rushed to the emergency room of a nearby hospital where she had life-saving surgery to repair her esophagus.

According to the opinion, plaintiff remained in a drug-induced coma for several weeks and continues to suffer from pain throughout the upper half of her body and from serious mental disorders as a result of the traumatic incident.

Plaintiff filed a medical negligence action against the medical center, several of the physicians and nurses present at the surgery, and others (collectively defendants). Among the issues litigated at trial were personal liability and vicarious liability, as well as the extent of the injuries, and whether they amounted to “catastrophic injury” under Florida law.

The jury ultimately found in plaintiff’s favor, determining that plaintiff suffered catastrophic injury. The jury awarded plaintiff $4,718,011 in total damages, with noneconomic damage awards of $2 million for past pain and suffering and $2 million for future pain and suffering.

Multiple post-trial motions were filed, and the court limited the noneconomic damage awards per the caps in Section 766.118, after applying an increased cap for the finding of catastrophic injury. As a result, the noneconomic damages award of $4 million was reduced by close to $2 million.

Plaintiff appealed the application of the caps. The Florida District Court of Appeal, Fourth District, agreed that the caps were unconstitutional as applied to medical malpractice actions.

In Estate of McCall v. United States, 134 So. 3d 894 (Fla. 2014), the Florida Supreme Court determined that the caps on noneconomic damages awards in Section 766.118 violated the equal protection clause of the Florida Constitution as applied to wrongful death cases.

Although McCall specifically addressed wrongful death actions, the appeals court said its reasoning also applied to personal injury lawsuits.

In McCall, a plurality of justices concluded that the medical malpractice "crisis," which the caps were enacted to address, no longer existed and, consequently, there was no justification for “the arbitrary reduction of survivors' noneconomic damages in wrongful death cases based on the number of survivors . . . without any commensurate benefit to the survivors and without a rational relationship to the goal of reducing medical malpractice premiums.”
The appeals court rejected defendants’ attempt to distinguish single claimant personal injury cases from the multiple claimant wrongful death action addressed in *McCall*, finding “no basis to do so that would not conflict with the reasoning of the Florida Supreme Court’s plurality and concurring opinions, which strike at the underpinning of the Legislature’s caps on noneconomic damages in general.”

As long as the caps “discriminate between classes of medical malpractice victims, as they do in the personal injury context they are rendered unconstitutional by *McCall*, notwithstanding the Legislature’s intentions,” the appeals court held.

The appeals court directed the trial court to reinstate the total damages award as found by the jury, noting, however, that the damages may still be limited by the doctrine of sovereign immunity.


**U.S. Court in Kentucky Says EMTALA Screening Claim Must Allege Disparate Treatment, Improper Motive**

A federal district court in Kentucky dismissed July 20 an action alleging a hospital violated the Emergency Medical Treatment and Labor Act (EMTALA’s) screening requirement, finding the complaint failed to allege disparate treatment and improper motive. The court also found the complaint failed to allege the hospital had actual knowledge of the patient’s emergency medical condition to state a violation of EMTALA’s stabilization requirement.

Madonna G. Perry sought treatment at Owensboro Health (OHI) on two separate occasions on November 6, 2009, complaining of fever, nausea, vomiting, and diarrhea stemming from a non-healing surgical wound.

On both visits, she received medical care and treatment but was discharged “despite her rapidly deteriorating condition,” according to the complaint. Perry died several hours later at home.

Plaintiffs sued OHI in state court for negligence and later added claims for violating EMTALA. OHI removed the case to federal district court and sought dismissal of the EMTALA claims.

The U.S. District Court for the Western District of Kentucky agreed to dismiss the EMTALA claims with prejudice.

Citing the Sixth Circuit’s decision in *Cleland v. Bronson Health Care Group, Inc.*, 917 F2d 266 (1990), the court said to maintain a claim for an inappropriate medical screening, a plaintiff must show both disparate treatment and improper motive on the hospital’s part.

In the court’s view, plaintiffs merely asserted that the hospital provided negligent care, not that Perry failed to receive the same treatment as a paying patient. Whether further diagnostic testing would have been advisable is a question that should be left to state tort law, the court added.

The court also wasn’t persuaded that intervening Supreme Court precedent called into question *Cleland*’s analysis of an “appropriate” medical screening. See *Roberts v. Galen of Virginia, Inc.*, 525 U.S. 249 (1999).

The Court in *Galen* addressed EMTALA’s stabilization, not screening, requirement, in holding that a plaintiff need not show improper motive. In fact, the Court specifically noted it was not deciding the correctness of *Cleland*’s reading of the screening requirement.
Next, the court held plaintiffs could not maintain a claim that the hospital failed to stabilize Perry before discharge in violation of EMTALA.

The duty to stabilize under EMTALA is only triggered when the hospital has actual knowledge of an emergency medical condition.

Plaintiffs argued the hospital specifically found Perry was hypertensive and had an escalated white blood cell count. But the court said the key to an EMTALA stabilization claim is actual knowledge, not facts that should have put the hospital on notice of an emergency medical condition.


**Arizona Appeals Court Says Medical Lien Timely Under Statute**

The Arizona Court of Appeals revived July 28 a health care provider’s medical lien finding that, under the statutory scheme, it applies retroactively to any services received by the patient within the 30 days preceding the recording of the lien and prospectively thereafter. Under Ariz. Rev. Stat. § 33-932 (2014), a health care provider, other than a hospital, may perfect a medical lien if it records the lien “before or within thirty days after the patient has received any services relating to the injuries.”

From June 29, 2011 until October 9, 2011, plaintiff Premier Pain Management treated a third party for injuries arising out of a car accident involving defendant Kimberly Navarro.

On September 16, 2011, Premier recorded a health care lien for the cost of the services it had rendered to the third party. On March 28, 2013, Navarro's automobile insurance carrier settled the third party's injury claim and paid the settlement sum to the third party. The third party did not pay Premier for any of the medical services she had received.

Premier sued the Navarros to enforce its health care lien. The Navarros moved to dismiss the complaint arguing that by waiting until September 16, 2011 to record its lien, Premier failed to perfect the lien within 30 days after it had provided "any services" to the third party as required by the statute.

The lower court agreed and dismissed Premier’s complaint.

On appeal, Premier argued it recorded its lien within 30 days after it had provided the third party "any services."

The Navarros countered that "any services" refer to when "any services" are first provided. The appeals court found, however, that under the Navarros’ construction it would have to insert an additional requirement into the statute, “effectively changing it to require a non-hospital health care provider to record a lien within 30 days after the patient first receives any services relating to the injuries.”

The appeals court conceded that its construction “ignores the distinction the statute draws between health care providers, such as Premier, and hospitals,” as the statute authorizes a hospital to record its lien within 30 days after it has discharged its patient, while it requires a non-hospital health care provider to record its lien "before or within thirty days after the patient has received any services relating to the injuries."

But the appeals court said that unless the lien is recorded before the patient receives services, the lien would apply retroactively only to the services provided to the patient within the 30 days prior to its recordation and prospectively thereafter.
“This construction maintains the distinction between hospitals and non-hospital health care providers and is consistent with the purpose of the health care provider lien statutes,” the appeals court said.

The appeals court found Premier’s lien applied retroactively to any services it provided to the third party within the 30 days prior to September 16, 2011 (on or after August 17, 2011) and prospectively to any services rendered thereafter.

The appeals court also awarded Premier reasonable attorney’s fees as the prevailing party on appeal.


**Seventh Circuit Rejects Class Action Against Provider Alleging Violations of Fair Credit Reporting Act After Laptop Theft**

The Seventh Circuit rejected a putative class action alleging a network of affiliated hospitals and physicians failed to safeguard patients’ private data in violation of the Fair Credit Reporting Act (FCRA) after four unencrypted laptops were stolen from the provider’s administrative offices. Affirming a lower court decision dismissing the action, the appeals court found Advocate Health and Hospitals Corporation was not a “consumer reporting agency” for purposes of the FCRA.

In August 2013, Advocate notified more than four million patients about the theft of four computers containing private data at its administrative office in Park Ridge, IL during a burglary in mid-July.

Six of the affected patients brought the putative class action, alleging claims for willful and negligent violations of FCRA and for negligence and invasion of privacy under state law.

The district court dismissed the FCRA claims and declined supplemental jurisdiction over the state law claims. The Seventh Circuit affirmed.

The appeals court sidestepped the issue of whether actual misuse of the stolen information was necessary for plaintiffs to establish standing, noting thieves had attempted to use the stolen information of two of the plaintiffs in the case.

Turning to the merits, the appeals court noted the FCRA requires every “consumer reporting agency” to “maintain reasonable procedures” to ensure that it does not “furnish[] . . . consumer reports” to unauthorized third parties or for impermissible purposes.

Plaintiffs alleged Advocate did not maintain reasonable procedures, which exposed their private information to thieves.

But the appeals court found plaintiffs failed to allege that Advocate was a “consumer reporting agency” under the FCRA.

Advocate does not assemble patients’ personal and medical information “for monetary fees,” as required by the FCRA to be considered a “consumer reporting agency.” Payments Advocate receives from third-party payers like Medicare are for health care services rendered, not for assembling patient information, the appeals court noted.

Advocate also does not assemble consumer information “for the purpose of furnishing consumer reports to third parties,” the Seventh Circuit said. The information Advocate transmits to insurers concerns its experiences with patients, which is specifically excluded from the FCRA definition of a "consumer reporting agency."
Plaintiffs argued Advocate met the definition of a “consumer reporting agency” because it shares patient data “on a cooperative nonprofit basis,” including through programs to improve health care quality and efficiency, the Medicare shared savings program, and the hiring of “outpatient care managers.”

“Judging by the allegations, these are internal Advocate programs . . . . Even drawing reasonable inferences in the plaintiffs’ favor, we think these allegations are too thin,” the appeals court said.


U.S. Court in Puerto Rico Allows EMTALA Screening Claim to Proceed

The U.S. District Court for the District of Puerto Rico said July 24 that plaintiffs could proceed with their claim that a hospital violated the Emergency Medical Treatment and Labor Act’s (EMTALA’s) screening requirement. The court held a reasonable jury could find the hospital failed to provide the deceased with a screening exam uniform to the screening it would provide to other patients presenting substantially similar complaints.

Plaintiffs are surviving family members of Eric Adams-Ramos (Adams). Plaintiffs sued Hospital San Gerardo (HSG) for failure to screen, diagnose, stabilize, treat, and transfer Adams adequately when he arrived at the hospital emergency room with multiple gunshot wounds. HSG moved to dismiss for failure to state a claim under EMTALA.

The court granted HSG’s motion to dismiss the EMTALA stabilization claim but said plaintiffs could move forward with the EMTALA screening claim.

According to the court, the issue was whether HSG routinely or uniformly disregarded its protocol requirements for gunshot wounds when screening patients who presented complaints that were substantially similar to those that Adams presented.

Evidence showed that while HSG had a protocol in place for screening patients with gunshot wounds, HSG only partially followed its own protocol in Adams’ case, resulting in a failure to identify three additional gunshot wounds, including the one that ultimately killed Adams.

The court held that a reasonable jury could find that HSG did not provide Adams with a screening exam uniform to the screening it provides to other patients presenting substantially similar complaints.


Eleventh Circuit Finds Hospital Did Not Violate ADA in Providing Accommodations to Deaf Patients

The Eleventh Circuit held July 31 that a hospital did not violate the rights of deaf/hearing-impaired plaintiffs under the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act (Rehab Act) when it provided a variety of ways to communicate effectively if or when a live American Sign Language (ASL) interpreter was unavailable. Plaintiffs are three hearing-impaired adults, two of whom were treated as patients in defendants’ hospital, and a third who accompanied a patient who was not hearing-impaired. In August 2012, plaintiffs filed a complaint against defendants Halifax Healthcare Systems, Inc. and Halifax Community Health Systems, asserting claims under Title II and Title III of the ADA, Section 504 of the Rehab Act, and the Florida Civil Rights Act, which requires
that deaf individuals have an equal opportunity to participate in and enjoy the benefits of the hospital’s services.

Plaintiffs alleged that the hospital failed to meet the obligations under the ADA and the Rehab Act by failing to provide live interpreters during the entirety of their stays, thereby creating a triable issue as to whether the hospital failed to provide auxiliary aids necessary to ensure effective communication.

Defendants moved for summary judgment, which the district court granted. The Eleventh Circuit affirmed.

The appeals court first found that defendants were entitled to summary judgment on plaintiff John D’Ambrosio’s claims as he was unable to show that the hospital failed to provide auxiliary aids necessary to ensure effective communication.

According to the opinion, D’Ambrosio was rushed to the hospital after suffering a major heart attack. The hospital staff immediately requested a live ASL interpreter, but canceled the request when doctors determined he had to undergo immediate, emergency cardiac catheterization, such that the patient did not have time to wait for an interpreter to arrive.

The appeals court pointed to undisputed evidence that D’Ambrosio’s physicians used a variety of appropriate auxiliary aids to ensure effective communication following the emergency procedure, including simple but detailed written notes and graphic depictions of the procedure. It also was undisputed that D’Ambrosio could read and write English; he regularly wrote and texted to communicate with others; and that the hospital provided webcam interpreting services as well as a total of eight hours of live ASL interpreting services after the surgery.

The appeals court rejected D’Ambrosio’s claim that he did not receive round-the-clock live ASL interpreting services throughout his hospitalization. Citing Liese v. Indian River Cnty. Hosp. Dist., 701 F.3d 334 (11th Cir. 2012), the appeals court stated defendants were not required by the ADA or the Rehab Act to provide every auxiliary aid that is demanded.

As to plaintiff Richard Martin’s claims, the appeals court agreed with the lower court that the hospital did not violate the ADA or the Rehab Act by failing to hire an interpreter as Martin was unable to cite to any evidence showing he had asked for a live interpreter during his brief, two-hour visit to the emergency room. Martin’s injury was considered minor, Martin did not request a live interpreter, and the physician did not believe one was necessary given how minor the injury was. Further, Martin, who could read and write English, indicated he understood the typed instructions upon discharge, the appeals court noted.

The appeals court also affirmed the district court’s grant of summary judgment on plaintiff Yolanda Gervarzes’ claims, holding that a reasonable jury could not conclude the hospital failed to provide necessary auxiliary aids for effective communication.

Gervarzes failed to specify in her complaint how she was unable to participate in her hearing daughter’s care, refused the LifeLinks system interpreting service offered by the hospital, was provided at least five hours of live ASL interpreting services during her daughter’s hospitalization, and was otherwise able to communicate with staff through her daughter by writing notes, the appeals court said.


**U.S. Court in Ohio Allows EMTALA Action to Go Forward**
The U.S. District Court for the Northern District of Ohio refused August 28 to dismiss a plaintiff’s Emergency Medical Treatment and Labor Act (EMTALA) action against The Cleveland Clinic Foundation (The Clinic). The court dismissed, however, plaintiff’s claim for statutory penalties. Plaintiff Tracy Scaife went to the emergency room because of severe pain in her abdomen. She was 33 weeks and four days pregnant.

According to Scaife, Lakewood Hospital failed to do the necessary screening tests to determine the cause of her pain, which would have revealed that she had a hematoma and was internally bleeding. Instead, plaintiff said defendants transferred her to another hospital in an unstable condition because of her medical history and her lack of medical insurance.

Plaintiff sued Lakewood Hospital, The Clinic, Dr. Mark Libertin, and Clinic Regional Physicians, LLC under EMTALA alleging her treatment resulted in physical injuries to herself and caused both of her unborn daughters to die in utero.

Plaintiff sought compensatory damages against defendants and also asked the court to impose the statutory penalties in Section 1395dd(d) of EMTALA. The Clinic moved to dismiss.

The court first addressed The Clinic’s assertion that it is a separate corporation from Lakewood Hospital. According to the court, plaintiff alleged to the contrary that The Clinic directly handled her care through its operation of Lakewood Hospital and its own employees.

The court said that “[a]t this point in the litigation,” plaintiff alleged sufficient facts to survive a motion to dismiss.

“Though barely, her allegations that The Clinic ‘operated’ Lakewood Hospital and that all of the individuals responsible for her care were employees of The Clinic and acted within the course and scope of their duties are enough to raise a reasonable inference that The Clinic is responsible for her injuries,” the court held.

The court granted, however, The Clinic’s motion to dismiss plaintiff’s claims for statutory penalties “because courts have consistently recognized that only the United States government or one of its agencies can enforce EMTALA’s civil statutory penalties.”


U.S. Court in Puerto Rico Holds Patient’s Relatives Can’t Assert EMTALA Claim for Personal Harm

The Emergency Medical Treatment and Labor Act (EMTALA) doesn’t provide a private cause of action for emotional damages to the relatives of a deceased patient, a federal court in Puerto Rico ruled September 4.

Ramon Santiago-Rios was taken to the emergency room of defendant Centro Medico Del Durabo, Inc., d/b/a HIMA San Pablo—Fajardo after a car accident. A hospital nurse and physician examined him and he was discharged. Two days later, he returned to the hospital by ambulance, where he died the next day.

Plaintiffs sued the hospital alleging improper screening and improper discharge of Santiago-Rios, their relative, under EMTALA. Plaintiffs did not assert, however, inherited claims of the deceased.
Rather, plaintiffs sought $300,000 each for emotional damages they sustained as a result of his death.

The U.S. District Court for the District of Puerto Rico held plaintiffs could not pursue their own personal EMTALA claims against the hospital apart from those that the decedent had.

According to the court, “only patients can have a cause of action in their own right under EMTALA.”

Because plaintiffs brought personal claims for emotional damages under EMTALA, rather than derivatively on the decedent’s behalf, the hospital was entitled to judgment as a matter of law, the court said.

The court also denied plaintiffs' motion to amend their complaint.


**Third Circuit Says Insurance Peer-Reviewer Owed No Duty to Insured**

The Third Circuit held in a non-precedential opinion September 22 that a third-party insurance reviewer had no duty of care to the patient and thus could not be held negligent in his death after his insurance company denied life-saving treatment. James Skelcy, who was insured by UnitedHealth Group, Inc., by and through Oxford Health Insurance, Inc. (collectively UnitedHealth defendants), was diagnosed with dermatomyositis and interstitial lung disease.

His treating rheumatologist prescribed Rituximab, which UnitedHealth and Oxford approved, and Skelcy received two doses of the drug, to which he responded well.

After his symptoms returned, his treating rheumatologist immediately prescribed another dose of Rituxan, but the UnitedHealth defendants denied the claim for Rituxan or alternatively an intravenous immunoglobin (IVIG) infusion.

Within two days of receiving the clinical information necessary to process an expedited appeal, the UnitedHealth defendants transmitted the appeal to Medical Evaluation Specialists, Inc. (MES) for a peer review assessment. MES assigned Dr. Denise Beighe, a rheumatologist located and licensed in Arizona, to provide the peer review assessment of the expedited appeal.

Beighe stated in her assessment that, “[t]his type of therapy is not [the] standard of care for this disease” and “[t]his specific therapy is not [the] standard of care for this patient’s disease.” But she also concluded that “IVIG would be [the] standard of care at this point for the member.”

The day after receiving Beighe’s assessment, the UnitedHealth defendants again denied the request to treat Skelcy with Rituxan or an IVIG infusion.

Eventually, 32 days after receiving Skelcy’s claim for treatment, the UnitedHealth defendants reversed their decision and approved the Rituxan treatment. Skelcy died before he could receive the treatment.

Linda Skelcy, in her individual capacity and as the administratrix of the estate of her husband, James Skelcy, asserted claims for negligence and negligence per se against MES and Beighe.

The district court granted MES and Beighe’s motion to dismiss, finding a lack of duty and causation. Because the appeals court agreed that MES and Beighe did not owe Skelcy a duty of care, the court did not reach the causation argument.
Mrs. Skelcy argued on appeal that, given the broad duty of care imposed on physicians under New Jersey law, MES and Beighe owed her husband a duty of care, even though no privity or doctor-patient relationship bound them.

But the appeals court found Skelcy was “likely wrong that New Jersey courts would impose a duty on facts such as the ones here.”

In the cases cited by Skelcy, the facts involved “personal interactions with or affirmative acts by a physician that induced the injured party to foreseeably and reasonably rely on the physician to discover or disclose serious illnesses,” the appeals court pointed out.

Whereas Mr. Skelcy had no interaction of any kind with Beighe, the appeals court said.

Even assuming that Mr. Skelcy relied on Beighe’s professional competence, “it was not the sort of reliance that New Jersey courts have protected in the past.”

“We thus doubt that the New Jersey Supreme Court would recognize a duty of care on these terribly sad facts,” the appeals court said.


**Fifth Circuit Revives Disability Discrimination Action Against Hospital**

The Fifth Circuit held recently that there was enough evidence for a lawsuit to go forward alleging a hospital violated Title III of the Americans with Disabilities Act (ADA) and the Rehabilitation Act (RA) by failing to provide effective communication to the hearing-impaired family of a patient. Plaintiffs, who are hearing impaired, took their four-month old daughter to the emergency room at Doctors Hospital at Renaissance (DHR) where she was diagnosed with a brain tumor that required monthly treatments.

Plaintiffs alleged that DHR repeatedly failed to provide them an interpreter and the video remote imaging (VRI) machines the hospital offered didn’t always function properly or staff was unable to operate the machines.

After plaintiffs sued DHR, a federal district court granted summary judgment to the hospital on their ADA and RA claims. On appeal, the Fifth Circuit reversed.

As to the ADA claim, the appeals court found enough evidence to create a genuine issue that plaintiffs faced a “real and immediate threat of future harm,” pointing to their affidavit that they experienced recent problems with DHR’s provision of auxiliary services.

“Furthermore, the evidence of DHR’s failure to revise its ADA compliance policy, which it admits needs revision, and its lack of training on addressing the needs of the hearing impaired, creates a possible inference that the plaintiffs’ problems with the provision of auxiliary services will continue in the future,” the appeals court said.

As to the RA claim, the appeals court held the present record was sufficient to create a dispute of material fact on whether DHR intentionally discriminated for purposes of establishing compensatory damages.

The appeals court pointed to evidence that, on several occasions, plaintiffs requested an interpreter but one was never provided and that the VRI machines often were ineffective.
U.S. Court in Kentucky Rejects EMTALA Claim Alleging Hospital Refused Transfer

A federal court in Kentucky granted summary judgment to a hospital in an action alleging it violated the Emergency Medical Treatment and Labor Act (EMTALA) because one of its physicians allegedly refused transfer of a critical patient.

The U.S. District Court for the Western District of Kentucky found no evidence that the physician refused the patient’s transfer when contacted by the emergency room physician at the hospital where she initially presented.

Instead, the record only showed the physician advised that another facility would be better equipped to handle the patient’s case.

Marilyn West presented to Breckinridge Memorial Hospital with complaints of respiratory distress where she was treated by Dr. Gregory A. West. Dr. West determined that she needed sophisticated airway management that Breckinridge was unable to provide so he sought her transfer to another hospital for a higher level of care.

To that end, Dr. West contacted defendant Owensboro Medical Health System, Inc. (OMHS) and spoke to Dr. Robert F. Huxol. They discussed the patient’s case and ultimately determined that University of Louisville Hospital was the best option for transfer because it had a wider range of available services. After having difficulty with University Hospital, Dr. West again contacted OMHS where another physician immediately accepted the patient’s transfer.

Marilyn West never regained consciousness and died several days later. Her husband (plaintiff), individually and as administrator of her estate, sued Huxol and OMHS for violating EMTALA and for medical negligence.

The court granted summary judgment to Huxol on the EMTALA claim, agreeing that the statute does not authorize a private right of action against individuals.

The court also granted summary judgment to OMHS on the EMTALA claim, finding no evidence that Huxol actually refused to accept an appropriate transfer. The court noted that both Dr. West and Dr. Huxol testified that Huxol never refused to accept transfer, but rather merely advised transfer to a tertiary care center in Louisville as a better option.

The court also considered and rejected plaintiff’s medical negligence claim, holding Dr. Huxol did not have a physician-patient relationship with Marilyn West. The fact that Dr. Huxol “brainstormed” with Dr. West about treatment options over the telephone wasn’t enough to establish a physician-patient relationship, the court said.


U.S. Court in Connecticut Allows EMTALA Claims to Proceed

The U.S. District Court for the District of Connecticut September 29 refused to dismiss a plaintiff’s claims under the Emergency Medical Treatment and Labor Act (EMTALA) against the hospital where his now-deceased wife received treatment. Laura D. Sheehan was transported to the emergency room at Stamford Hospital where she was seen and determined to be "heavily
intoxicated." Sheehan had a documented history of alcohol intoxication, and one nurse noted in her record that Sheehan was "[s]een [at the hospital] multiple times in the past for same issue."

Once Sheehan appeared to sober she was discharged without a blood alcohol test.

Just minutes later, however, Sheehan was readmitted to the emergency department, after Stamford's staff observed her "stumbling and walking with an unsteady gait."

Following a long period of observation, a medical evaluation revealed Sheehan was suffering from a stroke. Sheehan remained at Stamford, but by the time her stroke was diagnosed, she could not be revived. She died three days later.

Plaintiff Marc Grenier, in his capacity as administrator of the estate of Laura Sheehan, sued Stamford and others alleging, among other things, that they violated EMTALA when they “fail[ed] to properly screen or stabilize the plaintiff’s decedent or otherwise fail[ed] to treat her emergency condition.”

**Screening claim**

Defendants argued that the complaint failed to plead a claim of inadequate screening because it "contains no allegation of disparate treatment."

The court disagreed, however, pointing to facts such as: defendants failure to perform any blood work or internal examination upon Sheehan's admission to the emergency department; that Sheehan was discharged without any blood work or physical examination beyond observing her movements; and that upon her readmission, defendants performed only one blood alcohol test, which revealed an extremely high level of intoxication, and performed no other internal tests for nearly a 24-hour period, during which time her condition deteriorated.

These facts suggest that “Sheehan did not receive a standard examination, but one performed in light of her prior treatment, and which did not include any diagnostic examination,” the court commented.

**Stabilization claim**

The court found the allegations in the complaint sufficiently plead that Sheehan suffered from an "emergency condition" as defined by EMTALA when she was admitted to the emergency department.

Further, the “striking contrast” between the condition Sheehan was noted to be in upon discharge and her condition just minutes later upon her readmission “plainly implies that the Stamford Defendants discharged Sheehan prior to stabilizing her known emergency condition,” the court said.

**Georgia Appeals Court Says Parent Not Liable for Incapacitated Son’s Unpaid Medical Bills**

The Georgia Court of Appeals held October 6 a parent who signed a hospital admission form on behalf of her incapacitated son could not be held liable for his unpaid medical bills. In so holding, the appeals court reversed the lower court’s grant of summary judgment to the hospital. Janice Winterboer’s adult son Joshua was severely incapacitated after a motor-vehicle accident that occurred when he was a toddler. On April 25, 2011 and June 22, 2011, Winterboer took Joshua to
Floyd Medical Center for emergency medical treatment when he was in respiratory distress and, during the admission process, she signed registration consent forms for his treatment.

When the medical bills associated with these extended hospital visits went unpaid, Floyd Medical Center sued both Joshua and Winterboer, contending she personally guaranteed payment of her son’s bills when she signed the registration consent forms.

The trial court denied summary judgment to Winterboer and awarded Floyd Medical Center $243,204.96 for the unpaid medical bills.

On appeal, Winterboer argued she signed the registration consent forms in a representative capacity and not a personal capacity.

The appeals court said two conflicting portions of the consent forms—one part that contained language broadly associated with guaranteeing payment and then the lines and boxes associated with who was signing the form and why—rendered the contract ambiguous.

The signature line where Winterboer signed provided that a signatory other than the patient was "acting for the patient," the appeals court emphasized. “Thus, it is clear that Winterboer intended to sign—and did sign—the form in a representative capacity because these latter portions of the form limit the otherwise broad guarantee provision,” the appeals court held.

According to the appeals court, because Winterboer signed the form on behalf of her adult son as his agent, not in a personal capacity, she was not personally liable for any unpaid medical bills.


Pennsylvania Court Says State Professional Liability Fund Not Obligated to Pay After Physician Release

The Commonwealth Court of Pennsylvania held in an unpublished opinion October 16 that the Pennsylvania Insurance Department’s Medical Care Liability and Reduction of Error Fund (MCARE Fund) was not liable to a plaintiff after the defendant physician was released from excess liability. The MCARE Act is intended to make medical professional insurance affordable. It serves primarily as "a statutory excess carrier that provides excess medical malpractice insurance coverage to the extent a health care provider's liability exceeds its basic coverage in effect at the time of an occurrence."

Russell Myers, as executor of the estate of decedent Marlene Myers, filed a medical malpractice lawsuit against Dr. Christopher Evans and Memorial Hospital. The parties agreed to have the medical malpractice disputes decided by binding arbitration and entered into an arbitration agreement.

The final arbitration agreement provided that the maximum amount Myers could recover against Evans and Memorial Hospital was $500,000 each, which were the limits of the applicable primary insurance policies.
The arbitrator found in Myers' favor and entered an award of $1,503,504.99. Evans' counsel subsequently provided Myers with a proposed release, which would have expressly released the MCARE Fund, among various other entities. Myers' attorney objected.

The parties executed the release pursuant to the arbitration agreement and the cover letter sent with the draft of the release explained that Myers "never agreed to accord and satisfaction to release [MCARE Fund]."

Myers then made a formal demand for payment for the maximum amount of $500,000 from the MCARE Fund for the remaining arbitration award in excess of the basic coverage $500,000 limit.

The Pennsylvania Insurance Department, on behalf of the MCARE Fund, refused to pay Myers. MCARE argued that no payments were owed because not only was the basic insurance carrier released to the extent of its coverage limits, but Evans was released from all damages and there was no excess damages for it to pay.

The MCARE Fund moved for judgment on the pleadings. The court granted the motion.

While acknowledging that the arbitration agreement and the release between Evans and Myers "did not specifically release the MCARE Fund and it was clear that it was not their intent to do so," the court found MCARE coverage was not triggered in this case.

By "fully and completely" releasing Evans after he paid Myers the $500,000 award, "Myers also released the MCARE Fund from liability as the MCARE Fund is only obligated to 'pay claims against [Dr. Evans] for losses or damages awarded in medical professional liability actions against [him] in excess of the basic insurance coverage,'" the court held.


**Nevada Supreme Court Upholds State’s Noneconomic Damages Cap**

Nevada’s $350,000 noneconomic damages cap in actions involving professional negligence is constitutional, the state’s high court ruled October 1. In so holding, the Nevada Supreme Court reversed a lower court finding that the cap, Nev. Rev. Stat. 41A.035, violated the constitutional right to a jury trial.

The lower court concluded the cap took away the determination of damages—a question of fact—from the jury.

But the high court disagreed, noting precedent holding the cap did not interfere with the jury’s factual findings because it took effect after the jury assessed damages.

Although not addressed by the lower court, the high court for good measure also found the cap didn’t violate equal protection because the aggregate limit on noneconomic damages was rationally related to the legitimate governmental interest of ensuring that adequate and affordable health care is available in Nevada.

The high court further rejected the lower court’s conclusion that the cap applied on a per plaintiff and per defendant basis, rather than to the action as a whole. According to the high court, the cap applies per incident to the entire action.
Finally, the high court held the lower court erred in finding Nev. Rev. Stat. 41A.-35 applies only to claims of professional negligence and not to medical malpractice. The statute specifically references professional negligence, which the high court said encompasses medical malpractice.

The high court's ruling comes in a negligence action filed by Sherry Cornell, individually and as administrator of Charles Thomas Cornell after he died.

One of the defendants in the case, Dr. Stephen Tam, MD, filed a motion in limine requesting that plaintiffs' noneconomic damages be limited to $350,000 per the statutory cap. The district court denied the motion, and the high court granted Tam's petition for writ of mandamus.


**New York Appeals Court Says More Details Needed to Determine if Documents Protected by Quality Assurance Privilege**

The New York Supreme Court, Appellate Division, said October 22 that a medical center defendant failed to sufficiently support its assertion that certain documents should be protected as part of a "quality assurance" process under state law. In so holding, the appeals court observed that the affidavit tendered by one of the medical center's vice presidents went farther than a conclusory assertion of privilege, but lacked sufficient detail to make a definitive finding.

Plaintiff Dorah Bluth sued defendant Albany Medical Center alleging defendants failed to administer certain prescribed medications to her mother, Deeva Rosenzweig, while she was a patient at defendants' facility, causing her to fall and sustain various injuries.

During discovery, plaintiff sought production of "any accident or incident reports" relating to this event. Defendants objected, arguing that the documents sought were privileged. In response, plaintiff moved to compel disclosure and defendants cross-moved for a protective order.

The lower court granted defendants' request for a protective order and plaintiff appealed.

The New York statute at issue confers complete confidentiality on records relating to "quality assurance," the "prevention of medical, dental and podiatric malpractice," and investigations undertaken "[p]rior to granting or renewing professional privileges," among other things.

Defendants bore the burden of establishing that a review procedure was in place and that the requested documents were prepared in accordance with the statute, the appeals court noted.

Here, the defendants "failed to set forth sufficient details to enable either Supreme Court or this Court to conclude that such documents indeed are protected," the appeals court held.

Accordingly, the appeals court remanded to the lower court to conduct an in camera inspection of the documents and make a determination as to whether such materials fell within the asserted privilege.


**New York Appeals Court Says Medical Resident Under Direct Physician Supervision Not Liable for Malpractice**
A New York appeals court held November 12 that a trial court erred in denying summary judgment to a medical resident on medical malpractice claims. The Supreme Court of New York, Appellate Division, said a resident under the direct supervision of a physician “cannot be held liable for malpractice so long as the doctor's directions did not so greatly deviate from normal practice that the resident should be held liable for failing to intervene.”

Plaintiff's decedent underwent a surgical procedure to remove his gallbladder. He was cleared for surgery by defendant Dr. Alice Greene. The procedure was performed by defendant Dr. Louis Thayer Merriam and defendant Dr. Ira J. Rampil, an anesthesiologist, cared for the decedent in the recovery room after the operation. He was assisted by defendant Dr. Jennifer Whittemore, who was then a second-year anesthesiology resident.

The decedent suffered a heart attack two days after the operation. He recovered, but then suffered a second heart attack about a month later, and died.

Plaintiff, the decedent's wife, sued several parties, including all the physicians and residents involved in his care, for medical malpractice.

Many of the individual defendants moved for summary judgment, which the trial court denied. But the appeals court held the trial court erred in denying the motion of Whittemore, the anesthesiology resident.

“Whittemore satisfied her initial burden by relying on deposition testimony which demonstrated that she was under the direct supervision of Rampil at the time she cared for the decedent, and that Rampil did not so greatly deviate from normal practice that Whittemore should be held liable for failing to intervene,” the appeals court held.


**U.S. Court in Puerto Rico Allows EMTALA Screening Claim, But Dismisses Stabilization Claim**

The U.S. District Court for the District of Puerto Rico November 17 handed a hospital accused of violating the Emergency Medical Treatment and Labor Act (EMTALA) a partial victory, agreeing to dismiss a plaintiff's EMTALA stabilization claims. The court refused to dismiss, however, claims alleging an inadequate screening and state law medical malpractice claims. Plaintiff Zoraida Gonzalez-Morales sued defendants Presbyterian Community Hospital, Inc. (PCH) and several physicians after she presented to the emergency room at PCH three separate times with hip pain and other symptoms and was discharged each time without being admitted.

Ultimately, plaintiff was diagnosed with a “destruction and widening of the right sacroiliac joint with imaging findings consistent with septic arthritis, or a bacterial infection in her right hip.” As a result of this condition, plaintiff claims to have suffered destruction of her right hip bone, chronic pain, and difficulty walking.

Her suit alleged violations of EMTALA and included a supplemental cause of action for medical malpractice. The hospital moved to dismiss.

The court refused to dismiss plaintiff's screening claims. According to plaintiff, the physical examination she received was inadequate for a patient presenting the set of symptoms and vital signs recorded during her three visits to PCH.
The court found issues still remained because the hospital “failed to counter Plaintiff's allegation that the screening she was provided during her three visits was not uniform to the level of screening PCH provides other patients presenting similar complaints or symptoms.”

The court did dismiss, however, plaintiff's stabilization claim under EMTALA, finding she failed to allege that she was suffering from an emergency medical condition during any of her three visits or at the time of her discharges from PCH.

“The allegation that she was diagnosed with a bacterial infection in her right hip over a month and a half after her visits to PCH is insufficient to establish that at the time of her discharges from PCH she was in fact suffering from an emergency medical condition,” the court said.

In addition, because plaintiff's EMTALA screening claim was still active, the court said it would retain jurisdiction over the supplemental state law claims.


U.S. Court in California Says State Law Claims Related to Data Breach Preempted by ERISA

The U.S. District Court for the Northern District of California refused to remand November 24 a putative class action based on cybersecurity breaches of Anthem Life & Disability Insurance Company's data. In so holding, the court said the Employee Retirement Income Security Act (ERISA) completely preempted plaintiff's state law claims. On February 4, 2015, Anthem announced that cyberattackers gained unauthorized access to its data systems in December 2014. As a result of this breach, plaintiffs' personal health information (PHI) and the PHI of other current and former Anthem members were compromised.

Named plaintiffs Y. Michael Smilow and Jessica Katz filed a putative class action against defendants Anthem Life & Disability Insurance Company, and its affiliates, Empire Healthchoice Assurance, Inc. and Empire Healthchoice HMO, Inc.

Plaintiffs asserted the following causes of action under New York law: negligence, negligence per se, breach of implied contract, breach of covenant of good faith and fair dealing, unjust enrichment, invasion of privacy, bailment, conversion, violation of New York's data breach statute, and violation of New York's consumer protection statute.

Defendants removed the action to federal court, arguing there was federal question jurisdiction under ERISA and under the Health Insurance Portability and Accountability Act (HIPAA).

The case was eventually transferred from the Eastern District of New York to the Northern District of California where plaintiffs moved to remand.

The court found plaintiffs' claims completely preempted by ERISA giving the court subject matter jurisdiction over the action. Because the court found jurisdiction under ERISA, it declined to address whether federal question jurisdiction existed under HIPAA.

Looking at the first prong of the seminal case Aetna Health Inc. v. Davila, 542 U.S. 200 (2004), the court found plaintiffs could have brought their claims under Section 502(a) of ERISA.

Section 502(a) provides a cause of action for an ERISA “participant or beneficiary” to “enforce [their] rights under the terms of [an ERISA] plan.” Here, the court said, plaintiffs seek to enforce such rights through their breach of contract and unjust enrichment claims.
According to the court, plaintiffs’ unjust enrichment and breach of contract claims are premised on the insurance contract that plaintiffs entered into with defendants as their request for relief is a partial refund of the insurance premiums that plaintiffs paid to defendants.

Under the second Davila prong, the court rejected the plaintiffs’ argument that defendants had an independent legal duty to protect plaintiffs’ privacy pursuant to state law.

Under Davila, duties under state law are not independent of ERISA when “interpretation of the terms of respondents’ benefit plans forms an essential part of [respondents’] claim.”

Defendants would not have been under an obligation to protect plaintiffs’ privacy but for the fact that plaintiffs were members of an ERISA plan that defendants administered. Defendants did not have an independent legal duty to protect plaintiffs’ privacy pursuant to state law, the court held.


Texas High Court Says Slip and Fall Claim Against Hospital Wasn’t Connected to Health Care

A negligence action arising out of a visitor’s slip and fall in a hospital was not substantively related to the provision of health care and therefore shouldn’t be characterized as a health care liability claim (HCLC), the Texas Supreme Court held December 4. The hospital argued water on the floor outside a restroom that caused the fall implicated infection control standards, providing a nexus to the provision of health care.

But the high court disagreed, finding the instant action wasn’t distinguishable from a prior decision that held a hospital visitor’s action following a slip and fall didn’t assert a HCLC. See Ross v. St. Luke’s Episcopal Hosp., 462 S.W.3d 496 (Tex. 2015).

Plaintiff in this case, Sylvia Galvan, sued Memorial Hermann Southwest Hospital for negligence, alleging she was injured while visiting a patient there after slipping on water on the floor coming from a restroom.

The hospital moved to dismiss, arguing Galvan asserted a HCLC and failed to serve the required expert report.

The hospital relied on Texas West Oaks Hosp., LP v. Williams, 371 S.W.3d 171 (Tex. 2012), which held that a claim based on safety standards doesn’t have to be directly related to the provision of health care to be a HCLC.

The trial court denied the motion, but citing Williams, the appeals court reversed.

After the appeals court decision, the high court issued its opinion in Ross, which held that “a safety-standards-based claim against a health care provider is an HCLC only if there is a ‘substantive nexus’ between the ‘safety standards allegedly violated and the provision of health care.’”

The high court found that nexus wasn’t established in the instant case. Despite the hospital’s attempt to show otherwise, the high court saw no evidence in the record that the hospital’s duty regarding water on the floor implicated infection-control standards.

Rather, in the high court’s view, the hospital’s standards for floor maintenance likely weren’t any different than other businesses.
New York Appeals Court Allows Negligence Claims Against Nursing Home Based on Expert’s Testimony

A New York appeals court refused December 3 to dismiss a plaintiff’s state law claims against a nursing home for negligence in preventing and treating a former resident’s pressure ulcers. In so holding, the New York, Supreme Court, Appellate Division, found plaintiffs’ expert witness testimony was enough to raise a triable issue of fact.

Plaintiffs' decedent was admitted to St. Barnabas Hospital on February 10, 2009. During the hospital admission, decedent developed a stage II sacral ulcer measuring 11 by 10 centimeters. Decedent was later transferred to St. Barnabas Nursing Home, Inc.

After a brief readmission, decedent was transferred back to the nursing home where the size of the ulcer increased.

Decedent went back to the hospital on July 14, 2009 in septic shock. After treatment, she again returned to the nursing home where she ultimately passed away.

Plaintiffs sued the hospital and nursing home alleging medical malpractice, negligence, and violation of New York Public Health Law § 2801-d, citing defendants' failure to prevent and to halt the progression of decedent's pressure ulcers.

Defendants moved for summary judgment, arguing that decedent's ulcers were unavoidable based on her co-morbidities and deteriorating health.

Both sides presented experts to support their arguments. The experts disagreed on whether the ulcers were “unavoidable.”

After finding that the experts competent to render their opinions, the court said plaintiffs’ expert raised a triable issue of fact with respect to whether defendants departed from good and accepted medical practice.

U.S. Court in Texas Finds No EMTALA Violation in Hospital’s Treatment of Uninsured Child

The U.S. District Court for the Northern District of Texas granted January 25 a hospital's motion for summary judgment finding it did not violate the Emergency Medical Treatment and Labor Act (EMTALA) in treating an uninsured pediatric patient.

Plaintiff Melissa Fewins took her six-year-old son, D.A.F., to the emergency room at Lake Granbury Medical Center (LGMC) because he had been complaining of pain in his left leg since falling six days earlier. Plaintiffs lacked health insurance.

Tests performed at the hospital showed an elevated white blood cell count and a CT scan showed subcutaneous contusions and a hematoma/seroma on the right hip. The emergency room physician diagnosed D.A.F. with contusions on both hips and discharged him with instructions that he take Tylenol with codeine for pain, and follow-up with his pediatrician.
The next day plaintiffs returned to a different emergency room because D.A.F. had a fever and swelling and tenderness in his left leg. Test results suggested he was suffering from a bacterial infection so he was admitted to the hospital to receive antibiotics. D.A.F. remained hospitalized for more than a month, during which time he underwent several surgeries and was treated for a methicillin-resistant staphylococcus aureus infection.

Plaintiffs sued, alleging LGMC violated EMTALA by failing to provide D.A.F. with an appropriate medical screening examination to determine whether he had an emergency medical condition.

Based on the factual record, the court found that LGMC provided D.A.F. an appropriate medical screening examination as required by EMTALA. After pointing out all the steps the hospital took in treating D.A.F. and the tests that were conducted, the court concluded that “[t]his is not the type of screening that was so cursory that it amounted to no screening at all.”

The court also rejected plaintiffs’ argument that other patients with similar symptoms were admitted to the hospital for further evaluation and treated with antibiotics. After looking at the medical records plaintiffs offered, the court found the other patients were elderly or not in good general health and none were perceived to have the same medical condition as D.A.F.

Plaintiffs also claimed that LGMC violated EMTALA by failing to stabilize D.A.F.’s condition prior to discharge. But the court rejected this argument as well, noting that “the duty to stabilize does not arise unless the hospital has actual knowledge that the patient has an emergency medical condition.”

Here, it was undisputed that D.A.F. was diagnosed with a contusion, which is not an emergency medical condition, the court said.


Arizona Supreme Court Upholds Learned Intermediary Doctrine in Action Against Drug Maker

The learned intermediary doctrine applied to a consumer’s product liability action against the manufacturer of a prescription acne medicine for allegedly failing to adequately warn her of the drug’s potential side effects after long term use, the Arizona Supreme Court ruled recently. Under the learned intermediary doctrine, a drug manufacturer that warns the prescribing physician of a drug’s side effects or proper use satisfies its duty to consumers to inform them of their product’s risks.

The appeals court concluded that the learned intermediary doctrine was inconsistent with the state’s comparative fault law, but the state high court disagreed.

While the learned intermediary doctrine relates to how a manufacturer satisfies its informational duty to consumers, the comparative fault law is about apportioning damages based on the fault of tortfeasors who have breached a duty of care.

Plaintiff was a minor when she began taking the acne medicine, Solodyn, which is manufactured by defendant Medicis Pharmaceutical Company. The long term use of minocycline, which Solodyn contains, has been associated with certain autoimmune syndromes, including lupus.

Plaintiff was diagnosed with drug-induced lupus allegedly after taking Solodyn longer than the recommended 12 weeks.
Plaintiff sued Medicis for consumer fraud under the state’s Consumer Fraud Act (CFA) and for product liability, alleging the drug company failed to adequately warn her of the potential side effects from using Solodyn for long periods of time.

The trial court granted Medicis’ motion to dismiss, but the appeals court vacated the judgment, finding the learned intermediary doctrine was no longer viable.

The high court rejected the appeals court’s decision, finding the rationale for the learned intermediary doctrine was still persuasive, noting that a prescribing physician is in the best position to warn a patient of a drug’s risks.

The high court also disagreed with the appeals court that the learned intermediary doctrine was inconsistent with the state’s Uniform Contribution Among Tortfeasors Act (UCATA).

“UCATA requires apportionment of damages based on degrees of fault,” the high court noted. The learned intermediary doctrine, however, provides that a manufacturer satisfies its duty to warn—and by extension has no fault—if it adequately warns the end-user’s prescribing physician.

The high court remanded to the trial court for further proceedings on the products liability claim—namely, whether Medicis provided adequate warnings to plaintiff’s health care providers in accordance with the learned intermediary doctrine.

The high court affirmed the appeals court’s ruling that plaintiff alleged an actionable claim under the CFA, rejecting Medicis argument that prescription pharmaceuticals are not merchandise under the statute.


Illinois Supreme Court Says Hospital Must Produce Applications for Staff Privileges in Negligent Credentialing Suit

A hospital must provide a physician’s applications for staff privileges pursuant to a discovery order in a negligent credentialing action, the Illinois Supreme Court held January 22. In so holding, the state high court found the documents at issue not privileged and highly relevant to the legal action.

Plaintiffs Carol and Keith Klaine sued Frederick Dressen, D.O. and Southern Illinois Medical Services, d/b/a The Center for Medical Arts, for medical malpractice. In an amended complaint, plaintiffs added a claim against Southern Illinois Hospital Services, d/b/a St. Joseph Memorial Hospital and Memorial Hospital of Carbondale (SIHS), for the negligent credentialing of Dressen.

During discovery, SIHS refused to produce several categories of documents. After an in camera review, the trial court found the categories of documents at issue were not privileged and must be produced.

SIHS continued to withhold a category of documents that included Dressen’s three applications to SIHS for staff privileges, arguing the material was privileged. An appeals court affirmed the lower court’s ruling, and SIHS sought the high court’s review.

SIHS argued that the appeals court erred when it found that Section 15(h) of the Credentials Act did not explicitly create a privilege against discovery of a physician’s application for staff privileges.
Finding no error, the high court rejected SIHS’ premise that information that is confidential under the statute is implicitly privileged. “[A] confidentiality provision in a statute or rule does not necessarily mean that an impenetrable barrier to disclosure has been erected,” the high court held.

Instead, when information is identified as confidential, disclosure will depend on whether applying an evidentiary privilege "promotes sufficiently important interests to outweigh the need for probative evidence." University of Pennsylvania v. Equal Employment Opportunity Comm’n, 493 U.S. 182, 189 (1990) (quoting Trammel v. United States, 445 U.S. 40, 51 (1980)).

The high court said SIHS failed to demonstrate how interpreting the confidentiality provision in Section 15(h) as a blanket privilege against the discovery of the applications would advance other interests outside the truth-seeking process.

The high court then turned to whether any specific materials within the group of documents were privileged and should be redacted.

SIHS argued that information reported to the National Practitioner Data Bank (NPDB) is privileged pursuant to Section 11137(b)(1) of the Health Care Quality Improvement Act. Rejecting this argument, the high court noted SIHS cited “no cases in which section 11137 has been applied to prevent the discovery of information reported to the NPDB and, again, relies only on the ‘confidential’ designation within the provision.”

Reading the confidentiality provision in paragraph (b) of Section 11137 in conjunction with the Code of Federal Regulations, “we believe it is clear that information reported to the NPDB, though confidential, is not privileged from discovery in instances where, as here, a lawsuit has been filed against the hospital and the hospital’s knowledge of information regarding the physician’s competence is at issue,” the high court held.

SIHS also argued that nonparty medical information should be redacted because it was privileged pursuant to the Health Insurance Portability and Accountability Act. The court said that although defendants forfeited this argument, it was “without merit” in any case. Individual patient identifier either have not been included or have been redacted, the high court noted.


Third Circuit Tosses Class Action Claims Against GSK Finding No Actionable Loss

The Third Circuit affirmed February 12 a lower court’s dismissal with prejudice of a plaintiff’s claims under Missouri state law alleging GlaxoSmithKline LLC (GSK) misrepresented its drug Avandia.

The appeals court agreed with the lower court that the putative class action plaintiff received the “benefit of the bargain” with GSK and therefore sustained no actionable losses under the statute.

Plaintiff Staci Laurino is a former user of Avandia, a prescription diabetes drug manufactured by GSK.

On behalf of a putative class of similarly situated individuals, she alleged that GSK violated the Missouri Merchandising Practices Act (MMPA) because even though it had notice of the “dangerous propensities” associated with Avandia, the company “engaged in misrepresentations, and failed to adequately advise consumers and medical providers of the risks of Avandia, including but not limited to the increased risk of heart attacks and deaths.”
Plaintiff further alleged that Avandia is not more effective than other treatments for Type II diabetes and sought damages equal to the difference between the drug’s actual value and the value of the drug had it been as represented by GSK.

GSK moved to dismiss for lack of standing and failure to state a claim. The district court found plaintiff likely had standing, but determined she received all of the benefits of taking Avandia without suffering any harm and did not sustain an ascertainable loss.

Affirming, the appeals court said “Laurino received the drug she was prescribed, the drug did the job it was meant to do (i.e., controlled her blood sugar levels), and it caused no apparent physical injuries. Under such circumstances, there could be no ascertainable loss.”

The appeals court also found no reversible error in the district court's dismissal with prejudice, noting no indication plaintiff could correct the “fundamental 'ascertainable loss' deficiency” by amending her complaint.


**U.S. Court in Nevada Tosses EMTALA Claim Following Inpatient Admission**

A federal court in Nevada dismissed February 1 a claim under the Emergency Medical Treatment and Labor Act (EMTALA) against a hospital because the conduct at issue only involved care provided to the patient after she was admitted as an inpatient. The U.S. District Court for the District of Nevada noted no evidence that the inpatient admission was a ruse to avoid EMTALA’s requirements. The hospital therefore fulfilled its duties under EMTALA by admitting the patient for inpatient care.

The court declined to exercise supplemental jurisdiction over the negligence claims and remanded the case to the state trial court.

Edna Sumner was 91 years old when she presented to Summerlin Hospital's emergency room (ER) with chest pain. Dr. Stuart Myers evaluated Sumner in the ER and admitted her for observation.

Sumner's assigned physician, Dr. Shazia Hamid, ordered various diagnostic tests but did not physically examine her. Sumner shortly thereafter suffered three cardiopulmonary arrests and died.

Her children (plaintiffs) sued the hospital and Hamid for negligence and for wrongful death. They also asserted EMTALA violations against the hospital. The hospital moved to dismiss the EMTALA claims as a matter of law, arguing their duties under the statute ended once Sumner was admitted as an inpatient.

The district court granted the motion.

The court found no evidence that Sumner received an inadequate medical screening in the hospital's ER. The fact that Hamid may not have physically examined Sumner related only to her post-admission care and could not form the basis of a failure to screen claim under EMTALA.

While acknowledging that a hospital could not escape EMTALA liability by admitting a patient with no intent of treating her, the court found no evidence in the record that was the case with Sumner’s admission.
Instead, the evidence “unequivocally shows that medical staff took steps to treat Edna after her admission.” Allegations of substandard care post-admission are only cognizable under state tort law, not EMTALA, the court said.


**Texas Appeals Court Finds Hospital Did Not Breach Contract with Physician**

A Texas appeals court affirmed February 18 summary judgment for a hospital in a contract dispute with the director of its inpatient rehabilitation unit.

Valley Baptist Medical Center, now VB Harlingen Holdings, hired plaintiff Dorothy S. Nesmith, MD, PA to serve as director of the hospital's inpatient rehabilitation unit.

Specifically, Valley Baptist hired plaintiff to satisfy Medicare reimbursement requirements that inpatient rehabilitation units have a director who contributes at least 20 hours of service to the unit each week. 42 C.F.R. § 412.29(g).

The plain terms of the contract stated that Nesmith would perform and be paid for no more than 80 hours of administrative service each month at a rate of $130 per hour, with a "maximum annual compensation" of $128,400.

Multiple terms in the contract provided that Valley Baptist's obligation to pay was expressly conditioned upon Nesmith's submission of a monthly summary report.

During the next three years, Nesmith submitted reports that routinely documented fewer than 80 hours. When the form of the report subsequently changed, Nesmith began to regularly submit reports documenting a full 80 hours of administrative services each month.

Following the change in the report format, Nesmith demanded back-pay between May 2009 and September 2012, when she documented fewer than the full 80 hours a month. When Valley Baptist declined, Nesmith sued alleging the hospital breached the contract. The trial court granted summary judgment to the hospital.

Affirming, the appeals court agreed with Valley Baptist that its obligation to pay was only triggered when Nesmith submitted a report documenting the hours that she spent performing the administrative services.

Nesmith argued the trial court erred in granting summary judgment because the contract was ambiguous. She pointed to language that required Valley Baptist to pay her for a minimum of 80 hours per month, which Nesmith contended was inconsistent with other terms that supported Valley Baptist's interpretation.

But the appeals court found the contract was unambiguous, calling Nesmith's interpretation unreasonable. The undisputed evidence showed that Valley Baptist fully satisfied its obligations under the contract, the appeals court said.


**D.C. Circuit Revives Nurse’s Discrimination Action Against Hospital**

The D.C. Circuit reversed February 12 the dismissal of a nurse’s discrimination action against a hospital the termination of her employment was racially motivated. The appeals court found the
nurse provided sufficient evidence that hospital supervisors treated similarly situated nurses who were not African American more favorably in comparable circumstances to avoid summary judgment on her Title VII claim.

Plaintiff Patricia Wheeler was hired as a nurse at Georgetown University Hospital (hospital), where she was under the immediate supervision of clinical manager Angela Hollandsworth.

After several of her colleagues reported that plaintiff made a number of significant mistakes during one of her shifts, Hollandsworth, and the clinical director of the unit, Sue Howell, suspended Wheeler.

Following an investigation, Hollandsworth and Howell notified plaintiff that her employment was terminated based on poor work performance “reflect[ing] a serious lack of clinical judgment [that] jeopardized the health and safety of [the Hospital’s] patients.”

Plaintiff sued the hospital for racial discrimination in violation of Title VII of the Civil Rights Act of 1964. The federal trial court granted summary judgment to the hospital.

Under the familiar *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973) burden-shifting analysis, at issue in the appeal was whether plaintiff presented sufficient evidence for a reasonable jury to conclude that the hospital’s nondiscriminatory reason for firing her—poor work performance—was a pretext for unlawful discrimination.

Plaintiff identified six nurses who she alleged were similarly situated but who were not terminated for their “gross misconduct,” including medication and reporting errors.

In the appeals court’s view, plaintiff’s evidence was sufficient to raise a triable fact for a jury to resolve—whether the comparator nurses were similarly situated and treated more favorably.

Specifically, the appeals court noted that at least some of the identified nurses worked in the same unit as plaintiff and were subject to discipline by common decision makers (Hollandsworth and Howell). In addition, a reasonable jury could conclude that plaintiff’s alleged offenses were of “comparable seriousness” to at least some of the other nurses.

The hospital argued that plaintiff had a history of performance issues, which distinguished her from the other nurses at issue. But the appeals court pointed out that at least two of the identified nurses also had prior performance issues and that, in any event, the formal letter terminating plaintiff’s employment cited only to her conduct during one specific shift as the basis for her dismissal.

“To the extent that the Hospital relies after-the-fact on Nurse Wheeler’s prior work performance as a basis for her termination, that only bolsters her argument that her termination was in fact based upon pretext, as it suggests that the explanation has shifted over time,” the appeals court observed.


**Indiana Appeals Court Says Patient May Discover Insured Patient Discounts in Challenge to Hospital Lien**

An uninsured patient who disputed the reasonableness of a hospital’s charges under the Indiana Hospital Lien Act is entitled to discovery of discounts the hospital may have provided to patients with private or government insurance, two judges on a three-judge panel of the Indiana Court of Appeals held March 14. After plaintiff Thomas Frost was seriously injured in a motorcycle collision, he was transported by air to Parkview Hospital. Frost’s condition eventually improved after about a month in
the hospital and he was transferred to the skilled nursing facility at Parkview Randalia. Frost remained in skilled nursing for about another month. Frost did not have health insurance at the time he sustained his injuries.

Parkview filed in state court a hospital lien of $629,386.50, which included charges for Frost's inpatient and skilled nursing care at Parkview.

The hospital later filed an amended hospital lien in the amount of $625,117.66. Frost then filed a declaratory judgment action under the Indiana Hospital Lien Act to quash or reduce the claim in the court where the lien was perfected.

Frost's petition alleged in part that Parkview's charges were unreasonable because they were greater than the amounts Parkview accepts as payment in full from other patients. Frost served a written discovery request on Parkview for information about discounts provided to patients who either had private health insurance or who are covered by government health care programs.

Parkview then moved for partial summary judgment seeking an order that its chargemaster rates were reasonable as a matter of law. The trial court denied the motion, concluding that evidence of discounts provided to other patients was relevant to the determination of reasonable charges under the Act and was admissible. Parkview appealed.

Frost was not disputing a debt was owed to Parkview; instead, he argued that under the Act, he could challenge the reasonableness of the charges, and was entitled to discovery from Parkview to do so.

The appeals court agreed with Frost. "By frustrating Frost's discovery efforts, Parkview prevented Frost from meeting Parkview's prima facie evidence of reasonableness with contradictory evidence," the appeals court said.

The appeals court affirmed the trial court's finding that Frost should be allowed to discover such evidence and that it was admissible under the Act.

One judge dissented, arguing the Hospital Lien Act does not allow "an uninsured hospital patient to renegotiate the terms of his contract with the hospital."


**Seventh Circuit Rejects Physician’s Discrimination Claims Against Hospital**

A physician failed to show that the hospital where she worked for more than two decades discriminated against her based on national origin or sex when it suspended her privileges and denied her reappointment to the medical staff following repeated warnings that her non-operative treatment of appendicitis patients fell below the standard of care, the Seventh Circuit held March 15. Affirming a lower court decision granting summary judgment to the hospital, the Seventh Circuit agreed that the physician couldn’t demonstrate that the hospital’s reason for the actions it took was a pretext for discrimination.

Instead, the appeals court said, the record was “replete with evidence” that the hospital and its administrators believed the physician’s approach was dangerous and resulted in complications for patients.

Plaintiff Dr. Katherine Liu, an Asian woman of Chinese descent, began working at Stroger Hospital in 1984 and consistently received high performance appraisals.
She began clashing with hospital administrators in 2004 over her treatment of patients with appendicitis. According to the opinion, despite repeated instructions from hospital administrators over a number of years, plaintiff continued to pursue non-operative treatment of patients with appendicitis, using antibiotics instead.

The hospital in 2008 suspended plaintiff’s privileges and later denied her reappointment, citing her continued refusal to follow the hospital’s policy for treating patients with appendicitis.

Plaintiff sued the hospital and several physician administrators alleging race, sex, and national origin discrimination, as well as retaliation and harassment. The trial court granted summary judgment to defendants.

On appeal, the Seventh Circuit said the record demonstrated that plaintiff repeatedly refused to operate when patients presented with appendicitis, despite specific instructions to do so; that her privileges were suspended and reappointment denied after several of her patients experienced potentially life-threatening complications; and that her case was reviewed by no less than six different medical committees.

Plaintiff argued that defendants were medically off-base in rejecting the non-operative approach to treating appendicitis. But even if this argument was true, the reasons for defendants’ actions were still believable, particularly given the complications that some patients apparently suffered, the appeals court said.

While plaintiff noted that other surgeons use non-operative treatment in a small percentage of appendicitis cases, the appeals court distinguished her situation, noting she was repeatedly instructed to operate on appendicitis patients, refused to do so, and “her patients experienced several near-tragedies.”

“As a matter of medical science, we must assume for purposes of summary judgment that Dr. Liu might ultimately be correct that her approach to appendicitis treatment will provide to be sound,” the appeals court said. “But as we have said many times, we do not sit as a super-personnel department, examining the wisdom of employers’ business decisions.”


**Fourth Circuit Holds General Liability Policy Covers Data Breach Class Action**

The Travelers Indemnity Company of America must defend Portal Healthcare Solutions LLC under two commercial general liability policies against a class action filed by two individuals alleging a data breach exposed their personal medical information to public view for more than four months, the Fourth Circuit held in an unpublished opinion issued April 11. The appeals court’s decision affirms a 2014 lower court ruling that the lawsuit was covered by policies Travelers issued to Portal Healthcare, a medical records company for hospitals and other medical providers. See *Travelers Indemnity Co. of Am. v. Portal Healthcare Solutions, LLC*, 35 F. Supp. 3d 765 (2014).

Patients of a hospital that contracted with Portal for medical records electronic storage and maintenance, which were hosted on a third-party’s server, brought the lawsuit alleging negligence and other misconduct. According to the patients, they discovered that their confidential medical records were accessible to the public through an internet search for roughly four months between 2013 and 2014.
Travelers argued that it was not obligated to defend the class action because the policies only covered "publication" of electronic material that gives "unreasonable publicity" to and "disclosure" of information about patients’ private lives.

The lower court found, and the Fourth Circuit agreed, that posting on a public website could constitute a “publication” under the policies, even in the absence of evidence that any third parties beyond the patients viewed the records.

The courts also held that posting medical records online without security restrictions exposes them to general public view and amounts to “publicity” and a “disclosure.”


Eleventh Circuit Reverses Dismissal of Class Claims Against Hospitals for Allegedly Excessive Billing

A lower court dismissed prematurely class claims in an action alleging several Florida hospitals charged unreasonable amounts for emergency radiological services covered by Personal Injury Protection (PIP) insurance, the Eleventh Circuit held April 26 in an unpublished opinion. According to the appeals court, the district court should not have dismissed the class claims based solely on the pleadings. “Discovery could reveal that it is relatively easy to determine that these rates are unreasonable across the board without having to resort to analyzing subtle differences between hospitals,” the appeals court said.

The appeals court also held that individualized damages issues didn’t necessarily preclude class treatment.

“[E]ven if courts must confront some individualized damages issues, common issues predominate if liability can be determined on a class-wide basis,” the appeals court said.

Several patients brought the action against HCA Holdings Inc. and three of its subsidiary hospitals, alleging their excessive charges prematurely exhausted their PIP insurance benefits.

Plaintiffs were patients at HCA-operated defendant hospitals in Florida and received emergency CT scans, X-rays, MRIs, and ultrasounds, which were covered by their respective PIP insurance. According to plaintiffs, who signed admissions agreements that included a provision requiring them to pay the hospital’s “charge master” rates, they were charged up to 65 times higher than the charges for the same services billed to other patients covered by private or government-sponsored health insurance.

Plaintiffs filed a putative class action against HCA and its subsidiaries alleging violations of the Florida Deceptive Unfair Trade Practices Act (FDUTPA), breach of contract, and breach of the implied covenant of good faith and fair dealing.

In a February 2015 decision, the U.S. District Court for the Middle District of Florida held HCA could be directly liable for the billing practices of its subsidiary hospitals as it was directly involved in

The court also found plaintiffs sufficiently alleged a cause of action under FDUTPA and for breach of contract, but dismissed claims for breach of the implied covenant of good faith and fair dealing.

The court also agreed to strike plaintiffs' class allegations, concluding that the most important issues to settle—the reasonableness of the charges for the specific radiological service and damages incurred by each putative plaintiff—would be a highly individualized inquiry depending on geographic area and a number of other factors.

On interlocutory appeal of the lower court's decision to strike the class action allegations, the Eleventh Circuit reversed.

The appeals court emphasized, however, "that nothing in our opinion should be read to suggest how the district court should ultimately rule on the certification decision."


**U.S. Court in Louisiana Says Hospital’s Duty to Patient Under EMTALA Ends on Admission**

The U.S. District Court for the Western District of Louisiana held May 4 that a hospital did not violate the Emergency Medical Treatment and Labor Act (EMTALA) after a patient suffered complications during a transfer to another hospital. Before transfer, the patient was admitted as an inpatient, ending the hospital's duty under EMTALA, the court said.

George Richard Cotherman presented to Jackson Parish Hospital's emergency room with shortness of breath. Cotherman was admitted as an inpatient for further testing and treatment.

Cotherman's family members requested that he be transferred to St. Francis Medical Center. The Jackson Parish Ambulance Service undertook the transport, but Cotherman suffered complications during the ride and was rerouted to the North Louisiana Medical Center, where he died.

Cotherman's family (plaintiffs) sued the hospital arguing that Jackson Parish violated EMTALA by not providing an appropriate transfer from its hospital to St. Francis Medical Center.

Plaintiffs claimed that the transfer to St. Francis Medical Center was not affected through qualified personnel or through satisfactory equipment in accordance with EMTALA.

Jackson Parish moved for summary judgment, arguing that under Centers for Medicare & Medicaid Services (CMS) regulations, a hospital's duty under EMTALA ends when the hospital, in good faith, admits an individual for inpatient care. (See 42 C.F.R. § 489.24(a)(1)(ii), "[i]f the hospital admits the individual as an inpatient for further treatment, the hospital's obligation [to stabilize] ends.")

The court found "no dispute" that Jackson Parish admitted Cotherman for inpatient care or that it did so in bad faith to escape liability under EMTALA.

Plaintiffs urged the court not to defer to CMS' regulation and instead to side with the Sixth Circuit's decision in *Moses v. Providence Hosp. and Med. Cent., Inc.*, 561 F.3d 573 (6th Cir. 2009), which found the rule "contrary to EMTALA's plain language."
But agreeing with the majority of decisions to consider the issue, the court found that CMS’ interpretation of the statute was due *Chevron* deference.


**California Supreme Court Requires Custodial Relationship for Elder Abuse Act Claims**

The California Supreme Court held May 19 that the Elder Abuse and Dependent Adult Civil Protection Act (Act) does not apply unless the defendant health care providers had a “substantial caretaking or custodial relationship” with the elderly patient. From 2000 to 2009, Elizabeth Cox received outpatient treatment from defendant podiatrists working at Pioneer Medical Group, Inc. Defendants diagnosed Cox with peripheral vascular disease and prescribed antibiotics for infections resulting from vascular inefficiency.

Although Cox’s condition worsened in her repeated follow-up visits, defendants never referred her to a vascular specialist. Cox was admitted to the hospital and had her entire right leg amputated. She later died from blood poisoning.

Cox’s family (plaintiffs) sued Pioneer and the podiatrists, alleging their failure to “make a vascular referral” constituted “neglect” under the Act.

The trial court dismissed the complaint, finding plaintiffs’ allegations showed only “professional negligence and incompetence,” but not “malice, oppression, or fraud” as required by the Act.

The appeals court reversed and determined that the Act does not require a custodial relationship to establish a claim for neglect. The dissenting opinion said the majority blurred the lines between neglect under the Act and professional negligence.

Reversing, the high court ruled that neglect requires a caretaking or custodial relationship that arises where a person has assumed significant responsibility for attending to the fundamental needs of an elder.

“It is the nature of the elder’s relationship with the defendant—not the defendant’s professional standing—that makes the defendant potentially liable for neglect,” the high court wrote.

The high court found the legislative history supported the conclusion that the heightened remedies available to a plaintiff under the Act were intended for circumstances where a heightened risk of harm existed—i.e., “to combat pervasive abuse and neglect” arising in the context of caretaking and custodial relationships.

Although the concept of neglect is broad enough to encompass circumstances beyond residential care facilities, the Act is not intended to apply to any conceivable negligence that might adversely impact an elder patient, the high court said.

Life Sciences

**Second Circuit Finds FDCA Preempts Medical Device Claims**

The Second Circuit affirmed June 9 the dismissal of state law consumer fraud and product liability claims in connection with an allegedly defective medical device, finding they were expressly preempted by federal food and drug law. Plaintiff Koleen Otis-Wisher underwent spinal surgery in which the treating surgeon utilized Infuse, a Medtronic, Inc. product approved by the Food and Drug Administration (FDA) to augment bone fusion.

After plaintiff experienced excess bone growth and related pain, movement limitations, voice issues, and difficulty swallowing, she sued defendants Medtronic, Inc. and Sofamor Danek USA, Inc. (collectively, Medtronic) alleging fraudulent misrepresentation, constructive fraud, consumer fraud, negligence, negligent misrepresentation, strict-liability design defect, manufacturing defect, and failure to warn.

Defendants moved to dismiss. The lower court granted the motion, and plaintiff appealed.

The Medical Device Amendments to the Federal Food, Drug, & Cosmetic Act (FDCA) explicitly preempt any state law requirements "with respect to a device" that "relate[] to the safety or effectiveness of the device or to any other matter" governed by the statute and that are "different from, or in addition to" the requirements of federal law imposed by the FDA, the appeals court explained.

Common law claims challenging the safety of an FDA-approved medical device may survive preemption only if they constitute so-called "parallel" claims, such as claims "premised on a violation of FDA regulations" where state law provides a damages remedy for such violations. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

Plaintiff's claims for strict liability failure to warn, strict liability design defect, and negligent failure to warn "all seek to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA," the appeals court found. As such, the claims are expressly preempted under Section 360k(a), the appeals court held.

The appeals court found plaintiff's claim for strict liability manufacturing defect, to the extent that it was not preempted, must be dismissed as it was "wholly conclusory" and failed "to state a plausible claim grounded in fact."

In addition, the appeals court agreed with the lower court that plaintiff's fraud claims—which were premised on allegedly misleading off-label promotion—were not pled with the particularity required under Fed. R. Civ. P. 9(b).


**U.S. Court in New York Sides with Amarin, Says Truthful Promotion of Drug for “Off Label” Uses Is Protected Speech**

A federal court in New York cleared the way August 7 for Amarin Pharma, Inc. to disseminate truthful and non-misleading statements about the "off-label" uses of its drug Vascepa® without the threat of criminal misbranding charges by the Food and Drug Administration (FDA).
Granting preliminary relief, the U.S. District Court for the Southern District of New York found a substantial likelihood that Amarin would succeed on the merits of its claim that FDA’s regulation violated the First Amendment by prohibiting the dissemination of truthful and non-misleading statements about "off-label" uses of drug products to sophisticated health care professionals.

According to the court, the Second Circuit’s decision in United States v. Caronia, 703 F.3d 149 (2012), which held the government could not prosecute pharmaceutical manufacturers and their representatives under the Food Drug and Cosmetic Act for speech promoting the lawful, off-label use of an FDA-approved drug, had a broad reach and was not limited to the facts of that case as the agency argued.

"This lawsuit is based on the principle that better informed physicians will make better treatment decisions for their patients," said John F. Thero, Amarin President and Chief Executive Officer, in a statement. "Amarin will now be able to communicate efficacy data from ANCHOR and other relevant study results to these physicians and to others in the medical community in the context of appropriate disclaimers."

First Amendment Challenge

Amarin and four physicians filed the lawsuit in May arguing FDA regulations preventing the promotion of drug indications not approved by the agency are unconstitutional to the extent they restricted truthful and non-misleading speech.

Amarin manufactures the prescription drug Vascepa, which consists of pure eicosapentaenoic acid (EPA), an omega-3 fatty acid. FDA approved Vascepa for use in reducing very high triglycerides—500 mg/dL of blood or above—but not to treat patients with “persistently high” triglycerides—200-499 mg/dL of blood—although physicians frequently prescribe drugs such as Vascepa to patients who fall into this category.

According to the complaint, Amarin conducted a double-blind, placebo-controlled clinical trial demonstrating the favorable effects of prescribing Vascepa to patients with persistently high triglycerides. The FDA refused, however, to approve Vascepa for this use, citing inconclusive evidence that the drug lowers cardiovascular risks.

Amarin said to ensure the speech was not misleading, the company also would contemporaneously disclose that the FDA has not approved Vascepa for treating patients with persistently high triglyceride levels nor to reduce the risk of coronary artery disease.

The lawsuit sought a declaration from the court that plaintiffs have a First Amendment right to engage in such speech without fear of criminal prosecution or civil liability under the False Claims Act (FCA), as well as injunctive relief barring the agency from taking enforcement action against them.

Caronia’s Implications

According to the court, the FDA argued that Caronia was a “fact-bound decision” and that the agency did not read the ruling as precluding a misbranding action where the acts to promote off-label use consist solely of truthful and non-misleading speech.

But the court disagreed, holding “under Caronia, the FDA may not bring such an action based on truthful promotional speech alone, consistent with the First Amendment.” The court said further, a “fair reading of that decision refutes the FDA’s view that the Second Circuit’s ruling was limited to the facts of Caronia’s particular case.”
The court held that, “insofar as Amarin seeks preliminary relief recognizing its First Amendment right to be free from a misbranding action based on truthful speech promoting the off-label use of an FDA-approved drug, Amarin has established a substantial likelihood of success on the merits on this point.”

The court noted that FDA can still prosecute off-label marketing for misbranding where the speech is false or misleading.

**Specific Communications**

The court found the specific communications on Vascepa that Amarin sought to make mostly acceptable, although it required Amarin to add a disclosure that the FDA did not approve Vascepa for use in treating persistently high triglycerides because of the “current uncertainty” regarding the drug’s cardiovascular benefits.

As modified, the court declared Amarin’s package of proposed communications about Vascepa truthful and non-misleading and therefore not properly subject to a misbranding action.

The court cautioned, however, “[a] statement that is fair and balanced today may become incomplete or otherwise misleading in the future as new studies are done and new data is required.”


**U.S. Court in DC Strikes Interpretative Rule on 340B Orphan Drug Exclusion**

The U.S. District Court for the District of Columbia struck down October 14 an interpretative rule on the 340B orphan drug exclusion as contrary to the plain language of the statute. The Pharmaceutical Research and Manufacturers of America (PhRMA) mounted the legal challenge a year ago after the Department of Health and Human Services (HHS), through the Health Resources Services Administration (HRSA), which administers the 340B Program, issued the interpretative rule.

In a statement, 340B Health said the court’s ruling “will significantly raise the cost of orphan drugs for rural and cancer hospitals and their patients.”

The American Hospital Association (AHA) echoed those sentiments in its statement on the ruling. According to AHA Executive Vice President Tom Nickels, denying rural and cancer hospitals 340B discounts on all drugs with an orphan drug designation “will reduce access to critical services and treatments for some of the most vulnerable patients in society.”

The ruling comes shortly after HRSA proposed long-awaited “omnibus” guidance on the 340B Program, which allows eligible safety net health care providers to access lower-priced medicines. The proposed guidance was published in the August 28 *Federal Register* (80 Fed. Reg. 52300). Comments on the guidance are due October 27.


On the heels of that decision, HRSA issued an interpretative rule including the same position as the invalidated final rule that free-standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and children’s hospitals may purchase orphan drugs at 340B
prices as long as they are not being used for the rare condition or disease that resulted in their orphan drug designation.

**Orphan Drug Exclusion**

The Veterans Health Care Act of 1992 enacted Section 340B of the Public Health Services Act, which requires manufacturers who participate in Medicaid to sell “covered outpatient drugs” to certain covered entities at a price that does not exceed a ceiling price set by the Centers for Medicare & Medicaid Services under a statutory formula.

The Affordable Care Act (ACA) expanded the statutory list of entities eligible for the program to include certain free standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and children's hospitals. The statutory changes also included a provision excluding from the definition of “covered outpatient drugs,” and therefore from the 340B Program, orphan drugs designated under the Federal Food, Drug, and Cosmetic Act for treatment of a rare disease or condition.

In the complaint, which was filed as a separate action, PhRMA argued the interpretative rule, like the final rule, contradicted the statutory text establishing the 340B orphan drug exclusion by “grafting a ‘use-based’ limit on the language Congress enacted.”

According to PhRMA, the statutory text is self-executing and establishes the orphan drug designation, rather than how the orphan drug is used, as the trigger for the exclusion.

PhRMA asked the court to invalidate and permanently enjoin enforcement of the interpretative rule, which was identical in substance to the already vacated final rule, and to block HHS, through HRSA, from issuing any future pronouncements adopting the same interpretation of the orphan drug exclusion.

Granting summary judgment to PhRMA, the court found the interpretative rule (1) constituted final agency action subject to review under the Administrative Procedure Act, and (2) conflicted with the plain statutory language.

**Substantial Penalties, Costs**

On the issue of final agency action, the court found the interpretative rule “represents a definitive and purely legal determination that puts pharmaceutical manufacturers to the painful choice of complying with HHS’s interpretation or risking the possibility of an enforcement action at an uncertain point in the future.”

In particular, the court pointed to enforcement letters HHS sent to drug manufacturers indicating that failing to offer orphan-designated drugs at the 340B price when they are not used to treat a rare condition are “out of compliance with statutory requirements.”

According to the court, the interpretative rule imposed a significant burden on drug manufacturers and covered entities, including the need to implement new tracking and monitoring system for how an orphan drug is being used; financial losses for drug makers required to sell orphan drugs at reduced prices; and the potential for significant penalties in future enforcement activities.

“These penalties impose a particularly acute burden in this case because, at present, manufacturers have no meaningful recourse to dispute HHS’s reading of section 340B(e) or to avoid the continued accumulation of potential liability,” the court said, noting the agency is “now five years overdue” in setting up an administrative dispute resolution process as required by the ACA.
No Use-Based Limit

Next, the court held HHS’ interpretation was contrary to the plain language of Section 340B, which refers only to the designation of an orphan drug, not its use by the covered entity.

The court pointed to other statutory provisions indicating Congress knew how to add a use- or indication-based limitation in the context of an orphan drug. The fact that it added no such limitation here was dispositive, the court said.

The court acknowledged “the plain meaning of the broad, unqualified language that Congress chose to employ in section 340B(e) is somewhat curious, and might be more difficult to reconcile with the generally-stated goal of the 340B Program.”

But the court said its job wasn’t to rewrite the statute; Congress should step in if its desired results were not being achieved.

Long Term Care

Arkansas Supreme Court Approves Class Action Based on Nursing Home Understaffing

The Arkansas Supreme Court affirmed June 4 a lower court’s class certification of current and former nursing home residents claiming understaffing at the facilities caused them injuries. In so holding, the state high court agreed a class action was the most efficient way to litigate the issues presented. Putative class plaintiffs sued 12 nursing facilities doing business as Golden Living Centers (homes) throughout Arkansas.

Plaintiffs asserted the homes were chronically understaffed, which breached the facilities’ standard admission agreement and violated the Arkansas Long-Term Care Residents’ Rights Act and the Arkansas Deceptive Trade Practices Act.

The proposed class was made up of former residents of the nursing homes or special administrators, guardians, or attorneys-in-fact of former residents. The suit sought punitive damages and compensation for an array of injuries.

The circuit court entered an order granting class certification, and the homes appealed.

As their primary issue on appeal, the homes argued that the circuit court abused its discretion by finding that the issues common to the class predominated over individual issues.

According to the homes, the experiences and injuries of each resident were different and individualized proceedings would be necessary to determine if any alleged injury was proximately caused by understaffing.

The high court found the homes’ reliance on certain cited cases was misplaced because in each of those instances there was "no overarching issue common to the class that would establish the defendants’ liability."

"By contrast here, there are core issues common to each class member," the high court said.

According to the high court, "we have said time and time again, the mere fact that individual issues or defenses may be raised regarding the recovery of individual class members cannot defeat class certification where there are common questions that must be resolved for all class members."

The homes also contended that predominance was lacking because 5 of the 43 named class representatives and some of the putative class members may have entered into optional arbitration agreements.

While there could be instances where the number of class members subject to an arbitration agreement "could militate against class treatment," the high court said this was not one of those times.

The high court also rejected the homes' challenge to the superiority requirement for class treatment.

"Determining the central questions whether understaffing creates contractual or statutory liability and whether chronic understaffing occurred are more efficiently handled in a single proceeding," the high court said. "Otherwise, there exists the possibility of a multiplicity of suits across the state with the potential that circuit courts may reach inconsistent results."
A dissenting opinion argued class certification should not be granted because "no common question of law or fact that predominates over the questions affecting only individual class members."


**U.S. Court in Oklahoma Says Nursing Home Facing Termination Must Exhaust Administrative Remedies**

Joining a majority of the courts to consider the issue, the U.S. District Court for the Eastern District of Oklahoma said a nursing home facing termination of its Medicare and Medicaid provider agreements must exhaust its administrative remedies before seeking judicial review.

The Centers for Medicare & Medicaid Services (CMS) informed Sulphur Manor, Inc., which allegedly provides care to 72 residents, including 52 Medicaid recipients and three Medicare beneficiaries, that its provider agreements would be involuntarily terminated.

Sulphur initiated an administrative appeal but asked the court to block the termination of its Medicare and Medicaid payments in the meantime.

The court found that 42 U.S.C. § 405(h) applied, which requires channeling of claims arising under the Medicare Act through the administrative review process.

Sulphur argued exhaustion should be waived under *Matthews v. Eldridge*, 424 U.S. 319 (1976), because its claims were "entirely collateral" to those before the administrative law judge and it raised a colorable constitutional claim—i.e. a deprivation of due process.

The court found, however, that under applicable Tenth Circuit precedent, Sulphur did not assert a colorable constitutional claim entitling it to a pre-termination hearing.

Sulphur also contended the exception in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000)—which allowed a party to file a claim under the Medicare Act in federal court without first exhausting all administrative remedies if postponement of judicial review would have the effect of foreclosing judicial review entirely—applied.

"If this court were writing on a blank slate, equating financial collapse before the completion of appeal with 'no review' would not seem illogical," the opinion said.

But the court pointed to two recent decisions—*First Houston Health Care, LLC v. Burwell*, No. H-14-3055 (S.D. Tex. Dec. 16, 2014), and *THI of Kansas at Highland Park, LLC v. Sebelius*, No. 13-2360-JAR-JPO (D. Kan. Aug. 9, 2013)—that it said specifically found this exception inapplicable under similar facts.

"Under existing authority, the court lacks jurisdiction to proceed," the court held.


**U.S. Court in Wisconsin Says FNHRA Doesn't Confer Private Right of Action**
The U.S. District Court for the Western District of Wisconsin held September 18 that the Federal Nursing Home Reform Act (FNHRA) doesn’t create a private right of action enforceable through a 42 U.S.C. § 1983 claim. Richard Bendel was a resident at Lakeview Health Center, a skilled nursing facility operated by defendants La Crosse County and the Mississippi Valley Health Services Commission.

Bendel, who suffered from dementia and was a known elopement risk, wandered out of the facility one night and fell, sustaining serious injuries and dying four days later. The facility was cited with an “immediate jeopardy” violation.

Plaintiff, Bendel’s sister and the administrator of his estate, sued defendants alleging a Section 1983 claim for alleged violations of FNHRA as well as various state-law negligence claims.

Defendants moved to dismiss, arguing FNHRA did not provide a basis for a Section 1983 claim. The court granted the motion.

Pursuant to Section 1983, an individual may obtain relief for a violation of a federal statutory or constitutional right against anyone who, under color of state law, deprives that individual of such right. See Blessing v. Freestone, 520 U.S. 329 (1997).

Applying the Blessing test, the court found FNHRA did not create private rights enforceable through a Section 1983 action.

First, the court concluded that Congress did not “unambiguously” indicate that the statute was intended to confer federal rights.

According to the court, the FNHRA provisions at issue did not include “unambiguous, rights-creating language,” but rather were “drafted in terms of what nursing facilities must do to receive government funding.”

Second, the court found the "generalized, vague, amorphous quality-of-life interests" in FNHRA were insufficiently clear to confer a federal right.

The court declined to exercise supplemental jurisdiction over the state law claims and dismissed the action.

Fiers v. La Crosse County, No. 15-cv-88-jdp (W.D. Wis. Sept. 17, 2015).
Medicaid

U.S. Supreme Court Won’t Review Maine’s Challenge to ACA “Maintenance-of-Effort” Medicaid Provision

The U.S. Supreme Court let stand June 9 a First Circuit decision upholding the “maintenance-of-effort” (MOE) provision of the Affordable Care Act (ACA), which requires states to maintain their Medicaid eligibility standards for children until October 1, 2019. See 42 U.S.C. § 1396a(gg).

The state of Maine challenged the constitutionality of the MOE provision after the Department of Health and Human Services (HHS) Secretary disapproved of an amendment to their Medicaid state plan that would have dropped coverage for low-income 19 and 20 year olds, a group the program had covered since 1991.

The state in 2012 sought to end coverage for this group for budgetary reasons. HHS refused to approve the change, however, saying it was inconsistent with the ACA’s MOE requirement. Citing the Supreme Court’s decision in National Federation of Independent Businesses v. Sebelius, 132 S. Ct. 2566 (2012), the state argued that the federal disapproval of the amendment on this basis was unconstitutionally coercive in violation of the Spending Clause of the U.S. Constitution.


The appeals court went on to reject the state’s other arguments that the MOE provision was unconstitutional, thus refusing to disturb HHS’ decision disapproving the amendment.


D.C. Circuit Upholds Secretary’s Refusal to Pay Certain Medicaid Claims Without Prior State Determination of Responsibility

The D.C. Circuit held August 7 that the Department of Health and Human Services Secretary’s refusal to pay Medicaid claims for services provided to dual eligibles without a state determination of responsibility was not arbitrary or capricious. Grossmont Hospital Corporation and four other California hospitals provided certain health services to dual eligibles from May 1, 1994 through June 30, 1998.

Grossmont's fiscal intermediary and Medi-Cal implemented a system that was intended to automatically transmit all of Grossmont's claims for payment of dual eligibles' deductibles and co-insurance, but the system did not always work properly. As a result, some of Grossmont's claims were not transmitted to Medi-Cal.

After Medi-Cal reprocessed the claims in its system for May 1994 through March 1999, it issued a lump-sum payment to Grossmont. But Grossmont subsequently realized that some of its claims were not included in its lump-sum payments.

Grossmont eventually produced its own estimates of the missing claims, but there was no evidence in the administrative record that Grossmont took any other steps to obtain state determinations of payment responsibility for the missing claims, the opinion noted.

Grossmont submitted its estimates to its intermediary seeking payment, but the intermediary determined that such documentation was not appropriate. Grossmont appealed to the Provider Reimbursement Review Board, which reversed the intermediary’s determination, concluding that the
intermediary had sufficient information to determine the amounts that Medi-Cal was not obligated to pay.

The Centers for Medicare & Medicaid Services Administrator reversed the Board's decision, holding that under a longstanding policy, Medicare would not reimburse a hospital for dual eligibles' unpaid deductible and co-insurance amounts unless the hospital first billed the state Medicaid agency ('must bill' policy) and obtained a determination from the state of its payment responsibility (mandatory state determination).

The Secretary concluded there had been no state determination made on the missing claims and therefore the claims were not reimbursable. Grossmont challenged the ruling, and the district court granted the Secretary's motion for summary judgment.

On appeal, Grossmont challenged the mandatory state determination policy, arguing it violated a bad debt moratorium that was enacted by Congress in 1987 and prohibited changes to any policy in effect at the time of its enactment with respect to bad debt payments.

But the appeals court agreed with the court below that this argument was waived because Grossmont did not argue it during administrative proceedings.

Grossmont argued alternatively that even if the Secretary could lawfully apply the mandatory state determination policy, doing so under the facts of this case would be arbitrary and capricious and not based on substantial evidence.

The appeals court, however, found it “sensible for the Secretary to require that the state determine in the first instance the Medicaid eligibility of the claims and the appropriate amount of state payment owed because state policies vary widely and the state will have all of the necessary information under its Medicaid system.”

Here, Medi-Cal was not timely billed for the claims at issue, and consequently the Secretary disallowed the claims because the state determination requirement of the must bill policy was never fulfilled. “We conclude that as applied in this case, the Secretary’s state determination requirement was not arbitrary or capricious,” the appeals court said.

The appeals court also noted an independent basis for affirming the Secretary’s disallowance of Grossmont's claims was the failure of Grossmont to timely bill Medi-Cal for those claims.


**U.S. Court in Pennsylvania Says HHS Secretary Properly Reapproved State Medicaid Rate Adjustments**

The U.S. District Court for the Middle District of Pennsylvania granted February 18 summary judgment to the government in a long-running dispute over Pennsylvania’s Medicaid payments to nursing facilities.

In so holding, the court found the Department of Health and Human Services (HHS) Secretary’s interpretation of the relevant statute was reasonable and did not violate the Administrative Procedure Act (APA).

Since 1996, Pennsylvania has paid Medicaid nursing facilities 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) in June 2005 proposed a budget adjustment factor (BAF) to serve as a cap on payments to nursing facilities. The BAF is determined by legislative appropriations 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 state plan amendment (SPA) to HHS for approval of a proposed BAF that would reduce the case-mix rate by more than 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 approved the SPA.

Plaintiff private nursing facilities challenged HHS’ approval of the SPA, arguing it violated 42 U.S.C. § 1396a(a)(30)(A) equal access requirements and 42 U.S.C. 1396a(13)(A) public process requirements. Christ the King Manor, Inc. v. Secretary United States Dep’t of Health and Human Servs., (Christ the King I), Nos. 12-3401, 12-3501 (3d Cir. Sept. 19, 2013).

In that case, the Third Circuit found the record HHS had before it in approving the SPA in 2008 did not satisfy the "equal access" provision of Section 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 how the even more substantial rate cuts would affect quality and access to care.

Following the Third Circuit’s decision, HHS asked Pennsylvania to submit "information or analysis providing evidence of the effect on quality of care of the rates set out in SPA 08-007 on the quality of care for residents in nonpublic nursing facilities."

HHS subsequently reapproved the SPA, finding the data tended to show that the BAF for June 30, 2009 had no adverse impact on quality of care or access to care.

The instant plaintiffs, a subset of the plaintiffs in Christ the King I, sued again, arguing that the Secretary's reopening and approval proceedings were barred because the Third Circuit's decision did not authorize further agency action regarding the SPA.

Plaintiffs also argued that the Secretary's reapproval of the SPA was based on an impermissible construction of Section 30(A)’s requirements in that HHS relied on "post-hoc" data to support its determination.

The court agreed with HHS that the Third Circuit's opinion and mandate in Christ the King I "did not foreclose and in fact expected and authorized further agency proceedings with regard to SPA 08-007."

Although the Third Circuit did not expressly address further agency proceedings, the court found it "clearly telegraphed to Pennsylvania and the Plaintiffs that the battle over this payment rate was not over, and moreover, that the panel was not seeking to bless or condemn the payment rate."

"[T]he clear import of the Third Circuit's decision, even if its mandate was not explicit on this issue, was to allow the Secretary to engage in additional investigation and review of SPA 08-007, consistent with its guidance on what was required under Section 30(A)," the court concluded.
Plaintiffs argued that even if the appeals court’s decision allowed for further agency review, the Secretary violated the APA because the reapproval proceedings impermissibly considered data on the actual effects of SPA 08-007, as opposed to predictive data normally considered on the likely effects of an SPA.

Applying a *Chevron* analysis, the court agreed with HHS that the Secretary’s reading of Section 30(A) to allow use of such data is a “permissible” construction of the statute.


**U.S. Court in New Hampshire Enjoins Modified Method for Calculating Hospital-Specific Limits for Medicaid DSH Payments**

The U.S. District Court for the District of New Hampshire granted March 11 a hospital association and several hospitals a preliminary injunction blocking the Department of Health and Human Services from enforcing a modified method for calculating hospital-specific limits for purposes of Medicaid disproportionate share hospital (DSH) payments while the litigation was pending. The court found plaintiffs were likely to succeed on the merits of their argument that the Centers for Medicare & Medicaid Services’ (CMS’) interpretation of the DSH calculation in two Frequently Asked Questions (FAQs) violated the Administrative Procedure Act (APA) because it amounted to a substantive change to a 2008 final DSH rule without satisfying notice-and-comment procedures.

CMS posted to its website the two FAQs on January 10, 2010 regarding DSH audit and reporting requirements, which were set forth in a December 2008 final rule (2008 Rule).

FAQs 33 and 34 provide that in calculating the hospital-specific DSH limit, a state must subtract payments received from private health insurance (FAQ 33) and Medicare (FAQ 34) for dually-eligible Medicaid patients from the costs incurred in providing hospital services to those patients.

The New Hampshire Hospital Association and several hospitals sued, alleging that the government’s “policy clarifications” contradicted the plain language of the Medicaid Act and violated the APA because the FAQs amounted to a substantive change to the 2008 final DSH rule without satisfying notice-and-comment requirements.

Plaintiffs sought to enjoin defendants from enforcing or applying the policies set forth in FAQs 33 and 34.

The court found plaintiffs were likely to succeed on the merits of their claim, noting the language in the statute defining the payments that are to be deducted from costs is “unambiguous” and does not include payments from private health insurance or Medicare.

The government argued the payments at issue should be considered in the definition of the term "costs,” rather than in the definition of the term “payments.” But the court said such an interpretation was “unreasonable” and therefore not entitled to deference under *Chevron*.

The court also found that FAQs 33 and 34 substantively altered the obligations imposed by the 2008 Rule. “FAQs 33 and 34 made substantive changes to the formula for calculating the hospital-specific DSH limit, bind state Medicaid agencies, and effectively amend the 2008 Rule,” the court said. The FAQs should have been issued in accordance with the notice-and-comment provisions of the APA, and plaintiffs likely would succeed in their argument that the agency erred in not doing so.

The court also said plaintiffs would suffer irreparable harm absent a preliminary injunction and the balance of the equities and the public interest weighed in their favor.
The U.S. District Court for the District of Columbia also issued a preliminary injunction in 2014 on the same issue. In that case, two DSH hospitals, Texas Children's Hospital and Seattle Children's Hospital, argued that FAQ 33 was contrary to the provisions of the Medicaid Act and violated the APA. The court enjoined enforcement of FAQ 33. *Texas Children's Hosp. v. Burwell*, No. 14-2060 (D.D.C. 2014).


**Texas Appeals Court Says Beneficiary’s Medicaid Claims Unripe After Becoming Eligible for Medicare**

The Texas Court of Appeals rejected March 24 a plaintiff’s appeal of Medicaid’s denial of her request for a certain power wheelchair, finding her intervening eligibility for Medicare rendered her claim unripe.

Because plaintiff was dual eligible, Medicare was the primary payer for her durable medical equipment (DME) and the trial court lacked jurisdiction to consider the merits of her Medicaid appeal, the appeals court said.

Plaintiff Linda Puglisi was left paralyzed following surgery on her neck in 2011. On April 4, 2013, a Medicaid-enrolled DME provider submitted plaintiff’s prior authorization request for a particular wheelchair to Molina Healthcare, the Texas Health and Human Services Commission's contracted managed care organization. Molina denied the request.

Plaintiff next sought a Medicaid hearing, but the hearing officer sustained the denial. A subsequent administrative review also affirmed the denial.

Plaintiff sued in court in February 7, 2014. On May 1, 2014, while her suit for judicial review was pending, plaintiff became qualified for Medicare.

The Commission moved to dismiss, asserting that when plaintiff became dual eligible, Medicare became the primary payer and she had to seek benefits under Medicare before turning to Medicaid.

The trial court denied the Commission's motion to dismiss, and ruled the Commission’s decisions below were arbitrary and capricious.

On appeal, the Commission argued that the trial court lacked jurisdiction to determine medical necessity because plaintiff’s dual-eligible status required her to seek prior authorization from Medicare.

The appeals court agreed, finding that under federal law, a dual-eligible recipient must seek preapproval from Medicare for certain items of DME. Plaintiff’s claims against the Commission “have been rendered unripe by her new dual-eligible status,” the appeals court held.

Medical Staff, Credentialing and Peer Review

Texas Supreme Court Holds Certain Peer Review Records Discoverable in Action Alleging Anticompetitive Conduct

The Texas Supreme Court held certain medical peer review committee documents were not shielded from discovery because they fell into the “anticompetitive action” exception to the state’s privilege law. Documents discussing data on mortality rates, physician volume, and referral patterns all were relevant to a physician’s action against a hospital alleging tortious interference with prospective business relations and improper restraint of trade and therefore were discoverable under the exception, the high court found.

Plaintiff Miguel A. Gomez, II, MD is a cardiothoracic surgeon who held privileges at Memorial Herman Memorial City Medical Center from 1998 to 2012. Plaintiff made a name for himself in the Houston area “for quality patient care, technical excellence, and outstanding professionalism,” specializing in particular in robotic heart surgery.

Plaintiff alleged Memorial Herman started a “whisper campaign” that damaged his reputation, as well as called into question the efficacy of robotic heart surgery procedures, after it learned he would be moving some of his practice to a competing hospital that opened in 2009.

According to plaintiff, after this alleged conduct, the volume of surgeries he performed and the number of referrals he received from cardiologists dropped off dramatically.

Plaintiff sued Memorial Herman Hospital System and related parties for business disparagement, defamation, tortious interference with prospective business relations, and improper restraint of trade under the Texas Free Enterprise and Antitrust Act of 1983 (TFEAA).

Plaintiff sought to compel the production of certain documents, which Memorial Hermann asserted were shielded from discovery under the medical peer review committee privilege, Tex. Occ. Code § 160.007. The trial court found the documents fell into the “anticompetitive action” exception to the privilege and ordered their production. Memorial Herman sought a writ of mandamus from the state high court.

In general, records that fall under the medical peer review privilege are not discoverable in court; however, certain exceptions may apply, including one “for proceedings, records, or communications that are relevant to an anticompetitive action.”

Interpreting the statutory language, the high court said “anticompetitive action” wasn’t synonymous with “antitrust action,” with the former being a broader in scope than the latter.

The high court also established that the legislature intended the use of the word “action” to refer to a “civil or criminal judicial proceeding,” not to anticompetitive conduct generally as plaintiff argued.

For the exception to apply, a plaintiff therefore must assert a cause of action that requires proof of anticompetitive effects, the high court said. Tortious interference with prospective business relations is one such cause of action, the high court said.

The high court also noted that plaintiff sufficiently alleged an injury to competition under the TFEAA to support application of the exception. “We hold that Dr. Gomez’s petition presents multiple viable anticompetitive actions,” the high court held.
The next question the high court considered was whether the specific documents at issue were relevant to the anticompetitive actions, the other requirement of the exception.

The high court found at least some of the documents were relevant—specifically those pertaining to mortality rates, physician volume, and referrals—and held the trial court did not abuse its discretion in ordering Memorial Hermann to disclose them.

The high court did say, however, that certain other documents that did not discuss these types of issues were not relevant and therefore the trial court erred in compelling Memorial Hermann to produce them.


**Alaska Supreme Court Holds Peer Reviewers Immune from Physician’s Lawsuit**

The Alaska Supreme Court affirmed May 15 a superior court decision granting summary judgment to peer review physicians in an action brought by Dr. Michael Brandner after he lost his privileges at Providence Alaska Medical Center. The high court held the physician reviewers were immune from Brandner’s breach of contract and due process claims under the state’s peer review law—specifically Alaska Stat. 18.23.010, which grants immunity to witnesses providing information to peer review organizations that is not knowingly false, and Alaska Stat. 18.23.020, which immunizes participants in peer review proceedings so long as they made reasonable efforts to ascertain facts upon which their recommendations were based, acted in the reasonable belief that their recommendations were warranted by the facts, and their actions were not motivated by malice.

In late 2010, the Alaska State Medical Board (Board) investigated Brandner, who held hospital privileges at Providence. The Board ordered Brandner to submit to psychiatric and medical evaluations to determine his ability to practice medicine safely. Brandner completed the evaluations and was found fit to practice, but did not disclose the Board-ordered evaluations to Providence. Hospital bylaws require doctors to report “any limitations, restriction[s], or conditions” imposed by the Board. Violation of this reporting requirement results in termination of hospital privileges. Providence decided Brandner’s hospital privileges should be terminated after it learned of the Board’s order.

Brandner challenged the decision to terminate his privileges, resulting in peer review proceedings where he disputed that the Board’s order triggered the reporting requirement.

The peer reviewers found that the Board’s order imposed a condition upon Brandner’s license, which would have been automatically suspended if he failed to timely complete the requested evaluations.

Brandner sued Providence and several individual physicians, alleging breach of contract, due process violations, defamation, and other contract claims.

The physicians moved for summary judgment, asserting they were immune from suit under the federal Health Care Quality Improvement Act (HCQIA) and the state peer review law. Though it did not reach the question of immunity under HCQIA, the trial court found that the physicians were immune under state law. Brander appealed.

Although the high court noted the trial court applied the wrong summary judgment standard, it found no dispute of material fact that the requirements for immunity under Alaska Stat. 18.23.020 had been satisfied.
The high court noted the physician reviewers conducted factual investigations that were reasonable under the circumstances; relied on a reasonable reading of the reporting requirement and were not required to find Brandner posed a risk to patients to trigger the policy's termination sanction; and there was no evidence their decision to terminate his privileges was motivated by malice.


**Sixth Circuit Affirms Dismissal of Physician’s Antitrust, Other Claims After Privileges Revoked**

A lower court correctly held that a physician failed to state a claim for antitrust and other violations after his privileges were suspended, the Sixth Circuit held in an unpublished opinion issued June 4. John N. Semertzides sued Bethesda North Hospital, Tri-Health Hospitals, and Queen City Surgical Consultants, LLC, asserting hostile work environment, intentional infliction of emotional distress, and violations of the Sherman Act, the False Claims Act, and Ohio's whistleblower statute.

According to Semertzides, defendants interfered with his surgical practice by conducting an unwarranted and unfair investigation into whether he provided substandard medical care and by suspending, and ultimately revoking, his staff privileges.

Semertzides alleged defendants' actions were in retaliation for his reports that surgical groups and practitioners were engaging in "turf wars" to reduce competition.

The district court dismissed the complaint, finding Semertzides failed to state a claim upon which relief could be granted.

The appeals court agreed. Considering Semertzides' antitrust claims, the appeals court found he did not allege facts showing defendants' actions were manifestly anticompetitive.

In addition, Semertzides failed to specifically identify the relevant market and, further, only alleged an anticompetitive effect on him, not the market, the appeals court said. "Individual injury, without accompanying market-wide injury, does not fall within the protections of the Sherman Act," the court held. See *Care Heating & Cooling, Inc. v. Am. Standard, Inc.*, 427 F.3d 1008, 1012 (6th Cir. 2005).

The appeals court also found Semertzides failed to state a claim under either the False Claims Act or Ohio’s whistleblower statute because there were no allegations involving fraud on the federal government and Semertzides did not allege facts showing that he complied with the procedural requirements of Ohio’s whistleblower statute.

The complaint also failed to adequately allege claims of intentional infliction of emotional distress and hostile work environment, the appeals court said, because Semertzides failed to allege defendants' conduct was extreme and outrageous, or that he was a member of a protected class.

Finally, the appeals court found the district court did not abuse its discretion by denying Semertzides leave to amend his complaint because he did not move for leave to amend or specifically identify any proposed amendment to the complaint.


**Sixth Circuit Rejects Suit by Physician Who Failed to Obtain Board Certification**
The Sixth Circuit rejected August 18 claims by an osteopathic physician who failed to gain certification from a private certification board that the board’s actions violated principles of contract law or due process. Plaintiff Arthur S. Lieberman in 2010 twice failed the examination that the American Osteopathic Board of Family Physicians (AOBFP) requires candidates to pass for certification.

After the Board declined to certify Lieberman, he sued the AOBFP and the American Osteopathic Association (defendants). The district court granted defendants' motion to dismiss.

On appeal, plaintiff argued defendants violated the process due to him under Illinois common law. Plaintiff contended that it was arbitrary and capricious to require him to pass a test on material that he alleged was not related to his actual practice.

But the appeals court soundly rejected this argument, finding “[t]he equal imposition of a testing requirement, no matter how disagreeable to Lieberman, is not ‘arbitrary and capricious’ and certainly does not violate the process due to osteopaths who, like Lieberman, wish to be board-certified.”

Plaintiff next argued that it was arbitrary for the AOBFP not to grandfather him into lifetime certification when he was first certified in 2002 because the Board grandfathered physicians who obtained certification prior to 1997.

The appeals court also rejected this contention, noting that a grandfather clause does not violate the constitutional right of due process if applied by the government, and “[i]f a governmental unit may use a grandfather clause, there appears no reason why a private association may not.” See Dietz v. American Dental Ass’n, 479 F. Supp. 554, 561 (E.D. Mich. 1979).

Lieberman also alleged that the defendants tortiously interfered with his contracts by informing insurance companies that he had lost his certification. But the appeals court noted that the kind of certification in which defendants engage enjoys congressional encouragement in the Lanham Act’s provision for certification marks.

“Far from encouraging tortious interference with contracts, certification marks—and the certification processes established to make them function—stimulate the use of markets to further goals that the government may not advance directly,” the appeals court said.


Third Circuit Oks Anesthesiology Board's Action in Revoking Certifications

The Third Circuit October 7 affirmed the dismissal of a physician’s due process, antitrust, and state law claims against the American Board of Anesthesiologists after it revoked his certifications, finding the Board acted properly and the physician failed to state any of his claims sufficiently.

Amgad Hessein, a physician and anesthesiologist, had his licenses to practice medicine in New York and New Jersey temporarily suspended as a result of a pending criminal indictment. He was eventually charged with conspiracy, theft by deception, and 72 counts of health care insurance fraud.

Because Hessein’s licenses were suspended, the credentialing committee of the Board subsequently revoked his certifications in anesthesiology and pain management.
Hessein sued the Board and numerous Board members, alleging that the revocation of his specialty certificates violated his right to due process under the Fourteenth Amendment, violated the Sherman and Clayton Acts, and asserted several state law causes of action.

The district court determined that the Board properly revoked Hessein’s certifications, substantively and procedurally, because he had failed to maintain an active, unrestricted medical license and granted summary judgment to the defendants.

The appeals court first agreed with the lower court that Hessein could not establish a claim under section 1983 because defendants are not state actors, and did not act under color of law. Specifically, the Board "is a private association," the appeals court found.

Plaintiff argued in regard to his antitrust claims that the defendants conspired with the state medical boards to revoke his certifications and disrupt his medical practice, but "his complaint does not state a plausible claim of an unlawful antitrust conspiracy," the appeals court said.

Hessein asserted a challenge to an exclusionary scheme that keeps him out of the market, which is similar to the scheme in Daniel v. American Bd. of Emergency Medicine, 428 F.3d 408, 438-39 (2d Cir. 2005), the appeals court noted. In that case, the Second Circuit held that the physician-plaintiffs did not suffer an antitrust injury and did not have standing to sue when their medical specialty certification board denied them an opportunity to take the emergency medicine certification examination because they had not completed a formal residency program in emergency medicine.

"[B]y seeking relief that would permit them to join but not end the alleged exclusive arrangement, plaintiffs make plain that they are not complaining of an antitrust injury," the Daniel court held. Here, as in Daniel, "by seeking the restoration of his certificates, Hessein seeks to join the alleged exclusive arrangement and thus does not state an antitrust injury," the appeals court said.

The appeals court also affirmed the dismissal of plaintiff’s state law claims, finding the Board "breached no contract with Hessein, breached no duty of care owed to him, and did not defame him by noting on its website that his certifications had been revoked."


**North Carolina Appeals Court Dismisses Physician’s Claims Against Medical Peer Review Evaluators**

The North Carolina Court of Appeals dismissed October 6 a physician’s due process and negligence claims against medical peer review evaluators for failure to state a claim under Fed. R. Civ. P. 12(b)(6). Ophthalmologist William Shannon had medical staff privileges at Gaston Memorial Hospital. As a result of two patient incidents, Gaston Memorial requested Shannon “undergo a comprehensive neuropsychiatric assessment as part of their evaluation."

After a psychiatrist reported no issues, Gaston Memorial referred Shannon to North Carolina Physicians Health Program, Inc. (NCPHP) and the two individual defendants Testen and Jordan for further evaluation.

Shannon met with defendants for approximately two hours and they later submitted an assessment letter to Gaston Memorial recommending that he immediately obtain further professional evaluation.

According to Shannon, the assessment letter contained factual errors and significant omissions regarding the two incidents in question.
Gaston Memorial subsequently informed Shannon that, based on information provided by defendants, his staff privileges would not be reinstated.

Shannon sued Testen, Jordan, and their employer, alleging that Testen and Jordan were negligent in performing their evaluations, and that NCPHP was vicariously liable as their employer.

Defendants moved to dismiss Shannon's amended complaint pursuant to Rule 12(b)(6), arguing they were immune from suit under N.C. Gen. Stat. § 90-21.22(f). The trial court granted the motion.

On appeal, Shannon argued his complaint stated a claim for breach of duties that defendants owed him under the applicable peer review statutes. While Shannon acknowledged he had to allege defendants acted in bad faith to overcome the statutory immunity provided in Section 90-21.22(f), he asked the court to infer bad faith from the express allegations in the complaint.

The appeals court refused to do so. “Indeed, the complaint does not even contain a conclusory allegation that Defendants acted in bad faith; to the contrary, the allegations read like a run-of-the-mill negligence claim,” the appeals court said.

Shannon next argued that his complaint stated a claim for violation of statutory due process protections provided by the Health Care Quality Improvement Act (HCQIA). But the appeals court found HCQIA does not provide a private right of action.

The court also rejected Shannon’s attempt to pursue a state common law claim for the violation of his statutory due process rights provided by the federal law.


**U.S. Court in Michigan Affirms Medical Specialty Board’s Refusal to Certify Physician**


Meanwhile, Picard, a recovering drug and alcohol addict, suffered a relapse on March 6, 2010. Picard self-reported the relapse to Michigan's Health Professional Recovery Program (HPRP).

After failing to comply with his treatment plan and then failing a cocaine test, HPRP notified Picard that they were closing his file as non-compliant, denied Picard's appeal, and forwarded his file to the Michigan Department of Community Health.

The Department of Community Health summarily suspended Picard's medical license pending review of the allegations against him.

On July 28, 2011, the state reinstated Picard's medical license to full/unrestricted status after he provided verification that he entered a regulatory Monitoring Agreement with HPRP, to remain effective for at least three years.

In a letter dated October 5, 2011, ABFM informed Picard it obtained information from the Michigan Board of Medicine that his license had been subject to disciplinary action and that his Diplomate
certification was retroactively rescinded, effective March 28, 2011. Picard maintained he never received this letter.

After Picard obtained employment with a new employer, he claimed he contacted ABFM about the status of his certification on December 27, 2012.

ABFM allegedly told Picard that it would reinstate his certification if he provided proof he had an unrestricted medical license. Picard faxed ABFM proof of his reinstated medical license as well as the Monitoring Agreement.

ABFM subsequently e-mailed and mailed a letter to Picard's employer stating that the Monitoring Agreement was a restriction on his medical license and it refused to reinstate Picard's certification. Picard's employment was terminated as a result of his inability to gain ABFM certification.

Picard sued ABFM, claiming it maliciously denied him Board Certification and made defamatory statements to his employer about the status of his medical license.

Among other claims, Picard alleged ABFM violated his common law due process rights. ABFM countered that summary judgment is appropriate because its decision to revoke plaintiff's certification was not arbitrary or unreasonable. The court agreed, finding the “bases for ABFM's decisions are supported by the evidence.”

The court also found ABFM was justified in its decision to continue the rescission of Picard's certification. “ABFM could have properly found that the conditions of Picard's Monitoring Agreement constituted a restriction in violation of ABFM's professionalism standards,” the court said.

In addition, “ABFM as a professional organization is free to maintain more restrictive standards than state licensing departments,” according to the court.

The court also found ABFM's decision to rescind Picard's Diplomate status was procedurally fair because “ABFM is free to determine that those physicians facing license restrictions pursuant to a state order are a greater liability than those physicians facing license restrictions with state approval. In this way, ABFM's Guidelines are not procedurally unfair or arbitrary and capricious,” the court found.

The court also rejected Picard’s contention that he was denied sufficient notice when ABFM sent the October 2011 notice letter to an old address. “To the contrary,” the court said, “as a Diplomate with ABFM, it was Picard's duty to provide ABFM with a correct and updated address.”


**U.S. Court in California Allows Physician’s Action Against Association to Proceed**

The U.S. District Court for the Central District of California allowed some claims to go forward in a dispute over a physician's termination from her professional organization. After examining each claim, the court ultimately granted defendants' summary judgment motion as to plaintiff's claims under Title VII, the Fair Employment and Housing Act (FEHA), intentional interference with economic advantage, defamation, and two of her fraud claims. The court denied plaintiff summary judgment on all claims, finding issues of material fact existed.

Plaintiff Patricia Stewart was a member of the American Association of Physician Specialists, Inc. (AAPS), a nonprofit corporation that represents the interests of its 3,000-plus member physicians.
At one point during her membership, plaintiff was notified that AAPS would be holding a special meeting of its Disciplinary Committee to consider charges against her of conduct injurious to the best interests of AAPS and/or incompatible with its purposes.

The letter also informed her that she could appear in person, with or without counsel, to present evidence that she was qualified to remain a member in good standing with AAPS.

Plaintiff did not attend the meeting but instead sent a letter to each member of the Board refuting the allegations against her. Plaintiff also objected to having to appear before the Disciplinary Committee, claiming members on the panel purportedly had a conflict of interest that would prevent a fair hearing. The Board voted to terminate plaintiff's membership with AAPS.

Plaintiff sued, alleging breach of contract; four counts of fraud; discrimination under Title VII; violations of the Unruh Civil Rights Act and FEHA; interference with prospective economic advantage; defamation; and violations of California's Unfair Competition Law.

Both parties moved for summary judgment.

Defendants contended that the business judgment rule protected the Board's decision to terminate plaintiff's membership because the decision was made in good faith based on the information available at the time.

The court found, however, that plaintiff's allegations of fraud, bad faith, and conflicts of interest "create a factual dispute as to whether the business judgment rule should be applied, thus precluding its application as a matter of law."

The court also denied defendants summary judgment on plaintiff's breach of contract claim, noting it could not "find as a matter of law that Plaintiff's termination was carried out in a fair, reasonable, and good faith manner based on factual disputes surrounding the purported allegations of fraud, bad faith and conflicts of interest on behalf of AAPS."

Turning to plaintiff's claims under the Unruh Civil Rights Act, the court said that while it was inclined to agree with defendants, it could not find "as matter of law that Plaintiff's gender was not a motivating factor in her termination or exclusion."


**Seventh Circuit Says Hospital Privileges Not Constitutionally Protected Property Interest**

The Seventh Circuit held January 11 that a terminated physician has no property interest in his continued privileges at defendant hospital. The appeals court also agreed with the hospital’s alternative argument that it is not a state actor. Dr. William Babchuk was granted medical staff privileges at Indiana University Health Tipton Hospital, Inc. The hospital also gave his professional corporation an exclusive contract to provide radiology services at the hospital.

In June 2012, a four-member peer review committee summarily suspended Babchuk’s staff privileges on the ground that he delayed for eight days dictating a report on the result of an ultrasound. The Medical Executive Committee later voted unanimously to make the suspension permanent and canceled his professional corporation’s contract with the hospital.
Babchuk sued the hospital under 42 U.S.C. § 1983, arguing that by reporting the suspension of his medical privileges to Indiana's medical licensing board and the National Practitioner Data Bank, as required by both federal and Indiana law, the hospital "blemished" his medical license and by doing so had deprived him of property.

The trial court granted summary judgment to the hospital, and the Seventh Circuit affirmed.

The appeals court pointed out that Babchuk presented no evidence that his career was hindered by the hospital's reporting of the suspension.

The appeals court also rejected Babchuk's argument that he had a property interest in not only his license but also his medical privileges at Tipton Hospital. In asserting a property interest, Babchuk cited hospital bylaws that establish procedures for terminating physicians' medical privileges. "But the existence of such procedures creates no entitlement to continued privileges," the appeals court held, noting "hospital privileges terminable at will are not a constitutionally protected entitlement."

The appeals court also found the hospital is not a state actor, making Section 1983 inapplicable.


**U.S. Court in Vermont Denies Discovery of Joint Commission Documents in Wrongful Death Action**

A federal court in Vermont held January 25 that the state’s medical peer review statute protects from discovery in a wrongful death action documents related to The Joint Commission’s (TJC's) review of a patient's suicide at a mental health treatment facility. The U.S. District Court for the District of Vermont said while the law’s definition of "peer review committee," didn’t literally encompass TJC, the type of work the organization does in reviewing “sentinel events” like the untimely death here, “is precisely the sort of proceeding contemplated by the Vermont peer review statute.” See 26 Vt. Stat. Ann. § 1443.

The wrongful death action, brought under the federal court’s diversity jurisdiction, followed the suicide of a young woman in May 2014 at the Brattleboro Retreat (The Retreat) where she was a patient.

Plaintiff, the administrator and personal representative of the decedent, moved to compel production of records between The Retreat and TJC and Health New England, the Massachusetts-based health maintenance organization (HMO) that paid for the decedent’s stay, as well as records of similar incidents.

The Retreat argued the records were protected from discovery under Vermont’s medical peer review statute, which provides that the “proceedings, reports, and records” of peer-review committees “shall be confidential and privileged.”

The law enumerates four entities that qualify as peer review committees: the Vermont professional standards review organization or its subsidiary committees; the Vermont Program for Quality in Health Care, Inc., or its subsidiary committees; a peer-review or other comparable committee established by an HMO; and a committee of a state or local professional association or of a hospital or other health care provider.

The court acknowledged that TJC didn’t technically fall into any of these categories, but nonetheless held the statute applied to the TJC materials sought in the instant action.
The federal district court noted that Vermont courts have found that TJC is a “peer review committee” under the statute, focusing on the type of work they do, which is “clearly peer review in nature.”

The court spent little time determining that Health New England was a peer review committee pursuant to the statutory definition.

The court also rejected plaintiff’s argument that the materials were discoverable because they were not created as part of a formal peer review process, but rather constituted “conversations and documents arising in the course of ordinary business operations.”

Instead, the court pointed out that investigations conducted by TJC and Health New England "are precisely the sorts of formal peer-review processes contemplated by the statute" and are “very different than a mere conversation between staff about ‘quality control.’”

After an in camera review, the court also determined that none of the records at issue were “original source” materials that TJC and Health New England merely reviewed. Instead, the documents consisted of communications regarding the investigations, a physician chart review, analysis, recommendations, and conclusions—all of which fell within the statute’s protection.

The court further held that the exchange of information among the parties didn’t waive the peer-review privilege. Even assuming the peer review privilege is waivable, there was no waiver because the communications were between participants to the peer review, not adversaries or the public.

Finally, the court ordered the production of redacted records of similar incidents such as suicides and suicide attempts, leaving the parties, at this point, to define a reasonable scope of time for limiting the request.


**West Virginia Supreme Court Holds Physician’s Applications for Staff Privileges Not Discoverable**

The West Virginia Supreme Court held February 9 that a physician’s applications for renewal of his staff privileges were not discoverable in a medical malpractice action alleging negligent credentialing.

Citing the “urgent need for more precise guidelines” as to what documents the state’s peer review law, W. Va. Code § 30-3C-3, shields from discovery, the high court sought to craft bright-line rules for determining the application of the privilege.

In particular, the high court said to fall under the privilege, courts must consider both the origin of the document and its specific use.

To be privileged, documents must be exclusively created for or by the peer review committee and also be used solely by the peer review committee, the high court explained. Documents that are not created exclusively by or for a review organization, originate outside the peer review process, or are used outside the peer review process, are not privileged.
Stephanie Mills received treatment from a physician who performed a surgical procedure on her at Wheeling Hospital, Inc., where he held privileges. Mills alleged she was injured by the procedure and sued the hospital and the physician for medical malpractice, lack of informed consent, and negligent credentialing.

Mills sought discovery from the hospital of certain records involving the physician, including his credentialing files. The trial court granted discovery of most of the disputed documents, and the hospital sought to block enforcement of that order.

The high court found the trial court erred in ordering discovery of the physician’s applications for staff privileges and of documents used by the review committee for quality control or for determining the cost of health care related to various patient outcomes.

According to the high court, these documents were created exclusively for or by the credentialing committee and used solely in performing its function of ensuring quality health care.

The high court said it couldn’t determine whether the remaining documents were protected from discovery based on the hospital’s privilege log, which didn’t address the two elements outlined in the opinion as critical to the privilege analysis—i.e., origin and use.

The high court ordered the hospital to supply this information in an amended privilege log, which the trial court would then use in conducting a new in camera review to determine whether the statutory peer review privilege applied.


Ohio Supreme Court Finds Medical Board Hearing Examiner May Limit Subpoenas

The Ohio Supreme Court held February 23 that a hearing examiner appointed by the Ohio Board of Nursing has the discretion to limit or quash subpoenas in administrative proceedings. Plaintiff Beverly Clayton was employed as a staff nurse in the intensive-care unit (ICU) of Mercy Hospital Western Hills. After one of her patient's died, Clayton's supervisors informed her there would be an investigation into the death and that she would be suspended without pay until the investigation was completed.

After its investigation, the board commenced a professional disciplinary action against Clayton for her alleged failure to check the physician's orders and to follow those orders, which constituted a failure to practice in accordance with acceptable and prevailing standards of safe nursing care, and subjecting her to discipline under the applicable statutes.

At a hearing, Clayton requested subpoenas for the personal appearance of more than two dozen individuals, including two or more unidentified individuals. She also requested subpoenas duces tecum seeking to obtain approximately seven different collections of documents. The board filed a "motion to limit subpoena request," arguing that the number of requests was excessive.

The hearing examiner ultimately denied the board's motion in part, and granted the request to limit the subpoena duces tecum issued to Mercy Hospital's records custodian for the production of health records for other patients in the ICU during Clayton's shift.

The hearing examiner concluded that discipline was warranted, and the board suspended Clayton’s license.
Clayton challenged the decision, claiming the hearing examiner's decision to limit her subpoenas denied her the opportunity to be heard in a meaningful manner by rendering her unable to prove the extent to which she was overburdened by her duty to assist the other ICU nurses with other ICU patients.

The trial court concluded that the hearing examiner's decision was not an abuse of discretion or contrary to law. The appeals court likewise rejected Clayton's argument regarding the subpoena duces tecum, but implied that the hearing examiner's decision to limit the subpoena may have been erroneous. The appeals court found, however, that Clayton failed to establish prejudice and affirmed the trial court's judgment. Clayton appealed.

The high court found the ability to limit or quash subpoenas must necessarily be inferred from the power to issue subpoenas. "Having been granted the power to issue subpoenas, all administrative agencies must have the corollary power to quash subpoenas in licensure-related hearings" to manage the adjudication process, the high court held.

Clayton argued that even assuming that the hearing examiner had such authority, the ICU patient records were so crucial to Clayton's case that the limitation of her request was an abuse of discretion and a violation of her due process right to present a defense.

But the high court rejected this argument as well. "[W]e cannot say that the hearing examiner's decision was so irrational that it was an abuse of discretion or so capricious that it violated Clayton's procedural due-process rights," the high court said.


**Kentucky Appeals Court Reverses Grant of HCQIA Immunity to Hospital**

The Kentucky Court of Appeals reversed and remanded March 18 a trial court's finding that a hospital's actions were protected by the Health Care Quality Improvement Act (HCQIA) as a matter of law. The appeals court disagreed with the trial court's finding that the actions at issue were "professional review activities" as opposed to "professional review actions."

Because the appeals court found the physician was subject to a professional review action, it said the trial court must consider whether the hospital met the conditions set forth in the HCQIA to qualify for immunity.

General surgeon Benjamin Reid, Jr., was a member of the medical staff at Jewish Hospital & St. Mary's Healthcare, Inc. for more than 40 years. On February 4, 2013, Reid received a letter from the hospital's surgery quality committee that all of his cases from January 31, 2013 through June 30, 2013, would be subject to a focus review.

According to Reid, during an impromptu meeting on February 27, 2013, he was informed that the Medical Executive Committee (MEC), voted to cancel his surgical and endoscopy privileges, and that he could no longer perform any further surgical procedures unless he was accompanied by an actively practicing and board certified general surgeon or endoscopist.

On August 5, 2013, Reid received a second letter from the MEC informing him that the focus review ended without any finding of quality concerns. Reid was granted a conditional reappointment to the medical staff for six months, which permitted him to practice at the hospital as long as he met certain conditions. But Reid did not exercise his privileges during the six-month period, and his medical staff membership expired on August 26, 2014.
Reid filed a complaint in state court against KentuckyOne and its subsidiaries seeking compensatory and punitive damages for breach of contract, intentional infliction of emotional distress, tortious interference with business and contractual relations, and slander.

KentuckyOne argued that it was entitled to immunity under HCQIA. The trial court agreed and dismissed Reid’s claims.

Looking at whether the hospital's conduct constituted a professional review action or a professional review activity, the appeals court noted the MEC's recommendation effectively prevented Reid from performing surgery at the hospital unless he could find another qualified surgeon willing and able to be present.

“We believe that restriction fits squarely within the HCQIA's definitions of 'adversely affecting' and 'clinical privileges.' As such, the Hospital's conduct constituted a professional review action rather than simply professional review activities as the trial court found,” the appeals court said.

For a professional review body to be afforded immunity under HCQIA, the professional review action must meet the standards set forth in the statute that the action was taken: (1) in the reasonable belief that the action was in the furtherance of quality health care; (2) after a reasonable effort to obtain the facts of the matter; (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

According to the appeals court, Reid alleged in his pleadings, and the hospital did not dispute, that he was never afforded any notice or opportunity for a hearing prior to the restriction on his privileges.

Because it concluded that the hospital's conduct was a professional review activity, the trial court never considered this argument, the appeals court noted. Accordingly, the appeals court reversed and remanded for further proceedings.


Arkansas Supreme Court Dismisses Challenge to State Peer Review Law

The Arkansas Supreme Court dismissed March 17 a group of hospitals' constitutional challenge to the state peer review law, finding no justiciable controversy existed. Plaintiffs are three Arkansas corporations that operate private hospitals in the state. The hospitals sued the Attorney General in his official capacity; the Arkansas Department of Health; and a state official (collectively, defendants), seeking a declaratory judgment that the Arkansas Peer Review Fairness Act (Act) was unconstitutional under the Arkansas and U.S. Constitutions.

The hospitals argued the Act imposes additional requirements beyond the federal Health Care Quality Improvement Act. The trial court upheld the Act, and both parties appealed.

For a declaratory relief action to be appropriate, there must be (1) a justiciable controversy; (2) that exists between parties with adverse interests; (3) those seeking relief have a legal interest in the controversy; and (4) the issues involved are ripe for decision.

Defendants argued on appeal "because there is no present danger or dilemma," no justiciable controversy existed, noting the hospitals' references throughout their brief to hypothetical future events only.
Although the hospitals did not contend they were violating the Act or faced a threat of imminent enforcement, they argued that the Act imposed a present and ongoing injury by creating new standards that they had to comply with during the peer-review process.

Rejecting that argument, the court agreed with defendants that no justiciable controversy was presented for review.

A dissent disagreed, noting “if the Act is constitutional, then [the hospitals] could be subject to liability by failing to comply.”


**U.S. Court in Pennsylvania Upholds Secretary’s Refusal to Remove Data Bank Report**

A federal court in Pennsylvania granted March 31 summary judgment to the Department of Health and Human Services Secretary in a physician’s action challenging the agency’s refusal to remove an adverse action report against him in the National Practitioner Data Bank (NPDB). Plaintiff, an orthopedic surgeon, sued the Secretary and the American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons (AAOS) after it reported to the NPDB the two-year suspension of his membership.

The suspension resulted from an expert report that plaintiff submitted in a medical malpractice action in which he opined that the treating physician should have performed surgery immediately on a patient’s shoulder injury.

The physician who was the subject of the medical malpractice action filed a grievance report with AAOS, alleging violations of its mandatory standards of professionalism.

After conducting an investigation and various proceedings, AAOS determined that plaintiff violated five of its mandatory standards related to professional conduct that could affect patient care. AAOS suspended his membership for two years and reported the suspension to the NPDB.

The Secretary subsequently denied plaintiff’s request to remove the NPDB suspension report, citing the agency’s limited authority to review only whether the action was reportable and whether the report accurately depicted the actions taken.

The U.S. District Court for the Middle District of Pennsylvania granted AAOS’ motion to dismiss the action against it in February. The court now also ruled that plaintiff could not prevail on his claim that the Secretary’s refusal to expunge the NPDB report was arbitrary and capricious in violation of the Administrative Procedure Act.

First, the court noted that the Secretary correctly found AAOS, as a professional society, has a mandatory obligation under the Health Care Quality Improvement Act (HCQIA) to report to the NPDB “professional review actions related to competence or professional conduct that adversely affected a physician’s membership.”

Plaintiff argued the NPDB shouldn’t be used to sanction a physician who testifies against other physicians. According to plaintiff, the expert report that gave rise to his suspension didn’t impact patient medical care, and therefore wasn’t reportable.

Rejecting this argument, the court noted HCQIA “indicates that a physician’s conduct which could affect welfare or health qualifies as a reportable event.” In this case, AAOS found the expert report
showed plaintiff lacked knowledge of the proper standard of care and could cause harm to a future patient. In addition, the mandatory standards AAOS determined he violated involved physician competence, the court noted.

Finally, the court held plaintiff didn't have a viable claim that his free speech rights were violated.

The court pointed out that the First Amendment only applies to state action, not private entities like the AAOS. Moreover, neither AAOS nor the agency took any action that restricted plaintiff's free speech.

The court emphasized that AAOS repeatedly offered plaintiff the opportunity to present his case at every stage of its investigation, but he never responded to any of the group's inquiries.

And ultimately it was plaintiff who invited the Secretary to review the AAOS’ conduct. It was the adverse action report, not the expert report, that triggered any governmental action, the court said.


**U.S. Court in Colorado Says Peer Review Law Makes No Exception for Factual Information in Records**

The U.S. District Court for the District of Colorado granted April 18 a hospital’s motion for a protective order for peer review documents under state law. In so holding, the court rejected the plaintiff’s contention that the law allowed discovery of factual information contained in the peer review material, finding the state law made no such distinction.

Plaintiffs Jody and Delfina Blatchley initiated a personal injury action against defendant St. Anthony Summit Medical Center and others.

As part of discovery, plaintiffs sought “any and all information regarding Plaintiff Jody Blatchley created by or for any professional review, peer review or quality control or management from Defendant [St. Anthony Summit].”

St. Anthony Summit objected to producing the requested information on the basis of multiple privileges, and moved for a protective order under the Colorado Professional Review Act (CPRA).

Plaintiffs did not dispute that St. Anthony Summit's Trauma Executive Peer Review Committee was a professional review committee as defined by CPRA. Plaintiffs argued, however, that the documents at issue contained the factual basis for the peer review, and did not qualify as “records” under the CPRA.

After an in camera inspection, the court affirmed that the documents were peer review records under CPRA.

The court also rejected plaintiffs’ argument that even if the documents were peer review records, any facts they contained, separate from information about the peer review committee's deliberation, were discoverable.

According to the court, “[n]othing within the CPRA or its interpreting case law suggests that (1) a distinction is made between facts and deliberation under the CPRA's shield against subpoenas or discovery, or (2) facts are discoverable from records generated as part of the peer review process.”
The court said its conclusion was consistent with CPRA’s purpose, and from a practical perspective, “the facts considered by the peer review committee appear inextricably intertwined with the investigation by and deliberation of the committee.”

The court did allow, however, some additional discovery, unrelated to the peer review records.


**Maine High Court Says Physicians Immune from Defamation Action**

The Maine Supreme Judicial Court held April 21 that two physicians who gave a negative review of another physician to a credentials verification organization had absolute immunity from his defamation and tortious interference action against them.

The high court found the credentials verification organization was collecting the information for a hospital’s competence review process, and therefore the state’s peer review statute, 24 Me. Rev. Stat. § 2511, conferred absolute immunity to the responsive statements supplied by the two physicians.

Notably, the high court held that the statute did not impose an “acting without malice” requirement as a condition of immunity.

St. Mary’s Regional Medical Center contracted with Synernet, Inc. to collect credentialing information on behalf of the hospital. Synernet began collecting credentialing information on physician Kevin F. Strong after he applied for privileges at St. Mary’s. Synernet sent questionnaires to physicians Rebecca M. Brakeley and Jonathan M. Bausman, who allegedly made negative statements about Strong.

Strong sued defendants Brakeley and Bausman, alleging their negative statements caused St. Mary’s to deny him staff privileges. Strong asserted claims for defamation and tortious interference with his business relationship and sought punitive damages.

The trial court found defendants had absolute immunity under Section 2511 and granted them summary judgment. The Maine high court affirmed.

The high court noted that under the plain language of Section 2011, defendants, as physicians, were eligible for immunity as a matter of law. The high court also held that defendants were “assisting” a “board, authority or committee in carrying” out its duties.

Strong argued that Synernet didn’t qualify as a board, authority, or committee under the statute. But the high court disagreed, noting that Synernet was a “[p]rofessional competence committee” as a contractor that assisted in “performing professional competence review activities.”

The high court also rejected Strong’s attempt to inject an “acting without malice” requirement into the immunity statute. According to the high court, the “acting without malice” requirement did not apply to physicians.


**Eighth Circuit Finds Clinic Properly Fired Physician for Poor Performance**

The Eighth Circuit said May 20 a hospital properly discharged a physician based on his poor performance and concerns about patient safety. In so holding, the appeals court rejected the physician's claims that his effective termination violated state and federal law.
Plaintiff Dr. Alaa Elkharwily, a certified internal medicine physician, worked as a hospitalist at Mayo Clinic Health System–Albert Lea (Mayo) on probationary status as per hospital policy for new employees. An evaluation at the end of his probationary period from the hospital administrator noted many concerns about his performance.

Plaintiff also participated in a professional service program that required reports from his work-site supervisor. The report included many of the same concerns expressed in the administrator's evaluation.

Concerned about patient safety, Mayo placed plaintiff on paid administrative leave pending further investigation. Plaintiff eventually agreed to resign in lieu of termination.

Plaintiff sued Mayo alleging defamation and violations of the Minnesota Vulnerable Adults Act, Emergency Medical Treatment and Labor Act (EMTALA), Minnesota Whistleblower Act, and False Claims Act. The district court granted Mayo’s motion for summary judgment, dismissing plaintiff’s claims with prejudice.

On appeal, plaintiff argued that Mayo improperly terminated his employment in retaliation for his refusal to authorize the transfer of an unstabilized patient, in violation of EMTALA. Affirming the lower court’s grant of summary judgment on this issue, the appeals court noted that plaintiff provided a written statement to the Minnesota Board of Medical Practice that directly contradicted his EMTALA allegation.

The appeals court also agreed with the lower court’s determination that Elkharwily failed to establish pretext for his retaliation claims under the Minnesota Whistleblower Act and EMTALA, or that Mayo's decision to terminate his employment was motivated solely by his reports of False Claims Act violations.

“Rather, Mayo articulated a legitimate, nondiscriminatory reason for terminating Dr. Elkharwily's employment; namely, his poor job performance,” the appeals court found.

*Elkharwily v. Mayo Holding Co.*, No. 15-1492 (8th Cir. May 20, 2016).

**Washington Appeals Court Says Hospital Properly Terminated Physician**

The Washington Court of Appeals affirmed May 23 the dismissal of a physician's claims against the hospital where we formerly worked. The appeals court agreed with the court below that the hospital's actions in terminating the physician for unprofessional conduct and its subsequent report to the National Practitioner Data Bank (NPDB) were proper. Dr. Eric Shibley was employed as a hospitalist by King County Public Hospital District No. 4. He worked at Snoqualmie Valley Hospital (SVH) under an employment agreement.

After another physician complained that Shibley documented a history and physical examination without examining the patient, the hospital conducted an investigation and ultimately terminated him after a hearing.

Shibley signed a severance agreement and release with the hospital that stated that he unconditionally released SVH from any and all claims stemming from his employment or termination. SVH subsequently submitted a report to the NPDB.

Shibley sued SVH and two individual physicians alleging ten state law causes of action. The trial court granted summary judgment to defendants. Defendants moved for attorneys' fees, but the trial court denied that motion.
Shibley appealed the dismissal of his lawsuit, and defendants cross appealed the denial of their motion for attorney fees.

On appeal, Shibley argued that SVH failed to follow the appropriate procedures before it took action against his privileges and defrauded and defamed him through its reports to the NPDB.

The appeals court agreed with the trial court that Shibley could not prevail on his claims, finding the hospital made a reasonable effort to obtain the facts before it acted on Shibley's privileges.

In addition, the report to the NPDB of suspension for unprofessional conduct was accurate and therefore could not be defamatory, the appeals court said. SVH also was entitled to immunity for its reports to the NPDB.

The appeals court further noted that the severance agreement Shibley signed barred his employment, retaliation, and termination-related claims.

The appeals court also agreed with the lower court that defendants were not entitled to attorneys' fees because the lawsuit, although unsuccessful, was not frivolous.

Medicare

D.C. Circuit Says Secretary Must Explain “Per-Click” Ban

A D.C. Circuit panel said the Department of Health and Human Services Secretary didn’t offer a reasonable explanation for a 2008 regulation under the Stark Law that bans physicians from leasing equipment to hospitals on a “per-click” basis when the physicians also refer patients to the hospital for procedures using the equipment. While a majority of the panel agreed with the district court that the statute was ambiguous as to whether “per-click” leases are allowed, a different majority found the Secretary’s explanation for the ban was unreasonable in light of its previous stance regarding the legislative history and remanded to the agency to consider the issue “with more care.”

The appeals court unanimously upheld, however, a new expanded definition in the 2008 regulations of an “entity furnishing designated health services” to include joint ventures that lease equipment and perform outpatient procedures under contract with hospitals.

2009 Challenge

Plaintiff Council for Urological Interests is an association of physician-owned joint ventures formed to purchase specialized equipment for urologic laser surgery. The joint ventures lease laser technology to hospitals on a per-click basis, which the 2008 regulation prohibited, triggering the instant lawsuit, which was filed in March 2009.

The 2008 regulation also provided that an entity that either performs or bills for designated health services is considered to be “furnishing” such services, which means physicians with ownership interests in groups that perform outpatient services in hospitals cannot refer patients for the procedure, the opinion explained.

The lawsuit alleged that the Secretary violated the Administrative Procedure Act in promulgating the 2008 regulation.

The district court granted summary judgment to the government, concluding the regulations were entitled to Chevron deference, *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), and the agency’s interpretation was reasonable. See *Council for Urological Interests v. Sebelius*, 946 F. Supp. 2d 91 (D.D.C. 2013).

Per-Click Ban

In analyzing the first step of Chevron deference, two judges agreed that the Stark Law did not unambiguously preclude the Secretary from banning per-click rates for equipment rentals.

The appeals court majority on this issue pointed to the final clause in the statutory equipment rental exception stating that leases also must “meet[] such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

This “other requirements” language, the appeals court said, allowed wiggle room for the Secretary to ban per-click arrangements. The appeals court also pointed to other statutory provisions indicating that “Congress knew how to permit per-click payments explicitly” when it wanted to.

A different two-judge majority, however, found that the 2008 regulation faltered at the second step of Chevron deference.
The Secretary in previous rulemaking rejected banning per-click arrangements citing a 1993 House Conference Report, which indicated that "charges for space and equipment leases may be based on time-based rates or rates based on units of services furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period."

According to the appeals court, the Secretary’s explanation for changing the agency's stance in the 2008 regulation and treating the Conference Report instead as ambiguous on this issue “borders on the incomprehensible.”

“The Conference Report makes clear that the ‘units of service rates’ are what cannot ‘fluctuate during the contract period,’ not the lessor’s total rental income,” the appeals court observed. “The Secretary’s interpretation reads the word ‘rates’ out of the Conference Report entirely.”

On remand, the Secretary should explain, “with more care than she exercised here—whether a per-click ban on equipment leases is consistent with the 1993 Conference Report.”

One dissenting opinion argued that Congress unambiguously intended to authorize per-click equipment leases and would hold the regulatory ban failed at *Chevron* step one.

A second dissention opinion would uphold the per-click rule based on the reasoning offered by the Secretary on appeal.

**“Provide”/*Furnish” Interchangeable**

Under the 2008 rule, an entity that either performs or bills for designated health services is considered to be “furnishing” such services.

The new definition expands the regulation to apply to joint ventures that lease equipment and perform outpatient procedures under contract with the hospitals, the appeals court explained.

The appeals court panel unanimously found defining the “entity furnishing designated health services” to include the entity providing the services was reasonable and entitled to deference, noting the statute itself uses the terms “provide” and “furnish” interchangeably.

“Moreover, this definition furthers the purpose of the statute by closing a loophole otherwise available to physician-owned entities that would allow circumvention of the purpose of the Stark Law merely by having the hospital bill Medicare for the services.”


**U.S. Court in DC Orders HHS to Hand over Documents, Data in Outlier Payment Dispute**

A federal court in the District of Columbia said the Department of Health and Human Services (HHS) must supplement the administrative record in a dispute brought by a group of nonprofit hospitals challenging the sufficiency of their Medicare outlier payments for fiscal years 2008-2011. Plaintiffs argued the Secretary knew the formulas for calculating outlier payments in those years was faulty, but didn’t act to correct them in violation of the Administrative Procedure Act (APA).

Outlier payments are calculated based on the cost-to-charge ratio, which is the hospital’s average markup based on data in its most recent cost report; the fixed loss threshold, which is the loss a hospital must absorb before it is eligible to receive an outlier payment; and the outlier threshold, which is the point at which charges are eligible for reimbursement as an outlier.
Plaintiff hospitals challenged in particular HHS regulations they say led to incorrect determination of their outlier payment amounts for 2008-2011.

Plaintiffs moved to compel HHS to produce information used to determine the fixed loss threshold, including the draft Interim Final Rule from the 2003 amendments to the payment regulations, various formulas, and other raw data.

HHS initiated rulemaking in 2003 to address so-called “turbocharging” by a small group of hospitals that rapidly inflated charges to obtain greater outlier payments. Although HHS issued a draft interim final rule that would have lowered the 2003 fixed loss threshold, it was never implemented. According to plaintiffs, the failure to lower the fixed loss threshold would have corrected the problems with the faulty regulations, and the Secretary’s failure to do so amounts to an APA violation.

Under D.C. Circuit precedent, supplementation of the administrative record is only allowed in “unusual circumstances”: where the agency deliberately or negligently excluded documents that may have been adverse to its decision; where the additional information is needed to determine whether the agency considered all the relevant factors; and where the agency failed to explain administrative action so as to frustrate judicial review.

Applying this test, the U.S. District Court for the District of Columbia largely granted plaintiffs’ motion, finding the information they sought would be needed to resolve the dispute.

The court agreed with plaintiffs that the Secretary should produce the 2003 draft interim rule, noting it had been filed with the Office of Management and Budget and therefore was part of the public rulemaking process.

Along with the draft rule, HHS also must produce the impact file for the 2003 rulemaking. Impact files are spreadsheets containing data used to estimate Medicare’s hospital inpatient prospective payment system, including the fixed loss threshold.

Likewise, the court ordered HHS to hand over the relevant formulas it used to set the fixed loss thresholds and outlier payments and the instructions HHS followed for “data trims” (i.e. when to exclude certain data points from its analysis).

The court did reject, however, plaintiffs’ request for certain raw data underlying specific calculations.

The court ordered HHS to supplement the record by July 2.


U.S. Court in DC Upholds Denial of System’s $16.4 Million Claim for Bad Debt Reimbursement

The U.S. District Court for the District of Columbia upheld July 7 the denial of Medicare bad debt reimbursement to Community Health Systems, Inc. (CHS) of roughly $16.4 million for fiscal years (FYs) 2004 through 2006. The court found reasonable and long standing the Department of Health and Human Service’s (HHS’) interpretation of the applicable regulation, 42 C.F.R. § 413.89(e), as precluding hospitals from claiming a debt is “worthless” and “uncollectible” if it is referred to an outside collection agency and still pending.

The court also held that this interpretation did not violate the statutory “Medicare Bad Debt Moratorium,” which prevented HHS from making any changes in its bad debt reimbursement policies.
in effect as of August 1, 1987. According to the court, the moratorium was not intended to stop the Secretary from prohibiting bad debt reimbursements, so long as the denials were consistent with the policies that were in place when the moratorium took effect.

In the court’s view, denying reimbursement for a bad debt claim that was referred to an outside collection agency and still active, was consistent with pre-moratorium HHS policies.

**Regulatory Criteria**

For reimbursement of bad debt, which consists of unpaid coinsurance and deductibles from Medicare patients, a hospital must satisfy certain regulatory criteria under Section 413.89(e), including that “reasonable collection efforts were made,” “the debt was actually uncollectible when claimed as worthless,” and “[s]ound business judgment established there was no likelihood of recovery at any time in the future.”

Medicare applies a “presumption of noncollectibility” to bad debts that remain unpaid after more than 120 days from the initial bill.

**Bad Debt Claim**

CHS claimed bad debt reimbursement for a number of its hospitals in FYs 2004, 2005, and 2006 totaling some $16.4 million. The amounts at issue were more than 120 days past due and had been forwarded to outside collection agencies.

Intermediaries disallowed the bad debts because they had been referred to collection agencies and were still pending.

The Provider Reimbursement Review Board (PRRB) affirmed the intermediaries’ denial of the bad debt reimbursement.

CHS sued, claiming the decision was inconsistent with the applicable statutory and regulatory provisions and violated the bad debt moratorium and the Administrative Procedure Act (APA).

**Reasonable Interpretation**

The court held it was reasonable for the PRRB to conclude that if a provider sends a debt to a collection agency, and the debt remains in active collection, the debt is not “worthless” and does not meet the “no likelihood of recovery” criterion within the meaning of Section 413.89(e).

"[T]he agency’s interpretation of the regulation to mean that sending a debt to a collection agency disqualifies that debt from reimbursement so long as the provider persists in that referral, is reasonable and, until all collection efforts have ceased, the debt is not ‘worthless,’” the court reasoned.

The presumption of noncollectibility after 120 days is just that, a presumption, the court said. To hold the presumption is absolute, as CHS urged, would effectively nullify two of the Section 413.89(e) criteria.

**No Violation of Moratorium, APA**

The court also disagreed with CHS that the agency’s interpretation violated the bad debt moratorium.
Instead, the court found “substantial evidence” that the agency’s policy pre-dated the moratorium, citing the regulation itself and related interpretative guidance.

Finally, the court held HHS’ policy was an interpretative rule and therefore not subject to notice-and-comment rulemaking under the APA.


**Third Circuit Strikes Rule Prohibiting Medicare Geographic Reclassification for Certain Hospitals**

The Third Circuit struck down July 23 a Department of Health and Human Services (HHS) rule prohibiting hospitals designated as rural under Section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act from receiving additional recategorization by the Medicare Geographic Classification Review Board (Board) on the basis of that status (Reclassification Rule).

According to the appeals court, the Reclassification Rule is “contrary to the plain and natural reading” of the unambiguous statute.

Hospitals that are disadvantaged by their geographic location may reclassify to a different wage index area for certain Medicare reimbursement purposes by applying for redesignation to the Board. Section 401 creates a separate mechanism by which qualifying hospitals located in urban areas “shall [be] treat[ed] . . . [as] rural” for the same reimbursement purposes.

Geisinger Community Medical Center, a hospital located in an urban area, received rural designation under Section 401 but was unable to obtain further recategorization by the Board pursuant to the Reclassification Rule.

While its applications were pending before the Board, Geisinger filed a complaint in the U.S. District Court for the Middle District of Pennsylvania alleging that the Reclassification Rule violated Section 401 and the Administrative Procedure Act.

The district court upheld the regulation under *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), concluding that the Secretary’s decision to eliminate the potential for “inconsistent reclassifications of the same hospital for the same period” and other “unintended consequences” of the Reclassification Rule was a reasonable accommodation of Section 401.

On appeal, the Third Circuit reversed, finding the statute unambiguous.

Under *Chevron*, the Third Circuit noted, a court must first determine if the intent of Congress in a statute is clear or ambiguous.

Here, Congress unambiguously expressed its intent that the Secretary must treat hospitals with Section 401 status like hospitals physically located in rural areas for purposes of Board recategorization.

Geisinger argued that because Section 401 does not apply to every provision within the subsection, its applicability is ambiguous. But the appeals court rejected that argument, finding it applied to every provision where it was relevant.

“Congress could have granted the Secretary discretion to administer Section 401. It did not,” the appeals court found.
Accordingly, the appeals court said it did not need to move to step two of the Chevron analysis and held the Reclassification Rule unlawful.

A dissent argued that Section 401 is ambiguous and that the Reclassification Rule was a permissible interpretation of the statutory provision.


D.C. Circuit Rejects Hospital’s Challenge to Medicare Wage Index Calculation

The D.C. Circuit upheld August 14 the Department of Health and Human Services (HHS) Secretary’s inclusion of multi-campus hospitals outside of a given geographic area in the plaintiff hospitals’ “wage index” calculation for fiscal years (FYs) 2006 and 2007. Affirming a district court decision, the D.C. Circuit 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 FYs 2006 and 2007, resulting in lower Medicare payments.

The challenge stemmed from the Secretary’s decision in 2005 to adopt new CBSAs to calculate wage indices. The new geographic lines ran through three multi-campus hospital groups, leaving them straddling the border of more than one CBSA.

Citing the logistical challenges and administrative burden of collecting campus-specific data, the Secretary for FYs 2006 and 2007 included 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 the Secretary decided to use the number of full-time employees, or if unavailable, Medicare discharge data, to allocate the hospital’s wage-cost data to individual campuses.

Plaintiffs argued the calculation of their wage index for FYs 2006 and 2007 violated the statute and was arbitrary and capricious.

The U.S. District Court for the District of Columbia granted summary judgment in the Secretary’s favor. Anna Jacques v. Sebelius, No. 13-0053 (D.D.C. Mar. 31, 2014). The court held the statute did not spell out how to construct the wage index. The court also found it reasonable for the Secretary to treat a multi-campus facility as a single hospital where its main Medicare provider was located for purposes of the wage index.


In the appeals court’s view, the statute expressly afforded the Secretary the flexibility and discretion in compiling data and calculating the wage index. The Medicare statute is silent about how to treat unified hospitals with multiple campuses working under a single Medicare provider agreement and number, the appeals court noted.
Plaintiffs also overlooked the fact that for Medicare purposes, a multi-facility hospital is treated as a single “hospital” with a single provider number. Nothing in the statute compelled the Secretary to carve-out separate campuses for calculating the wage index, the appeals court said.

The Secretary’s calculation of the wage indices for 2006 and 2007 was entitled to *Chevron* deference because it went through notice-and-comment rulemaking, the appeals court added.

Under *Chevron*, the Secretary reasonably used unified wage data to calculate the hourly wage in the geographic area of the hospital’s main campus and its administrative site for Medicare reporting purposes instead of campus-specific data.

For example, the appeals court noted, the “Secretary reasonably determined that the effect of [the] extensive operational, organization, and financial integration is that multi-campus hospitals tend to have similar wages across campuses.” In fact, employees routinely migrate between campuses.

The Secretary also properly considered the administrative burden of calculating the wage index on the basis of campus-specific data in the two years at issue when separate wage data wasn’t yet available.

The appeals court also was not persuaded that the Secretary’s 2008 policy change made the initial policy unreasonable. The Secretary is entitled to change an approach as additional information becomes available and tips a previous balanced determination in another direction.

Plaintiffs also 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.

“[N]othing in the Medicare Act requires that hospitals be treated the same for reimbursement and wage-index measurement purposes,” the appeals court said.


**U.S. Court in Maine Says Hospital May Not Challenge CMS Determination Based on Failure to Implement Plan of Correction**

The U.S. District Court for the District of Maine held August 13 a psychiatric hospital failed to demonstrate that the Medicare Act or its implementing regulations afforded a right to challenge at a hearing CMS’ determination that the hospital failed to properly implement its own plan of correction. In a letter dated June 4, 2013, the Centers for Medicare & Medicaid Services (CMS) informed Riverview Psychiatric Center (Riverview) that CMS would terminate Riverview’s Medicare provider agreement effective September 2, 2013 due to “deficiencies . . . of such a serious nature as to substantially limit the psychiatric hospital’s capacity to provide adequate care.” The letter stated Riverview could “take steps to avert termination” by submitting an acceptable plan of correction within ten days.

Riverview did not seek administrative review of CMS’ June 4 decision. Under 42 U.S.C.A. §§ 405(b)(1), 1395cc(h)(1)(A), and 42 C.F.R. § 498.40(a)(2), a provider must request review by an administrative law judge (ALJ) within 60 days of receiving notice of CMS’ decision to terminate its Medicare provider agreement. Riverview instead submitted two plans of correction, which CMS rejected in July 2013. One of CMS’ rejection letters reminded Riverview that failure to provide an acceptable plan of correction would not delay the September 2 termination date.
On August 14, CMS sent another letter stating because Riverview failed to submit acceptable plans of correction, its Medicare provider agreement would terminate September 2. The same letter provided that “if Riverview . . . submits acceptable plans of correction immediately . . . CMS . . . may conduct a revisit survey to determine whether compliance has been achieved.” CMS warned, however, that such determination should not be interpreted as an extension of the September 2 termination date.

CMS accepted Riverview’s third plan of correction in a letter dated August 29, 2013. CMS conducted a survey of Riverview on September 17 and found Riverview failed to properly implement its plan of correction. In a letter dated September 27, CMS notified Riverview that it “was involuntarily terminated effective September 2” and that CMS would “not re-open and revise its initial determination to terminate [Riverview’s] provider agreement.”

Riverview filed an administrative appeal on October 11, 2013, which the ALJ dismissed, finding that Riverview had “no right to a hearing to challenge the declination by [CMS] to reopen its determination to terminate [Riverview’s] participation in the Medicare program” because Riverview failed to timely challenge the June 4 termination decision and therefore waived its appeal rights.

On August 4, 2014, the Departmental Appeals Board (DAB) upheld the dismissal, concluding the ALJ “correctly concluded that CMS’s September 27, 2013 decision not to reopen or revise its initial determination was not an initial determination and, therefore, conveyed no appeals rights.”

The Maine Department of Health and Human Services (Maine DHHS) sued on October 3, 2014 seeking review of CMS’ September 27 determination. The federal government asserted the court lacked jurisdiction to hear Riverview and Maine DHHS’ (collectively, plaintiffs’) claims and asked for dismissal pursuant Fed. R. Civ. P. 12(b)(1).

Plaintiffs argued the Medicare Act and the Administrative Procedure Act (APA) provided the court with jurisdiction. The court disagreed, and upheld the ALJ’s dismissal for lack of subject matter jurisdiction.

The court rejected plaintiffs’ assertion that CMS’ September 27 determination was a new and therefore “initial determination,” entitling plaintiffs to administrative and judicial review. According to the district court, neither the Medicare Act nor its implementing regulations support a right to challenge a decision that a plan of correction was not properly implemented.

Further, the district court pointed out that CMS made clear that its decision to terminate Riverview’s provider agreement effective September 2, 2013 was made on June 4, 2013. Plaintiffs’ effort to re-characterize CMS’ September 27 determination as an independent termination that revived plaintiffs’ right to judicial review “stretched[d] the facts of this case.”

The court also rejected plaintiffs’ argument that CMS’ eventual acceptance of Riverview’s plan of correction on August 29 constituted a “rescission” of the June 4 termination notice, making the CMS’ letter of September 27 a new and reviewable determination. Citing 42 C.F.R. §§ 498.22, 498.32, the court stated that the regulations provided for revision or reconsideration of decisions to terminate provider agreements, but not rescissions of such decisions.

Finally, the court concluded that the APA did not provide subject matter jurisdiction over plaintiffs’ claims because Section 405(h) of the Social Security Act, incorporated into the Medicare Act under 42 U.S.C.A. § 1395ii (2015), makes judicial review procedures under the Medicare Act “the exclusive mechanism for litigating claims that arise under the Medicare Act,’ thereby foreclosing APA review.

U.S. Court in Washington Uphold Secretary's Exclusion of Certain Patients from Hospitals' DSH Reimbursement

The U.S. District Court for the Western District of Washington upheld September 1 the Department of Health and Human Services Secretary’s decision not to include certain patients in the plaintiff hospitals’ Medicare disproportionate share hospital (DSH) reimbursement. The court relied on Ninth Circuit precedent finding that although the patients at issue are mentioned in Washington’s Medicaid plan, they are not eligible for medical assistance under that plan.

The state of Washington extends hospital care to two groups: the General Assistance-Unemployable (GAU) and the Medically Indigent (MI). These groups are needy, but are ineligible for traditional Medicaid because they are not aged, blind or disabled, and they do not have dependent children.

In a previous case, University of Washington Medical Center v. Sebelius, 634 F.3d 1029 (9th Cir. 2011) (UW-I), plaintiff hospitals from Washington state sought to include their GAU and MI patients in their Medicare DSH reimbursement calculations, but the Ninth Circuit upheld the Secretary’s decision to exclude such patients.

Seventeen plaintiffs from UW-I sought to distinguish or overturn that case, but the district court granted summary judgment to the Secretary finding UW-I was binding Ninth Circuit precedent and resolved the issues presented in the instant case.

In 2000, the Secretary expanded DSH reimbursement to experimental or "demonstration projects," in which the Secretary waives compliance with the general federal requirements for Medicaid state plans.

Section 1115 of the Social Security Act authorizes the Secretary to approve such projects to encourage states to adopt innovative programs that are likely to assist in promoting the objectives of Medicaid and other social programs. Thus, the Medicaid numerator clearly includes those who are "eligible for Medicaid" and those who are "regarded" as eligible because they are treated under an approved Section 1115 demonstration project, the court said.

Plaintiff hospitals argued that the numerator also should include patient days for those who are not in one of these categories, but who are in every other respect functionally identical to those treated under a Section 1115 demonstration project.


“Neither Congress nor the Secretary has approved a third method for hospitals to tap into the DSH funds for additional reimbursements” and nowhere “has Congress or the DHHS delegated to the States the authority to unilaterally change or expand the eligibility requirements prescribed for DSH Adjustments,” the court said.

Plaintiffs next argued that the Secretary's interpretation of the Medicare DSH statute to include Section 1115 patient days, while excluding MI and GAU patient days, is arbitrary and capricious and violates the plaintiffs' rights under the Equal Protection Clause of the U.S. Constitution.
But the court rejected this argument as well, finding the Secretary provided a rational basis for the decision to exclude "state only" programs like MI and GAU programs, while including Section 1115 projects.


**U.S. Court in Mississippi Says Inpatient Day Limit Properly Applied to New Medicare Hospice**

A federal court in Mississippi said neither the Medicare statute nor implementing regulations exempted a hospice that had been participating in the program for less than a year from the 20% limit on inpatient days. Congress has imposed a cap on hospice provider’s overall Medicare reimbursement for each fiscal year, as well as an inpatient day limitation.

Under implementing regulations, “the total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days not exceed 20% of the total days for which these patients had elected hospice care.” 42 C.F.R. § 418.302(f)(1). The regulation further provides that the limitation on payment for inpatient care be calculated “[a]t the end of the cap period,” which is defined as the 12-month period ending October 31.

Canon Hospice became a Medicare participating provider on January 3, 2007. Canon’s intermediary determined the hospice exceeded the limit on inpatient days for the period January 3, 2007 through October 31, 2008 and therefore had to reimburse Medicare $344,363.

The Provider Reimbursement Review Board (PRRB) found the intermediary should have calculated the inpatient day limitation separately at the end of the cap periods on October 31, 2008 and October 31, 2007, although the overpayment amount remained the same. The Centers for Medicare & Medicaid Services Administrator declined review.

Canon appealed, arguing that the PRRB was wrong to conclude that an inpatient day limitation should be calculated for the cap period ending October 31, 2007, because the hospice had not been in operation for an entire 12-month cap period.

Granting summary judgment to the Department of Health and Human Services Secretary, the U.S. District Court for the Southern District of Mississippi noted the Medicare statute, implementing regulations, and other guidance didn’t require a hospice to be in operation for the entire cap period before applying the inpatient day limitation, as Canon contended.

According to the court, the regulations and statute left no room for an exception for newly created hospices. And the Secretary wasn’t requiring Canon to satisfy the requirement during months it wasn’t in operation, since there was no “inpatient care” during that time.

“Medicare is simply requiring Canon to satisfy the statute’s twenty percent inpatient day limitation during the time that it actually cared for patients participating in the Medicare program,” the court reasoned.


**U.S. Court in California Refuses to Grant Stay Pending Appeal in Long-Running Part D Payment Dispute**
The U.S. District Court for the Northern District of California denied September 11 a federally qualified health center’s motion for a stay pending appeal in its long-running dispute with the California Department of Health Care Services (DHCS) over Medicare Part D payments. The court found plaintiff unlikely to succeed on the merits of its claims. Plaintiff La Clinica De La Raza, Inc. provides medical services to the poor, uninsured, or otherwise medically underserved individuals.

When Medicare Part D was enacted in 2006, Congress shifted the responsibility for payment of dual eligibles’ prescription drug costs from state Medicaid programs to Part D. Plaintiff argued DHCS mishandled the shift in payment responsibility.

Plaintiff, along with North East Medical Services, Inc., sued for declaratory and injunctive relief, alleging California’s “seizure” of their Medicare Part D funds, in excess of what would be owed under the per-visit rate for their expenses, was unlawful. Plaintiffs also sought reimbursement for all amounts previously paid to California under Medicare Part D, interest, and attorney’s fees.

A Ninth Circuit panel affirmed in part a lower court’s finding that the Eleventh Amendment barred providers’ claims for reimbursement.

The panel held that where the clinics already paid money to California, they could not avoid the Eleventh Amendment’s general bar to seeking money damages from a state. The panel reversed, however, the dismissal of claims alleging prospective relief and remanded to allow the district court to assess whether the clinics could proceed with those claims.

On remand, both parties moved for summary judgment.

The court held under the doctrine of Ex parte Young, 209 U.S. 123 (1908), the Eleventh Amendment generally does not bar suits for prospective, non-monetary relief against state officers; however, Ex Parte Young did not apply to plaintiff North East’s claim because it was seeking retrospective monetary relief. Accordingly, the Eleventh Amendment barred those claims.

The court found the Eleventh Amendment didn’t bar plaintiff’s claim because it was not seeking compensation for services already rendered. The court did determine, however, that plaintiff’s claim was moot.

Plaintiff moved for leave to file a motion for reconsideration, which the court denied and entered judgment. Plaintiff then filed its notice of appeal to the Ninth Circuit. The appeal is still pending.

DHCS subsequently contacted plaintiff to request a reporting of plaintiff’s Part D revenues for dual-eligible patients from fiscal year 2011. DHCS sent a written notice that it would begin the reconciliation process to determine whether plaintiff had been under or overpaid for fiscal year 2011.

Plaintiff requested that DHCS delay the reconciliations because the payments were the subject of litigation on appeal before the Ninth Circuit, but DHCS indicated it would move forward with the reconciliation process.

Plaintiff then filed the instant motion seeking an injunction against “all actions by [Defendants] with respect to [Plaintiff’s] pending reconciliation requests” until resolution of its appeal.

The court found no reason to grant a stay, holding that plaintiff was unlikely to succeed on the merits of its claim and had not made a strong showing that it would suffer irreparable harm absent an injunction.
Plaintiff argued that if it must pay the settlement amount for the reconciliation request, it would have no adequate legal remedy in federal court because its claims would then be characterized as seeking retrospective monetary damages and would be barred by the Eleventh Amendment.

But the court said that even if plaintiff did have to pay the settlement amount, “it will merely lose the federal forum for that claim, but it will still have the option to file an administrative appeal and to seek a writ of administrative mandate in state court if it loses its administrative appeal.”

The court also found the balance of harms weighed in favor of defendants and that the public interest would not be served in granting the injunction.


U.S. Court in DC Partially Rules for Hospital in DSH Challenge

The Department of Health and Human Services Secretary’s decision to deduct observation bed days from a hospital's licensed inpatient beds for its 2003 cost year conflicted with the plan language of the governing regulation at that time, a federal court in the District of Columbia ruled September 16. Plaintiff hospital therefore properly included inpatient beds used for observations services but otherwise available for inpatient use on its 2003 cost report for purposes of determining its disproportionate share hospital (DSH) adjustment.

The U.S. District Court for the District of Columbia also found, however, that the Secretary’s subsequent promulgation of amended regulations that specifically excluded inpatient bed days used for observation services in the “bed count” foreclosed plaintiff’s challenge to its DSH payments in cost years 2004 and 2006.

Plaintiff Health Alliance Hospitals, Inc., a nonprofit urban hospital in Massachusetts, filed two lawsuits challenging its DSH adjustments in cost years 2003, 2004, and 2006, alleging the Secretary’s deduction of days that its 103 licensed inpatient beds were used to treat observation patients from its “bed count” was arbitrary, capricious, and otherwise contrary to the law.

An urban hospital’s DSH payment is capped if the hospital has fewer than 100 beds, but not if it exceeds this threshold, the court explained. The DSH statute does not define “beds” for purposes of the adjustment.

Under the DSH regulation promulgated in 1986, and applicable to the 2003 cost year, the number of hospital beds was determined “by counting the number of available bed days during the cost reporting period, not including beds assigned to newborns, custodial care, and excluded distinct part hospital units . . . “

In 2003 and 2004, the Secretary amended the regulation to provide that the count of available beds excludes bed days used for observation services, except to the extent the patient was subsequently admitted as an inpatient. The Secretary characterized the amendment as a “clarification” of long-standing policy.

For the three cost years at issue, the Secretary deducted the number of observation bed days from plaintiff’s “bed count,” reducing its available bed days below the 100 threshold and thereby lowering its DSH reimbursement.

The court found the Secretary’s interpretation of the regulation for the 2003 cost year violated the plain language of the bed count regulation as it stood at that time.
The court noted that the pre-amended regulation specifically listed certain types of beds that were excluded from “available bed days” and observation beds were not among them.

The regulation, as well as related guidance, “makes clear that the location of a bed and not individual day-to-day bed use governs whether a bed is included or excluded from the bed count.”

But the court reached a different result for the 2004 and 2006 cost years, which were after the Secretary amended the regulation to specifically exclude bed days used for observation, unless the patient was ultimately admitted as an inpatient.

Although the change in policy was couched as a “clarification,” the court found the Secretary adequately explained the reasons for the policy she sought to clarify through rulemaking.

The court said it was reasonable to exclude observational services from “available beds” even though other categories of non-inpatient days aren’t excluded. The critical distinction, according to the court, was that observation services are compensable under Medicare Part B, not Part A, whereas the categories highlighted by plaintiff were non-compensable activities ancillary to patient care.

The court upheld the Secretary’s DSH determinations for the hospital’s 2004 and 2006 cost years.


**U.S. Court in Kentucky Rejects Hospital’s Bid for $2.7 Million in DSH Payments**

A federal district court in Kentucky upheld September 15 the exclusion from a hospital’s Medicare disproportionate share hospital (DSH) adjustment of patient days for individuals covered by the Kentucky Hospital Care Program (KHCP), which enrolls low-income state residents who are ineligible for traditional Medicaid. Plaintiff Owensboro Health, Inc. argued that if this population were counted in the calculation, it would have received an additional $2.7 million Medicare DSH adjustment in fiscal years 2003 to 2005.

According to Owensboro, the Department of Health and Human Services Secretary should have included KHCP patients in the numerator of the Medicaid fraction used to set its Medicare DSH reimbursement for those years.

The state includes KHCP patients, along with traditional Medicaid patients, in determining the Medicaid DSH payment.

KHCP patients are low-income state residents who are otherwise ineligible for Medicaid. They are not, however, a federally approved expansion population under Section 1115.

After unsuccessfully appealing the exclusion of its KHCP patient days through administrative review, plaintiff hospital sued in court, arguing the Secretary violated the Administrative Procedure Act and Equal Protection under the Fourteenth Amendment.

The court found the Medicare Statute didn’t allow non-Medicaid patient days to be counted for Medicare DSH purposes.

Plaintiff argued that KHCP, though not traditional Medicaid, was approved by the Secretary as part of Kentucky’s Medicaid state plan.
But the court disagreed, noting while Kentucky included the program in its state plan for purposes of the Medicaid DSH adjustment, that didn’t mean the Secretary approved KHCP for purposes of the Medicare DSH adjustment.

The court held the Secretary correctly found KHCP patients were not eligible for medical assistance under Kentucky’s Medicaid plan and properly excluded them from plaintiff’s Medicare DSH adjustment.

The court also rejected plaintiff’s argument that excluding KHCP patients from the Medicare DSH adjustment while including expansion populations approved under a Section 1115 waiver violated equal protection.

The court found a rational basis for distinguishing between KHCP patients and Section 1115 waiver patients—namely, “the programs have different purposes and the federal government has control over only Section 1115 projects.”


Hospitals Score Partial Victory in Challenge to Two-Midnight Rule Offset

The Department of Health and Human Services (HHS) Secretary had authority to promulgate an across-the-board rate cut for Medicare inpatient payments as part of the agency’s new “two-midnight” policy, but her failure to explain the methodology for calculating the 0.2% reduction amounted to a serious procedural error that wasn’t harmless, a federal district court ruled September 21. The U.S. District Court for the District of Columbia found the fiscal year (FY) 2014 inpatient prospective payment system (IPPS) proposed rule didn’t describe the methodology agency actuaries used in arriving at the reduction rate, which deprived plaintiff hospitals and other stakeholders of a meaningful opportunity to comment before the rule was finalized, in violation of the Administrative Procedure Act (APA).

But citing the potential for “serious disruptions,” the U.S. District Court for the District of Columbia declined to vacate the rule and instead ordered the Secretary to submit, by October 1, a timetable for re-promulgating the proposed rule and considering stakeholder comments.

Invalid Offset

The challenge stems from the two-midnight policy, which the agency included in the FY 2014 IPPS final rule. Under the policy, where a physician admits a patient with the assumption the stay will span at least two midnights, the admission will presumptively qualify as appropriate for payment under Medicare Part A. Conversely, admissions spanning less than that time period presumptively should have been provided on an outpatient basis under Medicare Part B.

HHS estimated the new policy would shift a net 40,000 hospital encounters from outpatient to inpatient, costing Medicare some $220 million. HHS used this estimate to implement an across-the-board 0.2% rate reduction for inpatient services as an offset.

Plaintiff hospitals argued, among other things, that the agency failed to explain its calculations or include its actuarial estimates in the proposed IPPS rule to justify the offset and to allow them a meaningful opportunity to comment.

According to plaintiffs, the agency grossly underestimated the volume of encounters that would shift from inpatient to outpatient status under the two-midnight rule and overestimated the number of cases that would shift from outpatient to inpatient.
Statutory Authority

The court at the outset rejected plaintiffs’ argument that the Secretary exceeded her general “exceptions and adjustments” authority under the Medicare Act in promulgating the rate reduction. See 42 U.S.C. § 1395ww(d)(5)(I)(i).

Plaintiffs pointed out that other provisions in Section 1395ww(d)(5) only authorized the Secretary to adjust reimbursement rates in certain, limited circumstances.

But citing D.C. Circuit precedent, Adirondack Med. Ctr. v. Sebelius, 740 F.3d 692 (D.C. Cir. 2014), the district court said Section 1395ww(d)(5)(I)(i) provides a “broad-spectrum grant of authority” that doesn't unambiguously foreclose an across-the-board rate reduction.

The court also found the Secretary’s interpretation was reasonable, even if she previously declined to rely on her “exceptions and adjustments” authority in other instances where she may have invoked it.

Faulty Notice

Plaintiffs did succeed, however, on their argument that the Secretary violated the APA by not providing, in the IPPS proposed rule, sufficient notice of the actuarial assumptions and methodology used to determine the 0.2% reduction.

In the final rule, according to the opinion, the Secretary disclosed that actuaries examined only “outpatient claims for observation or a major procedure” in estimating the number of “encounters” that would shift from outpatient to inpatient status, and only claims for surgical, not medical, procedures in estimating the likely shift from inpatient to outpatient status.

Plaintiffs argued that both of these assumptions were flawed and resulted in an inaccurate estimate of the net shift in outpatient to inpatient encounters.

Siding with plaintiffs, the court said the Secretary’s failure to disclose the critical assumptions until the final rule was issued deprived the public of a meaningful opportunity to comment on the proposed 0.2% reduction.

The Secretary argued that the Medicare claims data was publicly available and the exclusion of the medical cases was “self-evident,” but the court disagreed. The problem, the court said, was that the Secretary failed to disclose the methodology the HHS actuaries used, which was something the public would have no way of knowing based on publicly available information.

“Until the actuarial assumptions were disclosed . . . the Secretary’s thought process was a black box, even then, her analysis was not fully explained,” the court observed.

The court also found the failure to disclose this information wasn’t harmless error. “The assumptions the HHS actuaries applied substantially curtailed the universe of hospital stays the Secretary considered and likely affected the outcome of the Secretary’s analysis. The validity of those assumptions, moreover, is far from self-evident.”

The court refused to vacate the rule, however, and instead remanded to the agency to address the procedural error.
“Although the deficiencies in the rule are serious, the Court is not convinced that they are so grave that the Secretary should be precluded from taking corrective steps with respect to the 2014 inpatient prospective payment system,” the opinion said.

The court added it would consider vacatur of the rule in the future if the Secretary failed to comply with the timetable to re-promulgate the proposed rule and to meaningfully consider stakeholder comments.


**U.S. Court in Pennsylvania Tosses FCA Action Against PBM Alleging Medicare Part D Fraud**

A federal trial court in Pennsylvania granted September 22 summary judgment to pharmacy CVS Caremark in a qui tam action under the False Claims Act (FCA) alleging the pharmacy benefits manager (PBM) defrauded Medicare Part D.

The case was filed by whistleblower Anthony Spay, a former pharmacist whose company was hired to audit the Part D claims processed by CVS Caremark on behalf of Medical Card System (MCS), a Puerto Rican health insurance company. The audit report documented six areas where defendant allegedly illegally adjudicated, paid, and submitted to the Centers for Medicare & Medicaid Services (CMS) claims for Medicare Part D drugs.

Spay initiated an FCA action alleging CVS Caremark and related entities engaged in a nationwide scheme to defraud the Part D program through the submission of false prescription drug event (PDE) data to CMS, which caused CMS to make payments under the Part D program.

Specifically, Spay asserted that CVS Caremark used dummy identification numbers (IDs) on PDE records; failed to perform concurrent drug utilization review (DUR) for gender-related contraindications; approved claims for expired drugs; intentionally and fraudulently failed to provide MCS the benefit of maximum allowable cost pricing; improperly submitted claims for drugs that required prior authorizations; and “fraudulently processed” pharmacy claims involving “drugs or days supply” over quantity limits.


But in its latest decision, the court agreed to grant summary judgment to CVS Caremark on all plaintiffs' theories of liability under the FCA. As to the dummy prescriber IDs, the court held CVS Caremark sufficiently established the “government knowledge inference” to defeat a finding of scienter.

According to the court, “the unequivocal evidence in this case shows that CMS knew that PBMs were having trouble complying with the need to use a unique physician identifier, recognized that many PBMs were using dummy identifiers . . . , and condoned—albeit with some reluctance—the use of such dummy identifiers in keeping with its policy of ensuring access to prescriptions for its beneficiaries during the[] early stages of the Medicare Part D program.”

As to the gender DUR allegations, the court found no evidence that CVS Caremark violated any federal rule.
The court made a similar ruling as to the allegations that CVS Caremark knowingly approved claims for expired drugs. “The evidence of record clearly establishes that screening for expired drugs was not part of a Part D Sponsor or PBM’s role.”

Finally, on the MAC pricing, prior authorization, and quantity limits, the court held Spay failed to show either CVS Caremark had the requisite scienter or provided worthless services to support a valid FCA claim.


**U.S. Court in DC Gives Hospital Provider Another Crack at Medicare Bad Debt Reimbursement**

A federal trial court in the District of Columbia told the Provider Reimbursement Review Board (Board) to take another look at a hospital provider’s claim for Medicare bad debt reimbursement. The Board found the hospital wasn’t entitled to Medicare reimbursement of the unpaid deductibles and copayments at issue because it failed show “reasonable collection efforts” before declaring the debt uncollectible.

Specifically, the Board pointed to the fact that the hospital didn’t treat Medicare and non-Medicare the same in that it didn’t refer the former to a secondary collection agency as it did the latter.

But the U.S. District Court for the District of Columbia said the inflexible application of Section 310 of the Provider Reimbursement Manual, which specifies that to qualify as a “reasonable collection effort, a provider’s effort must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients,” was at odds with administrative decisions that pre-dated the so-called “bad debt moratorium” that Congress put in place in 1987.

The court refused to rule on the record evidence, however, whether the hospital sufficiently showed that the referral of its Medicare accounts for external collection wouldn’t have been cost effective. Instead, the court remanded to the Board to determine whether the providers engaged in “reasonable collection efforts.”

Plaintiff Mountain States Health Alliance operates two acute care facilities in Tennessee. During the two years at issue, 2004 and 2005, plaintiff’s hospitals treated the accounts of Medicare and non-Medicare plaintiffs similarly for one year—six months of in-house collection efforts followed by referrals to a primary collection agency for another six months.

At that point, however, plaintiff hospitals diverged in their treatment of Medicare and non-Medicare accounts—sending only the non-Medicare accounts to a secondary collection agency and writing off all the Medicare accounts as bad debts.

Citing the disparate treatment of the Medicare and non-Medicare accounts, providers’ fiscal intermediary disallowed roughly $700,000 in Medicare bad debts for the cost reporting years ending on June 30, 2004 and 2005.

Before the Board, the providers argued their collection efforts were “similar” under Section 310 and that applying a categorical and inflexible rule violated the moratorium enacted by Congress in 1987, which prohibited the Department of Health and Human Services Secretary from changing bad debt policies in place as of that time.

The Board agreed, however, with the fiscal intermediary’s denial of reimbursement, finding plaintiff’s hospitals failed to satisfy the “reasonable collection efforts” requirement.
Although rejecting plaintiff’s argument that Section 310 was an invalid legislative rule that did not satisfy notice and comment rulemaking requirements under the Administrative Procedure Act, the court went on to find that the bad debt moratorium precluded the Board from giving the collection agency requirement in PRM Section 310 the strict construction that it applied.

Specifically, the court noted pre-moratorium administrative precedent where providers referred non-Medicare bad debt to collection, but not Medicare bad debt. The providers in those cases successfully argued on appeal that their claims should have been allowed because the prospect of recovering on the Medicare accounts was negligible, a similar argument that plaintiff made in the instant action.

“The Board did not cite, and the administrative record does not contain, any pre-Moratorium decision or guidance that applies section 310’s referral requirement as a hard and fast rule,” the court observed.

The court concluded that “the inflexible interpretation of section 310 endorsed by the Secretary and applied by the Board represents an impermissible change from the more flexible pre-Moratorium policy reflected” in two Board decisions.

The court wouldn’t decide, however, whether plaintiff hospitals had demonstrated that their collection efforts were reasonable under the circumstances. The court said that determination would be left to the Board on remand.


**Fourth Circuit Won't Review SNF's Challenge to “Per Instance” CMP**

The Fourth Circuit dismissed October 13 a skilled nursing facility’s (SNF’s) petition seeking review of a per instance civil monetary penalty (CMP) imposed against it for an immediate jeopardy determination of noncompliance with Medicare rules.

In an unpublished opinion, the appeals court said it lacked jurisdiction to review the Department of Health and Human Service Secretary’s imposition of a per instance CMP because the level of noncompliance—in this case, immediate jeopardy—wasn’t relevant to determining the range of appropriate penalties.

NMS Healthcare of Hagerstown (NMS), a SNF, sought the appeals court’s review of the Secretary’s final decision imposing a per instance CMP against it for an immediate jeopardy deficiency. While a facility generally may appeal a finding of noncompliance, it may not appeal the level of noncompliance unless it affects the range of CMP amounts that could be imposed, the appeals court noted.

The range of penalties is higher for immediate jeopardy deficiencies—$3,050 to $10,000 per day—than for deficiencies that have the potential for more than minimal harm—$50 to $3,000 per day.

But, in the case of a single instance of noncompliance, penalties range from $1,000 to $10,000 per instance regardless of the existence of immediate jeopardy, the appeals court explained.

Because the CMPs imposed against NMS were per instance, rather than per diem, the appeals court lacked jurisdiction to review the finding of immediate jeopardy, which played no role in determining the range of CMPs levied in the case.

NMS also asserted that the appeals court had jurisdiction “because the immediate jeopardy determination is a separate agency action with harmful consequences that fall within the Administrative Procedure Act.”
Such a challenge, the Fourth Circuit said, would belong before the district court under its federal question jurisdiction, not before a court of appeals where no direct-review statute specifically conferred jurisdiction.


**U.S. Court in DC Allows Challenge to DSH Rule to Proceed**

The U.S. District Court for the District of Columbia refused October 29 to dismiss a lawsuit challenging certain disproportionate share hospital (DSH) payments that plaintiff hospitals claimed were based on a previously vacated final rule. The Provider Reimbursement Review Board (PRRB) granted the hospitals expedited judicial review, finding it was "without authority to decide" plaintiffs’ challenge to the 2012 DSH calculations at issue.

The court held the PRRB correctly determined it lacked the necessary authority to determine the legality of the DSH calculations because plaintiffs alleged the Department of Health and Human Services Secretary unlawfully continued to apply a 2004 DSH rule that the D.C. Circuit vacated in April 2014.

Plaintiffs also alleged, in the alternative, that the 2012 DSH calculations, even if they didn’t involve the application of the vacated 2004 final rule, violated the notice and comment requirements of the Medicare Act and the Administrative Procedure Act (APA).

“Plaintiffs correctly contend that the PRRB lacked the authority to decide this second issue, and Defendant has offered no argument in opposition,” the court said.

In April 2014, the D.C. Circuit upheld 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 fraction of the DSH calculation.

The appeals court agreed with the lower court’s 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 APA. _Allina Health Servs. v. Sebelius_, Nos. 13-5011, 13-5015 (D.C. Cir. Apr. 1, 2014).

The appeals court also found, however, that the district court erred in directing the Secretary to calculate the DSH payments in a particular way instead of simply remanding. Following the D.C. Circuit’s decision, the Secretary published in June 2014 new calculations for the 2012 fiscal year, which plaintiffs contended were improperly based on the vacated 2004 final rule.

The Secretary also sought voluntarily remand to the PRRB, but the court declined. The Secretary in seeking remand was arguing the PRRB improperly granted expedited judicial review, which the court already determined was not the case.

“To be clear, the Secretary is not conceding that the vacated 2004 Final Rule was mistakenly applied in the 2012 DSH Calculations, nor is she seeking to cure any alleged errors in the 2012 DSH Calculations,” the court said.

By statute, the PRRB’s expedited judicial review determination is “not subject to review by the Secretary,” so remanding for that purpose would circumvent that provision, the court observed.
Moreover, the PRRB lacked authority over the alternate basis for plaintiffs’ challenge—that the 2012 calculations violated the APA—making remand inappropriate.


**U.S. Court in California Refuses to Order Secretary to Provide Timely ALJ Hearing for Medicare Claims Appeal**

The U.S. District Court for the Central District of California granted the government’s motion to dismiss claims related to its failure to provide a hospital with an Administrative Law Judge (ALJ)-level hearing within 90 days of the filing of a Medicare claims appeal. Plaintiff Casa Colina Hospital and Centers for Healthcare filed a mandamus claim asking the court to order the Department of Health and Human Services (HHS) Secretary to provide an ALJ hearing.

HHS is required under the Medicare Act to provide an ALJ decision within 90 days of the filing of a claims appeal. However, as the result of an extremely long, Medicare-wide systemic delay in processing appeals at the ALJ level, hearings have not taken place in a timely manner.

Nevertheless, the court said it would deny relief as it “fails to see how mandamus would address the problem in any constructive way.”

“There is no question that the delay in question is systemic,” the court noted. “It is also clear from the record that both HHS and Congress are aware of the problem and the possible solutions.”

According to the court, granting mandamus “would merely allow Casa Colina to jump the queue of other identically situated parties. Not only would this be arbitrary and unjust, it would encourage a barrage of mandamus actions by others seeking to also jump to the front of the line.”

“This would both greatly burden the courts and would ultimately be self-defeating—not everyone can jump to the front of the line at the same time,” the court said.

The court also refused to waive the administrative exhaustion requirement, finding that although Casa Colina had been economically harmed in the past, it failed to allege irreparable, future harm as economic damages would make it whole.

The court rejected plaintiff’s Administrative Procedure Act (APA) claims as well, noting the APA provides federal question jurisdiction only where no other remedy is available, but here “multiple avenues for judicial review of Casa Colina's Medicare claims” exists, the court said.

Lastly, the court rejected plaintiff’s due process claim, finding a timely hearing is not a property or liberty interest.


**U.S. Court in DC Rejects Home Health Group’s Challenge to Medicare Face-to-Face Documentation Rule**

The U.S. District Court in the District of Columbia rejected November 3 a lawsuit brought by the National Association for Home Care & Hospice (NAHC) challenging a Centers for Medicare & Medicaid Services (CMS) rule requiring a “physician narrative” to document a face-to-face encounter that determines a patient’s homebound status for purposes of home health care services.
According to the lawsuit, filed in June 2014, the Affordable Care Act (ACA) did not authorize the narrative requirement but instead only sought documentation of the encounter itself, not an explanation of why the clinical findings supported a determination that the patient was homebound.

The court found, however, that Congress did not unambiguously foreclose the narrative requirement, and CMS' interpretation cleared deferential review under *Chevron* as rationally related to the goals of the statute—i.e., to curb fraud, waste, and abuse.

NAHC said the lawsuit was necessary because of a “dramatic upsurge in the retroactive denials of patient claims for payment under Medicare” as a result of the narrative rule. The court in January dismissed some aspects of NAHC’s challenge, but allowed the group to proceed on its claim that CMS lacked statutory authority to promulgate the narrative requirement. *National Ass’n for Home Care & Hospice, Inc. v. Burwell*, No. 1:14-cv-00950 (CRC) (D.D.C. Jan. 6, 2015).

On summary judgment, however, the court sided with the government, finding while the rule wasn't the most natural reading of the term “document,” as used in the ACA, the narrative requirement was a reasonable interpretation that wasn’t contrary to the statute.

In November 2014, CMS shelved the narrative requirement effective January 1 “to simplify the face-to-face regulations,” but the agency simultaneously reaffirmed that its prior rule was valid.

NAHC decided to proceed with the lawsuit because CMS did not make the rescission of the narrative requirement retroactive—thus, Medicare claims denied between 2011 and 2014 based on an insufficient narrative would not be reopened and paid.

The fact that CMS eventually reversed course on the narrative requirement didn’t change the outcome in this case, the court said, because the agency “reasonably explained” why it decided to require a narrative in the first place.

Although the rule may have led to more claims denials in practice, it didn’t allow, in the court’s view, Medicare to second-guess a physician’s medical judgment. Had that been the case, the court’s analysis would have been different, the opinion said.

“[H]ome-care organizations that have been denied reimbursement on the basis of insufficient documentation are free to contest HHS’s implementation of its rule on a case-by-case basis,” the court observed.


**U.S. Court in California Says Medicare Advantage Organization Must Pay for Out-of-Network Emergency Care**

A Medicare Advantage Organization (MAO) is financially obligated to pay for an enrollee’s emergency care at an out-of-network hospital until the treating physician determines the enrollee is stable for transfer, a federal district court in California ruled November 30. The U.S. District Court for the Northern District of California sided with the Department of Health and Human Service Secretary in finding that an MAO can’t second-guess a physician’s medical judgment in determining whether a patient is stable for transfer. Rather, the treating physician’s determination that a patient isn’t stable is binding on the MAO and triggers its financial obligation to pay for emergency medical care, the court said. In this case, an out-of-network hospital provided emergency care to an enrollee of Kaiser Foundation Health Plan, Inc., which provides Medicare-covered services through a MA plan. Kaiser refused, however, to pay for services after the point it
believed the patient was stable and could have been transferred to an in-network facility. Kaiser was successful before a private review contractor and an administrative law judge (ALJ), who concluded the enrollee was stable before the hospital physician made that determination. But the Medicare Appeals Council (MAC), after the hospital appealed, disagreed, finding the ALJ wasn’t at liberty to decide when a patient was stabilized; rather, under the applicable regulation, 42 C.F.R. § 422.133(b)(3), that determination was left to the treating physician. Specifically, Section 422.133(b)(3) provides “[t]he physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the MA organization.” According to the MAC, the regulation makes clear that “the treating physician’s decision with respect to when the enrollee stabilized for transfer or discharge binds both the MAO and subsequent adjudicators.” Before the court, Kaiser disputed that the treating physician’s determination that a patient isn’t stable was binding with respect to its financial obligation to pay for emergency care. According to Kaiser, the MAC misinterpreted the regulation in reading it this way. Applying deferential review, the court wasn’t persuaded, finding instead the MAC reasonably construed Section 422.133(b)(3). “Kaiser’s attempt to divorce the duty of assuming the provision of emergency care without prior authorization from the obligation to pay for that care runs counter to the regulatory scheme,” the court observed. The court also found that the regulation itself didn’t conflict with the Medicare statute. According to Kaiser, the applicable statutory provision imposes an affirmative obligation on the treating physician to apply the Emergency Medical Treatment and Labor Act’s (EMTALA’s) definition of “stability,” and, in this case the physician used a checklist based on Medi-Cal (California’s Medicaid program) guidelines. Apart from other flaws in this argument, the court noted that EMTALA uses an objective standard of reasonableness that doesn’t preclude the use of a checklist, nor does such use mean the physician failed to exercise medical judgment. The court also rejected Kaiser’s constitutional due process and takings claims, noting no cognizable property interest given that participation in Medicare is voluntary. While acknowledging “the serious policy concerns raised by Kaiser about potentially perverse financial incentives for a provider to prolong medical emergency status at the expense of MAOs,” the court said such concerns are better left to the regulatory process and Congress to address. Kaiser Found. Health Plan, Inc. v. Burwell, No. 14-cv-05255-EMC (N.D. Cal. Nov. 30, 2015).

D.C. Circuit Rejects Hospital’s Bid to Revive Challenge to Medicare Rule for SNF Reimbursement


Plaintiff Canonsburg General Hospital owns and operates a hospital-based SNF and was reimbursed on a reasonable cost basis, subject to RCLs. For a number of years, both hospital-based and freestanding SNFs were able to receive full reimbursement for “atypical services” under an exception to the RCLs.

In 1994, however, HHS added Provider Reimbursement Manual (PRM) Section 2534.5, which changed the calculation for the atypical services exception as to hospital-based SNFs; freestanding SNFs continued to receive reimbursement for the full cost of their atypical services, creating a so-called “reimbursement gap.”

Plaintiff sued in the U.S. District Court for the Western District of Pennsylvania (Canonsburg I), arguing PRM Section 2534.5, as applied to its reimbursements for fiscal years (F’ys) 1987 through 1990 and 1993, improperly interpreted 42 U.S.C. § 1395yy(c) and 42 C.F.R. § 413.30(f) (the cost
limit statute and regulation); was a substantive rule that was not passed according to the Administrative Procedure Act’s (APA’s) notice-and-comment requirements; and 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 Section 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.”

Plaintiff did not appeal the grant of summary judgment in the Secretary’s favor.

In the late 1990s, plaintiff, separate from the Canonsburg I litigation, began an administrative challenge to its reimbursement for FY 1996. The intermediary granted an atypical services exception for that year but disallowed $526,293 in applying PRM Section 2534.5.

The Provider Reimbursement Review Board (PRRB) reversed the intermediary’s decision, finding PRM Section 2534.5 was invalid on substantive and procedural grounds. The Centers for Medicare & Medicaid Services Administrator reversed the PRRB’s decision, concluding PRM Section 2534.5 was reasonable.

Plaintiff then sued in the U.S. District Court for the District of Columbia, which granted summary judgment to the Secretary based on issue preclusion. According to the court, plaintiff was barred from re-litigating the issues resolved in Canonsburg I. On appeal, the D.C. Circuit affirmed.

The appeals court rejected plaintiff’s argument that the Secretary waived issue preclusion as an affirmative defense because it was not raised during administrative proceedings. The Secretary raised issue preclusion in the the court proceedings; she wasn’t required to do so at the administrative stage, the appeals court said.

Plaintiff also contended that because the Secretary did not raise issue preclusion 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 cannot exercise their duty of review unless they are advised of the considerations underlying the action under review.”

The D.C. Circuit agreed with the lower court that Chenery didn’t apply to legal principles like issue preclusion, which aren’t within the agency’s specific area of authority to determine.

Finally, the appeals court found that this wasn’t a case where equitable considerations weighed against issue preclusion.

Plaintiff argued the Secretary had a pattern of settling litigation challenging PRM Section 2534.5 before courts ruled on its validity.

While acknowledging that settlements have prevented a definitive resolution of the Secretary’s interpretation of the atypical services exception in PRM Section 2534.5, the appeals court noted that plaintiff decided not to appeal Canonsburg I and the Secretary’s decision to settle unrelated cases didn’t result in any particular harm to plaintiff.

D.C. Circuit Upholds HHS Calculation of Medicare Reimbursement for Psychiatric Hospitals

The D.C. Circuit affirmed December 29, 2015 a lower court ruling that the Department of Health and Human Services (HHS) reasonably interpreted the Medicare statute and its implementing regulations in calculating the reimbursement amount for psychiatric hospitals in the period between the expiration of certain payment caps and the start of the transition to a prospective payment system (PPS). Because Congress initially excluded psychiatric hospitals from the PPS, the Centers for Medicare & Medicaid Services (CMS) reimbursed those hospitals on a reasonable-cost basis, but limited reimbursements to a “target amount” under the Tax Equity and Fiscal Responsibility Act (TEFRA).

The Balanced Budget Act of 1997 (BBA) added a new section to TEFRA that imposed caps on target amounts. From 1998 through 2002, a PPS-exempt hospital's target amount could not exceed the 75th percentile of the 1996 target amounts of a similar class of PPS-exempt hospitals, plus an update factor.

Later, the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act moved psychiatric hospitals onto a PPS, leaving the HHS Secretary to determine how to calculate reimbursements in the period between the expiration of the BBA caps in 2002 and the beginning of the PPS transition, which was delayed until 2005.

Fayetteville City Hospital, an Arkansas inpatient psychiatric facility, argued that calculating its 2003 reimbursement based on its 2002 target amount (which was limited by the 75th percentile cap) effectively extended the BBA caps after their expiration. Fayetteville contended the Secretary should have based the 2003 reimbursements on its “hospital specific target amount,” i.e., the net allowable costs in its base period, updated by the appropriate rate-of-increase percentage.


The appeals court noted that Congress didn’t anticipate the gap between the BBA caps and the implementation of the PPS for psychiatric hospitals. With little guidance, the appeals court found HHS had the most “straightforward” reading of the statute for calculating Fayetteville’s 2003 and 2004 target amounts.

Moreover, interpreting the statute to require reimbursements based on the prior reasonable-cost system would undermine the cost-reduction goals that motivated Congress to impose the caps in the period leading up to the PPS, the appeals court observed.

The appeals court also held that the 2003 and 2004 calculations were consistent with HHS regulations.


D.C. Circuit Reverses Dismissal of Challenge to Medicare Appeals Backlog

A federal appeals court ordered February 9 a lower court to reconsider a lawsuit seeking to compel the Department of Health and Human Services (HHS) Secretary to meet statutory deadlines for
reviewing Medicare claim denials. The D.C. Circuit reversed the U.S. District Court for the District of Columbia’s December 2014 decision dismissing the action, directing the lower court to determine whether “compelling equitable grounds” now exist to issue a writ of mandamus requiring the Secretary to clear the growing backlog of Medicare appeals.

On remand, the appeals court noted the district court could find the worsening backlog a year after its initial decision warranted the judicial intervention it previously found was premature. The district court also could determine that Congress and the Secretary are making progress on addressing the problem and decline to step in at this time, the appeals court said.

“[G]iven the unique circumstances of this case, the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle,” the appeals court opined.

The American Hospital Association (AHA) and several hospitals that derive a substantial portion of their revenue from Medicare filed the lawsuit in May 2014, seeking mandamus relief.

At the end of 2013, the Office of Medicare Hearings and Appeals (OMHA) decided to suspend assignment of most new requests for Administrative Law Judge (ALJ) hearings—the third level of appeal—for at least two years as a result of the Medicare appeals backlog.

According to the lawsuit, “[I]n lengthy, systematic delays in the Medicare appeals process, which far exceed statutory timeframes, are causing severe harm to providers of Medicare services, like the Plaintiff hospitals.”

While sympathetic to the hospitals’ plight in having to wait well beyond the 90-day statutory timeframe to have their claim denials reviewed by an ALJ, the U.S. District Court for the District of Columbia declined to step in, saying the job of fixing the appeals backlog belonged to Congress and HHS, not the courts. See American Hosp. Ass’n v. Burwell, No. 14-851 (D.D.C. Dec. 18, 2014).

The court instead weighed more heavily HHS’ competing priorities and budgetary constraints, noting that the best way to allocate those resources was a judgment call better left to the agency and Congress.

The D.C. Circuit acknowledged that HHS essentially is caught between a rock and a hard place—i.e., implementing the Medicare Recovery Audit Contractor (RAC) program, which is cited as a substantial factor in the uptick in OMHA’s workload, and meeting statutory timeframes for deciding Medicare appeals.

While the audit program has generated sizeable Medicare overpayment recoveries, hospitals appealing RAC denials have at least a 43% success rate before the ALJs, as conceded by the government at oral argument, the appeals court said. “This reversal rate is hardly negligible,” the D.C. Circuit noted.

The appeals court agreed with plaintiffs that the statutory deadlines are mandatory, even though Congress allowed providers to “escalate” their appeal to the next level when those timeframes weren’t met.

The appeals court concluded that the Medicare statute does impose a clear duty on the Secretary to comply with the deadlines, and that escalation isn’t an adequate remedy for non-compliance.

The appeals court noted that on remand, the district court had weighty issues to consider.
On the one hand, should the lower court decide to issue a writ of mandamus, HHS likely would have to make “major changes to its operations and priorities,” including its implementation of the RAC program, which has “recovered billions of dollars in incorrectly paid funds.”

On the other hand, several factors weighed in favor of granting mandamus relief—the delays, now an average of 572 days for the ALJs to issue their decisions, “are having a real impact on human health and welfare.” Namely, plaintiffs and other hospitals have substantial funds tied up in the appeals process, which may affect their “willingness and ability to provide care.”

The appeals court also noted that while HHS must implement the audit program, Congress gave the agency substantial discretion in doing so, suggesting that curtailing the RACs may be the only option if further resources aren’t made available to meet the statutory deadlines.

“Federal agencies must obey the law, and congressionally imposed mandates and prohibitions trump discretionary decisions,” the appeals court said.

In a statement, AHA’s Senior Vice President and General Counsel Melinda Hatton said the decision “affirms that hospitals simply cannot afford to have billions of dollars that are needed for patient care tied up indefinitely in the appeals process.”

According to Hatton, the decision “refutes attempts by the agency to excuse compliance because of the Recovery Audit Contractor program.”


**Second Circuit Strikes Rule Barring Hospitals Redesignated as Rural from Being Classified as Urban for Wage Index**

The Second Circuit invalidated February 4 a Department of Health and Human Services (HHS) rule preventing hospitals redesignated as rural under Section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act from seeking recategorization to an urban area for wage reimbursement purposes. Reversing a lower court decision granting summary judgment to the government, the appeals court held Congress unambiguously expressed its intent that the Secretary treat hospitals with Section 401 status as physically located in a rural area for purposes of recategorization to a different geographic area.

The Second Circuit joined the Third Circuit in holding the so-called “reclassification rule” invalid under the Medicare Act, saying the statute explicitly allows hospitals to be viewed as “rural” for some purposes and as “urban” for others. *See Geisinger Cmty. Med. Ctr. v. Dept. Health and Human Servs.*, No. 15-1202 (3d Cir. Jul. 23, 2015).

**Reclassification Rule**

Medicare sets a standardized rate for hospital payments that is adjusted using a “wage index” for each Core Based Statistical Area (CBSA) that is tied to local average wages as compared to the national average. Hospitals in CBSAs with higher labor costs are reimbursed more while those with lower labor costs are reimbursed less.

A hospital can file an application with the Medicare Geographic Classification Review Board (MGCRB) to be recategorized to a different CBSA if it shows its wages are higher than those of other hospitals in the area where it is physically located; its wages are comparable to those of other hospitals in the area to which it seeks to be recategorized; and it is proximate to the area to which it seeks to be recategorized.
Reclassification requirements are relaxed for rural hospitals and the first and third elements are waived entirely for hospitals designated as rural referral centers (RRCs).

A separate provision, Section 401, 42 U.S.C. 1395ww(D)(8)(E), allows hospitals in urban areas to be reclassified as rural for certain purposes—such as easier access to the 340B Program—provided they meet certain qualifying conditions.

In adopting regulations implementing Section 401, the Secretary expressed concern that some hospitals might inappropriately seek to be treated as being located in a rural area for some purposes and as being located in an urban area for others. In fact, hospitals could seek to be reclassified as rural so as to become RRCs exempt from the MGCRB proximity requirement.

As a result, the Secretary adopted the challenged regulation, 42 C.F.R. 412.230(a)(5)(iii), which bars hospitals that have redesignated under Section 401 from being reclassified to a different urban CBSA for purposes of receiving a higher wage index.

**Challenge**

Lawrence & Memorial Hospital, which was originally designated as part of the Norwich-New London, CT urban area, sought and obtained reclassification under Section 401 from an urban to a rural hospital and was additionally designated as an RRC. Lawrence then applied to MGCRB for reclassification to the Nassau-Suffolk, NY urban area, which had a higher wage index.

Lawrence sought to enjoin the Secretary and MGCRB from applying the reclassification rule to its application.

The district court in December 2013 denied Lawrence a preliminary injunction, finding the hospital was unlikely to succeed on the merits that the regulation was invalid. Applying a *Chevron* analysis, the court found Section 401 didn’t address the issue and the statute’s lack of specific guidance could not trump the broad discretion given to the Secretary to develop rules for MGCRB applications. *Lawrence & Mem’l Hosp. v. Sebelius*, No. 3:13cv1495(JBA) (D. Conn. Dec. 6, 2013).

The district court granted summary judgment to the Secretary in December 2014.

**Invalid Regulation**

The Second Circuit found the reclassification rule violated the Medicare Act because the statute unambiguously required MGCRG to review Section 401 hospitals according to the standards applied to hospitals geographically located in a rural area.

Specifically, the appeals court noted Section 401 provides that qualifying hospitals located in urban areas “shall [be] treat[ed] . . . [as] rural.”

The statute makes no distinction between “geographically rural hospital” and hospitals with “acquired rural status” as the Secretary argued, the appeals court said.


**U.S. Court in DC Rejects Hospitals’ Challenge to Medicare Wage Index Accounting Method**
A federal court in the District of Columbia tossed February 22 a challenge brought by more than 100 hospitals to the way the Department of Health and Human Services (HHS) Secretary calculated their wage indices for fiscal years 2007 and 2007.

The hospitals contended that HHS retroactively changed the accounting method used for pension costs.

The U.S. District Court for the District of Columbia disagreed finding the Secretary only applied the rule to prospective reimbursement rates, even if the wage indices at issue were based on cost data that the hospitals reported before the change in accounting for pension costs. The wage index, which is adjusted to reflect geographic variations in labor costs, is based on data reported by hospitals three or four years earlier. At issue in the instant action was the specific accounting method used to calculate the wage index for FYs 2007 and 2008, which were based on cost reports from 2004 and 2005.

Under a 1994 rule, the HHS Secretary directed hospitals to follow Generally Accepted Accounting Principles (GAAP) in reporting their wage-related costs. GAAP, however, didn’t necessarily comport with Medicare payment policies—in particular, that pension and other deferred compensation be included as wage costs not just when they are accrued for accounting purposes, but when those liabilities are liquidated within a specific timeframe.

The same issue came up in a review conducted by the HHS OIG, which found hospitals “overstated their wage data by a total of $326.4 million by reporting unliquidated and/or other postretirement benefit costs.” To address the issue, the HHS Secretary issued a final rule in 2005 clarifying that “pension and other deferred compensation plan costs used to calculate the wage index must comply with the timely liquidation of liability rule”—i.e., liabilities that would be liquidated within one year. The 2005 rule was effective as of FY 2007, although hospitals already had reported the wage data used to calculate the 2007 and 2008 wage indices.

Plaintiffs, 107 hospitals and 13 entities that owned or operated Medicare participating hospitals, cried foul on the HHS rule, saying their FYs 2007 and 2008 wage indices declined because of downward adjustments to their pension costs, which had not been reported in accordance with the liquidation of liability rule.

According to plaintiffs, applying the 2005 rule to the data that pre-dated it amounted to impermissible retroactive rulemaking. In the court’s view, however, the 2005 rule didn’t apply retroactively—it only affected reimbursement rates prospectively, i.e. for FYs 2007 and 2008.

Reimbursement rates for fiscal years before 2005 were not altered. “[A]ll the Secretary did was decide that future payments for future services would be based on a complex calculation that considered, among other variables, the providers’ historical pension costs that were actually and timely liquidated, and not merely accrued for accounting purposes, ” the court reasoned.

Nor did the Secretary “alter the past legality” of reporting pension costs in accordance with GAAP, or impose any liability for doing so. She instead changed how that already-reported data would be used to set future wage indices.

Plaintiffs argued that they may have made different pension-funding decisions for FYs 2004 and 2005 had they known the wage indices would not be calculated based on the accrual method of accounting alone. But the court doubted “the statutory goals of the Medicaid Act would be served by requiring that the Secretary give advance notice simply for the purpose of allowing providers to restructure their finances to maximize their reimbursement rates.”

Plaintiffs also contended that the 2005 rule was inconsistent with the Medicare Act. The court noted the wage index provisions of the Medicare Act vested broad discretion to the Secretary. The statute
did not mandate a particular accounting methodology, and the Secretary’s interpretation was entitled to deference under *Chevron*.

The court also rejected plaintiffs’ argument that the Secretary applied the 2005 rule inconsistently, noting it was based on one expert’s speculation rather than evidence about how the rule was actually applied.

Finally, certain hospital plaintiffs argued the 2005 rule shouldn’t apply to them because their pension plans were not underfunded. The Secretary acted within her discretion in applying the rule uniformly to all retirement costs “to further her broader goals of combatting the ‘overreporting’ of costs in the wage index and ensuring that it reflected only ‘reasonable deferred compensation plan cost,’” the court said.


**U.S. Court in Missouri Tosses Reopening Challenge Finding Provider Did Not Exhaust Administrative Remedies**

The U.S. District Court for the Eastern District of Missouri found February 24 a home health provider failed to exhaust administrative remedies in its challenge to Medicare’s reopening and recoupment request of previous reimbursement. The court also held plaintiff failed to qualify for a constitutional exception from the statutory exhaustion requirement. Plaintiff Triple A Home Care Agency, Inc. provides home health care to Medicare beneficiaries. The Department of Health and Human Services (HHS) originally reimbursed plaintiff’s claims for services. In 2010, however, a Medicare contractor notified plaintiff that it was reopening 30 therapy claims, for therapy provided in 2007, 2008, 2009, and 2010.

HHS demanded repayment of $1,397,353. Plaintiff exhausted the first two levels of appeal. Plaintiff initiated the third level of review, requesting a hearing before an Administrative Law Judge, but filed suit before a hearing took place.

Although the Medicare statute clearly requires exhaustion, the court noted that the Eighth Circuit has recognized a constitutional exception to the requirement.

“This exception applies where the litigant: (1) raises a colorable constitutional claim collateral to his substantive claim of entitlement; (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures.” *Great Rivers Home Care, Inc. v. Thompson*, 170 F. Supp. 2d 900, 903-004 (E.D. Mo. 2001)

The court found plaintiff did not qualify for the exception.

First, the court agreed with HHS’ argument that plaintiff’s claims were not collateral to its substantive claim of entitlement; rather, “Plaintiff seeks review of the Medicare contractor’s determination that it overbilled the program, relief ‘inextricably intertwined’ with [Plaintiff’s] claims for benefits.”

The court also found plaintiff failed to show irreparable harm, “as the Medicare statute itself provides an escalation remedy designed to provide either an expeditious resolution of claims or access to judicial review in a timely manner.”

U.S. Court in Michigan Upholds Medicare Lien on Malpractice Settlement Proceeds

The U.S. District Court for the Eastern District of Michigan upheld March 3 a Medicare Appeals Council (MAC) decision requiring plaintiff to reimburse Medicare $22,668.01 from a $140,000 medical malpractice settlement pursuant to the Medicare Secondary Payer law. After Barbara Anderson passed away under the care of Dr. Sudha R. Patel, Dr. Chandrakant Pujara, and Dr. Mansoor G. Naini, her son (plaintiff) filed a medical malpractice suit alleging the physicians ignored indications of unstable angina and/or acute coronary syndrome and failed to refer his mother to the hospital for immediate cardiac evaluation in an inpatient setting.

Plaintiff eventually agreed to settle the action for $140,000.

Meanwhile, the Centers for Medicare & Medicaid Services (CMS), through a designated Medicare Secondary Payer Recovery Contractor (MSPRC), sent plaintiff a letter notifying him that $41,340.46 paid by Medicare on his mother's behalf was subject to reimbursement pursuant to the Medicare Secondary Payer provisions.

Plaintiff disputed this amount, and the MSPRC issued a second conditional payment letter notifying plaintiff that Medicare paid $1,713.77 in conditional payments related to his claim.

Instead of waiting for a final payment demand letter from Medicare, plaintiff filed a motion in state court requesting approval of the settlements using only the $1,713.77 amount noted in the second, conditional payment letter as the amount reserved in the total settlement for the Medicare lien, which the court approved.

The MSPRC subsequently issued a notice to plaintiff requesting payment for its final demand amount of $22,668.01. Plaintiff filed an appeal with the MSPRC and a request for reconsideration to Medicare's Qualified Independent Contractor (QIC). The QIC affirmed the MSPRC's decision, finding that plaintiff remained responsible for payment of the lien amount.

After a hearing, an administrative law judge (ALJ) also found in favor of Medicare. Plaintiff then filed an appeal with the Medicare Appeals Council (MAC), which adopted the ALJ's decision.

Plaintiff challenged the government's findings, arguing that the medical expenses would have been needed regardless of the alleged negligence and therefore Medicare was not entitled to the entire amount demanded.

Rejecting this argument, the court noted that it was “irrelevant whether the defendant-doctors could ultimately have been found liable for Mrs. Anderson's medical expenses if the case had been tried on the merits.” Instead, the “focus in a Medicare reimbursement case is whether the tortfeasors were responsible for payment, based on, for instance, a settlement and release," as was the case here, the court said.

The court likewise rejected plaintiff’s claim that the MAC erred in concluding that the state court's order allocating only $1,713.77 to the Medicare lien was not binding on the amount reimbursable to Medicare.

The state court order “merely rubber stamped the medical expenses reflected in the $1,711.77 lien amount included in the Settlement Statement submitted by Plaintiff,” and there was no evidence the state court was aware that the amount was conditional.

U.S. Court in Georgia Says Hospitals Must Exhaust Administrative Remedies Against MA Organization

A federal court in Georgia held February 11 that a group of hospitals had to exhaust their administrative remedies before bringing their payment dispute with a Medicare Advantage (MA) organization to court.

Key to the court’s decision was the fact that the 11 hospitals that brought the lawsuit didn’t have contracts with the defendant Care Improvement Plus South Central Insurance Company. Instead, they provided non-contracted emergency services to defendant’s enrollees after obtaining preauthorization to do so.

Defendant initially paid the hospitals’ bills, but later “unilaterally recouped substantial sums” from them based on post-payment audits. Defendant refused to return the payments, and the hospitals sued for unjust enrichment and quantum meruit.

Defendant argued the claims should be dismissed because the hospitals failed to exhaust their administrative remedies under the Medicare Act.

The hospitals argued that the payment decisions were not “organization determinations” subject to the Medicare administrative appeals process. In support of their argument, they cited the Fifth Circuit’s decision in RenCare, Ltd. v. Humana Health Plan of Tex., Inc., 395 F.3d 555 (2004), which held a kidney dialysis provider’s claims against an MA organization about services provided to its enrollees under contract weren’t “inextricably intertwined with a claim for Medicare benefits.”

The U.S. District Court for Northern District of Georgia found, however, that RenCare was distinguishable, because unlike the provider in that case, the hospitals didn’t have a contract with the defendant MA organization.

Instead, the instant action was more akin to the circumstances in Doctors Med. Ctr. Of Modesto, Inc. v. Kaiser Found. Health Plan, Inc., 989 F. Supp. 2d 1009 (E.D. Cal. 2013), where the hospital didn’t have an a contract with the MA organization and therefore the dispute over its payment obligation turned on Medicare standards and federal regulations governing the payment of non-contracted emergency providers.

“It is critical here that Plaintiffs are non-contracting providers under the MA program, because Medicare regulations provide the standards governing their relationship with Defendant, including the standards governing Plaintiffs’ claims,” the court said. The court therefore held the hospitals claims were “inextricably intertwined with the Medicare Act” and subject to administrative exhaustion.

The court also noted that since RenCare, applicable regulations changed to alter how MA organizations are paid. Under the new framework, MA payment decisions have a financial impact on the government and enrollees.

Because decisions on current claims could affect bids in future years, the court found an additional reason for holding the hospitals’ claims should be channeled through the administrative process.


Fourth Circuit Rejects Hospital’s Bid to Require HHS Review of Medicare Appeal
A North Carolina hospital system lost March 7 its appeal before the Fourth Circuit seeking to require the Department of Health and Human Services (HHS) to provide an Administrative Law Judge (ALJ) review of its Medicare claims within the 90-day statutory timeframe. The hospital said it had some $12.6 million in Medicare payments at stake and sought a writ of mandamus compelling the Secretary to adjudicate its claims immediately.

The Fourth Circuit agreed with a lower court that denied the hospital system such relief, finding the Medicare Act already included a specific remedy for the agency's failure to comply with the statutory review times—health care providers could escalate their claims to the next level of review and eventually reach the courts that way.

While calling the current ten-year backlog for ALJ review “incontrovertibly grotesque,” the appeals court said it wouldn’t be fair to send one health care provider to the head of the line of those also waiting. And doing so, the appeals court added, would likely flood the courts with other delayed claimants.

“One can hardly dispute that HHS’ procedural arteries are seriously clogged and that its backlog of ten years is risking its procedural vitality,” the appeals court observed. But the Fourth Circuit said fixing the broken system was better left to the political branches, which are well aware of the problem and presumably working on solutions.

**RAC Denials**

Plaintiff Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System had 1,169 claims from its inpatient rehabilitation facility audited. Of those claims, Recovery Audit Contractors (RACs) reversed payment in 940.

By September 2014, the hospital system had more than 750 appeals—roughly $12.3 million in claims—pending more than 90 days before the Office of Medicare Hearings and Appeals (OMHA)—the third level of administrative appeal.

The hospital sought a declaratory judgment and a writ of mandamus compelling HHS to assign an ALJ and decide its appeals within 90 days of their filing, as required by the Medicare Act,

The U.S. District Court for the Western District of North Carolina dismissed the hospital’s complaint, finding no “clear and indisputable” right to an ALJ hearing within 90 days and that the political branches, rather than the courts, were best suited to address the backlog in the administrative process. *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, No. 5:14-CV-508-BR (E.D.N.C. Mar. 18, 2015).

**“Terrible Choice”**

Affirming the lower court’s decision, the Fourth Circuit held the Medicare Act didn’t create a right to go to court to enforce the 90-day deadline, but instead gave health care providers the option of waiting for the ALJ hearing beyond the statutory time frame or continuing with the administrative process by escalating to the next level of review, eventually reaching the courts if necessary.

The hospital system argued that such an interpretation of the Medicare Act left it with a “terrible choice”—either waiting “interminably” for an administrative hearing or denying itself the opportunity to create a full administrative record at the ALJ level.

The appeals court disputed, however, the hospital system’s contention. “[H]ealthcare providers could, in anticipation of delays at the ALJ stage and beyond create their record at the QIC [Qualified...
Independent Contractor] stage and thereafter escalate their claims to the courts within a period of months," the Fourth Circuit suggested.

The appeals court also agreed with the district court that the administration—which recently proposed substantial funding increases for OMHA—and Congress were best suited to take action. *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, No. 15-1393 (4th Cir. Mar. 7, 2016).

**Other Litigation**

One other federal circuit recently has signaled that it may be time for the courts to step in and address the mounting Medicare appeals backlog.

In a February decision, the D.C. Circuit ordered a lower court to take another look at a lawsuit also seeking to compel HHS to meet statutory deadlines for reviewing Medicare claim denials and determine whether "compelling equitable" grounds now exist to warrant judicial intervention.

The appeals court agreed with plaintiffs in the case that the statutory deadlines are mandatory, even though Congress allowed providers to "escalate" their appeal to the next level when those timeframes weren’t met.

Unlike the Fourth Circuit, the D.C. Circuit concluded that the Medicare statute imposes a clear duty on the Secretary to comply with the deadlines, and that escalation isn’t an adequate remedy for non-compliance. *American Hosp. Ass’n v. Burwell*, No. 15-5015 (D.C. Cir. Feb. 9, 2016).

**Eighth Circuit Upholds Repayment Demand Above Medicare Hospice Cap**

Department of Health and Human Services (HHS) demands for reimbursement of Medicare payments above the statutory hospice cap is not a “taking” under the Fifth Amendment, the Eighth Circuit held March 10.

The fact that enrollment in Medicare is voluntary forecloses the possibility of a takings claim, the appeals court held.

Southeast Arkansas Hospice, Inc. (SEARK) was enrolled as a provider of Medicare services for its two hospice facilities. Long-standing Medicare law annually caps reimbursement and any payment above the statutory cap must be refunded to the program. See 42 C.F.R. § 418.308(d).

Invoking the reimbursement cap, HHS sent SEARK seven demands for repayment. SEARK sued, arguing the cap violates the Takings Clause of the Fifth Amendment.


Here, the reimbursement cap allocates the government's capacity to subsidize health care; SEARK presented no evidence to suggest the cap makes it impossible "to profitably engage in their business"; and SEARK voluntarily chose to participate in the Medicare hospice program.

"This voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation," the appeals court said.


U.S. Court in Texas Rejects Bid for Critical Access Hospital Designation

A federal trial court in Texas refused February 19 to disturb the Department of Health and Human Services Secretary's decision to deny a Medicare-participating hospital the Critical Access Hospital (CAH) designation for failing to meet the 35-mile distance requirement.

In so holding, the U.S. District Court for the Northern District of Texas held the Centers for Medicare & Medicaid Services' (CMS') definition of "primary road" as set forth in its State Operations Manuel (SOM) was reasonable, even under the less-deferential Skidmore review.

Baylor County Hospital District operates Seymour Hospital, which is located in the rural area of Seymour, TX. Seymour Hospital, which is located 31.8 miles from another hospital, sought status as a CAH under 42 U.S.C. § 1395i-4.

The CAH designation is intended to ensure beneficiaries have access to hospital services in rural areas by allowing greater Medicare payments. To qualify for CAH status, the statute requires that a hospital be "located more than a 35-mile drive . . . . from a hospital." The distance requirement is 15 miles in the "case of mountainous terrain or in areas with only secondary roads available."

The statute and implementing regulation don't define “primary” or “secondary” roads, but CMS' SOM says a primary road is a numbered federal highway, a numbered state highway with two or more lanes in each direction, or a road that is shown as a primary highway divided by a median strip on a map prepared according to U.S. Geological Survey Standards.

Although only one road connects Seymour to the nearest hospital, most of the road is designated as a U.S. Highway, even though it is only one lane in each direction. CMS therefore found that Seymour didn't meet the 35-mile distance requirement for CAH status.

Baylor argued CMS’ rule was arbitrary, and that the road at issue should have been classified as “secondary” rather than "primary" from a qualitative standpoint. The court agreed with Baylor that CMS’ definition of “primary” roads in the SOM wasn’t entitled to Chevron deference, but held the agency’s interpretation was entitled to some deference under Skidmore.

Under this standard, the court found CMS’ interpretation was reasonable and advanced the purpose of Section 1395i-4—to target funding at not just rural hospitals, but at those that are "less accessible and more isolated from other sources of hospital care than other such hospitals."

Developing a bright-line rule for defining a primary road, the court said, made sense for purposes of uniformity and consistency. The court therefore granted summary judgment to the Secretary.

U.S. Court in Florida Upholds Reimbursement Denials Under Local Coverage Determination

A federal court in Florida upheld the final decision of the Department of Health and Human Services Secretary denying Medicare reimbursement on 16 claims for remote cardiac monitoring services performed by an Independent Diagnostic Testing Facility (IDTF).

Plaintiff Medicomp Inc., a supplier of remote cardiac monitoring services, argued that the Secretary erred in relying on a Local Coverage Determination (LCD) in determining that the documentation for the 16 claims didn't establish medical necessity.

The LCD was issued in 2009 by First Cost Service Options, plaintiff's Medicare Administrative Contractor. According to plaintiff, the LCD was more restrictive than and conflicted with a National Coverage Determination (NCD) that went into effect in 2004.

The U.S. District Court for the Middle District of Florida disagreed, finding that plaintiff was attempting to challenge the validity of the LCD, which it couldn't do as part of appealing denied claims.

While Medicare regulations provide a process for challenging an LCD, such a review is separate from the Medicare appeals process. For example, in an LCD review proceeding, "medical evidence that was before the Contractor when the LCD was formulated is relevant, and the complainant may present scientific evidence of its own," the court noted.

Moreover, only a Medicare beneficiary or the estate of a Medicare beneficiary is an “aggrieved party” under the regulations for purposes of initiating an LCD review. Medicare providers such as plaintiff may not seek to invalidate an LCD. And in the court’s view, although the LCD was more specific, that didn't mean it conflicted with the NCD.

“The LCD informs providers what medical documentation is required to support a particular claim for payment, and it does not conflict with the NCD in doing so,” the court said.

The court also found no error in the Secretary’s interpretation of the LCD’s documentation requirements.

Plaintiff argued that it wasn't in possession of medical record documentation. According to plaintiff, the LCD required certain documentation from the ordering physician, not the IDTFs.

But the court said it was reasonable for the burden of producing that documentation to rest on the provider submitting the claim. “Substantial evidence supports the Secretary’s conclusion that for each of the sixteen claims at issue, the noted documentation is missing,” the court held.

Medicomp, Inc. v. Secretary, United States Dep’t of Health and Human Servs., No. 4:14-cv-1848-Orl-28DAB (M.D. Fla. Mar. 3, 2016).

U.S. Court in DC Dismisses Claims That Medicare Pre-Payment Review Unconstitutional

The U.S. District Court for the District of Columbia dismissed for failure to exhaust administrative remedies a chiropractor's claims that being placed on Medicare pre-payment review violated the Administrative Procedure Act (APA), the Due Process Clause, and the First Amendment. The court
held in its March 24 opinion that the plaintiff’s admitted failure to pursue an administrative remedy rendered the court without jurisdiction to hear the case.

Dr. Gregg Popkin is a chiropractor who owned and operated Atlantic Medical. In March 2014, Popkin moved Atlantic Medical from Ft. Lauderdale to Miami. As part of the move, Popkin submitted an application for Atlantic Medical to serve as a Medicare supplier in Miami.

First Coast Service Options, Inc. was assigned as the Medicare Assistance Contractor to process Atlantic Medical's application.

As part of its review, First Coast determined that Atlantic Medical was at high risk for fraud and abuse and placed it on pre-payment review for claims over a certain dollar amount, which required Atlantic Medical to submit substantiating documentation for each claim before it could receive payment.

Between June 23, 2014 and April 30, 2015, First Coast denied 97% of Atlantic Medical's requests for payment. Of the payment denials that Atlantic Medical appealed through the administrative process, 87% were upheld.

Due to the lack of Medicare income, Atlantic Medical closed in August 2015. Popkin and Atlantic Medical then sued the Department of Health and Human Services seeking a preliminary injunction terminating pre-payment review and requiring the Secretary to remit all payments.

The court dismissed the claims, finding plaintiffs' failure to pursue administrative review under the Medicare Act was fatal to their claims.

The court rejected plaintiffs' claim of hardship caused by the delay inherent in the channeling requirement, finding any delay “insufficient to avoid the duty to exhaust.”

The only exception to the channeling requirement is where the administrative process would result in the complete preclusion of judicial review, the court noted, but plaintiffs' contention “that administrative review will be time-consuming does not demonstrate complete preclusion of court review.”

The court also rejected plaintiffs' argument that the delay inherent in seeking administrative review violates their right to due process because of the large backlog currently pending in the third level of appeal at the Office of Medicare Hearings and Appeals.

The court said the Medicare Act contains a remedy for this issue as it permits a claimant to escalate its appeal to the fourth level when an administrative law judge fails to render a decision in 90 days, and plaintiffs “have not utilized the escalation provisions.”


**U.S. Court in Indiana Dismisses Home Health Agency’s Constitutional Claims Against HHS, State Survey Agency for Lack of Exhaustion**

The U.S. District Court for the Southern District of Indiana held April 5 that home health agency plaintiffs must exhaust administrative remedies in their challenge to actions taken by the state survey agency. According to the court, plaintiffs’ claims arose under the Medicare Act and they could not avoid the exhaustion requirement. The fact plaintiffs asserted constitutional claims “does not change the analysis because the Secretary has the authority to review such a challenge,” the court said.
Plaintiffs are Home Care Providers, Inc., Nightingale Home Healthcare, Inc., Nightingale Hospice Care, Inc., and owner Dev A. Brar.

In 2015, the Indiana State Department of Health (ISDH)—the state survey agency—conducted complaint surveys at a Nightingale facility and made findings regarding patient health and safety.

Based on these findings, the Centers for Medicare & Medicaid Services (CMS) notified Nightingale that it was terminating the home health agency's participation in the Medicare program. Nightingale initiated an administrative appeal of that determination, which is pending.

Meanwhile, plaintiffs sued the Department of Health and Human Services Secretary for injunctive, prospective relief, claiming that the Secretary violated the Due Process Clause of the Fifth Amendment, Equal Protection, and the First Amendment by ratifying the actions of the state survey agency, and asked the court to enjoin CMS from using ISDH to conduct further surveys.

Plaintiffs also alleged that various state defendants—officials at ISDH—abused the survey process by harassing, discriminating, intimidating, and retaliating against Brar on the basis of race.

According to plaintiffs, the court had jurisdiction to entertain their claims because they sought only prospective relief for ongoing constitutional violations and the sovereign immunity defense did not apply to suits for injunctive relief against the Secretary.

Rejecting this argument, the court found any equitable decision to change the process for reviewing plaintiffs' eligibility to participate in Medicare "is inextricably intertwined with standards and rights created by and under the Medicare Act; therefore, Plaintiffs' exclusive remedy is under the Act through the appeals process."


**Ninth Circuit Affirms HHS' Denial of Medicare Payment to Hospital After Asset-Only Purchase**

The Ninth Circuit agreed April 11 with the Department of Health and Human Services (HHS) Secretary finding a hospital that attempted to circumvent an acquired facility's Medicare liabilities by using an asset-only purchase structure was not entitled to bill Medicare until the new facility had its own provider agreement. On June 30, 2009, Mission Hospital Medical Center purchased the assets of South Coast Medical Center. According to the opinion, Mission attempted by an assets-only purchase to avoid South Coast's potential liabilities under its Medicare provider agreement, which was terminated.

The HHS Secretary subsequently determined that Mission was not entitled to bill Medicare for patient services at its new facility until that facility had a provider agreement of its own. The decision blocked Mission from collecting $1.4 million for services rendered between July 1, 2009 and September 29, 2009 at South Coast, which was now known as Mission's Laguna Beach campus.

Mission also was barred from collecting $7 million for normally Medicare eligible services between July 1, 2009 and March 18, 2010, when the Laguna Beach campus was finally accredited and properly enrolled as a provider in Medicare, after the Joint Commission found material deficiencies during an accreditation survey.

Mission appealed through the Departmental Appeals Board, which affirmed the Secretary's decision. The district court also held in favor of the Secretary.
On appeal, Mission argued that 42 C.F.R. § 489.13(d)(1)(i) permitted it to avoid South Coast's Medicare liabilities simply by submitting, along with South Coast, CMS Form 855A "requesting that Mission's Medicare provider agreement encompass the Laguna Beach campus effective July 1, 2009."

According to Mission, its submission of the form complied with Section 489.13(d) and should have made July 1, 2009 the effective date of Medicare enrollment for the Laguna Beach campus under Mission's existing provider agreement as Mission was entitled to the benefit of the retroactivity provision in Section 489.13(d)(2).

However, in 2009, Section 489.18(d) provided that "[a]n assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued." (Emphasis added).

According to the appeals court, the statutory language references the terms and conditions under which the existing provider agreement was issued originally because the regulation, "which Mission tried to circumvent, provides continuity of obligations, continuity which is essential to the functioning of Medicare's Prospective Payment System."

But Mission did not take assignment of South Coast's provider agreement, the appeals court pointed out. Accordingly, the Laguna Beach campus on July 1, 2009 became for Medicare purposes a "new hospital," without a provider agreement.

As a consequence, because of the accreditation issues the Laguna Beach campus did not meet "all requirements" within the meaning of Section 489.13(d)(1)(i), and thus Mission was not entitled to the retroactivity provision.

Upholding the Secretary's decision, the Ninth Circuit held the effective date of billing privileges for services provided at Mission's Laguna Beach campus could not be earlier than March 18, 2010.


Eleventh Circuit Upholds $8.9 Million Overpayment Determination

The Eleventh Circuit in an unpublished opinion held April 29 that the Department of Health and Human Services (HHS) properly recouped some $8.9 million from a Florida ophthalmology practice for improperly billing Medicare.

At issue in the case was Vitreo Retinal Consultants of the Palm Beaches, PA's (VRC's) practice of "multi-dosing" the drug Lucentis, an injection approved by the Food and Drug Administration (FDA) to treat age-related macular degeneration.

According to the FDA-approved label for Lucentis, a single 0.5 mg dose should be injected into the patient's eye once each month from one 2.0-mg vial, with the remainder discarded. VRC instead treated up to three patients from a single vial and billed Medicare for every 0.5 mg dose of Lucentis it administered.

The Medicare contractor issued an overpayment determination to VRC of roughly $8.9 million, finding that because it extracted up to three doses from a single vial, it was reimbursed three times the amount it would have received had it administered the drug according to the label. VRC complied with the repayment demand, but pursued administrative remedies for recoupment.
When those efforts failed, VRC sued in a Florida federal district court, which also denied relief. The Eleventh Circuit affirmed, upholding the Secretary’s overpayment determination.

VRC argued that the Secretary’s reason for denying payment for each dose of Lucentis administered—that VRC overstated its expense—was flawed because Medicare reimbursement isn’t tied to the physician’s expense.

The appeals court disagreed, noting “the very concept of ‘reimbursement’ contemplates payment for money that was actually spent.” Medicare’s “lawful policy that reimbursement to providers should reflect more-or-less actual expense to the physician” was not arbitrary or capricious, the Eleventh Circuit said.

The appeals court also upheld the Secretary’s alternate basis for denying reimbursement—that multiple doses of Lucentis from a single vial were medically unreasonable based on the FDA-approved label.


**DC Circuit Upholds HHS’ Determination that Nonprofit Hospital Combination Not a Bona Fide Sale**

The D.C. Circuit affirmed April 29 the government’s position that a transaction is not a bona fide sale qualifying for adjusted depreciation under the Medicare regulations without arm’s-length bargaining between economically self-interested parties. After St. Francis and St. Joseph hospitals consolidated to form Via Christi Health Center, Via Christi sought an upward adjustment of the capital-asset depreciation reimbursement paid to its predecessor hospitals under Medicare.

As a general matter, the opinion explained, the Department of Health and Human Services (HHS) reimburses Medicare providers for their reasonable costs actually incurred, including an appropriate share of depreciation on buildings or equipment used to supply Medicare services. See 42 U.S.C. §§ 1395f(b)(1), 1395x(v)(1)(A); 42 C.F.R. §§ 413.130, 413.134(a).

The HHS Secretary denied both of Via Christie’s claims on the ground that the consolidation was not a bona fide sale qualifying for adjusted depreciation under the regulations.

Under applicable law, “if an asset is sold for less than its net book value, the Secretary makes an additional payment to the provider, reflecting an understanding that the previous depreciation payments fell short of reflecting true cost.” The Secretary, consistent with the relevant Medicare regulations, makes that payment only when the loss results from a bona fide sale.

The Secretary reasonably concluded that a bona fide sale requires an arm’s-length transaction between economically self-interested parties, the appeals court found.

The Secretary determined that St. Francis did not negotiate at arm’s length because it “never pursued any efforts to maximize gains upon the consolidation or ‘sale’ of [its] assets.” Instead of aiming to “maximize the proceeds received from selling its assets,” the hospital sought to “advance [its] ministry,” according to the opinion.

Via Christi argued that transactions need not be motivated by financial gain maximization to qualify as arm’s length under the regulation.
But the court sided with the Secretary, finding it “permissible for the Secretary to conclude that a bona fide sale requires arm’s-length bargaining between economically self-interested parties.”

“The Secretary’s interpretation of the bona fide sales rule makes sense, and Via Christi cites no authority disallowing it,” the appeals court said.


**U.S. Court in Connecticut Refuses to Reinstate Hospital's 340 Eligibility After Reclassification Rule Invalidated**

The U.S. District Court for the District of Connecticut refused to reinstate a hospital to the 340B Program after it relinquished its rural status under now invalidated Department of Health and Human Services (HHS) regulations. The court denied the hospital’s motion for a preliminary injunction and instead remanded to the agency to determine an appropriate remedy.

The Second Circuit invalidated February 4 an HHS rule that prevented hospitals redesignated as rural under Section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act from seeking reclassification to an urban area for wage reimbursement purposes.

The appeals court reversed the lower court decision granting summary judgment to the government, holding Congress unambiguously expressed its intent that the Secretary treat hospitals with Section 401 status as physically located in a rural area for purposes of reclassification to a different geographic area.


The appeals court remanded to the district for further proceedings. The plaintiff hospital in the case had cancelled its Section 401 status to avoid the denial of its reclassification application under the now invalidated regulations, making it no longer eligible for the 340B Program.

The hospital asked the court to order HHS to reinstate its Section 401 status and 340B eligibility.

“The hospital’s assertion that it should be restored to the position it would have occupied had the Secretary not issued an invalid regulation has been squarely rejected by the D.C. Circuit,” the court said.

“Remand is particularly appropriate here, where the statutory scheme at issue is highly complex, and its administration has been specifically committed by Congress to the expertise of the Secretary,” the court added.

Lawrence & Memorial Hospital, which was originally designated as part of the Norwich-New London, CT urban area, sought and obtained reclassification under Section 401 from an urban to a rural hospital and was additionally designated as an rural referral center (RRC). Lawrence then applied to the Medicare Geographic Classification Review Board (MGCRB) for reclassification to the Nassau-Suffolk, NY urban area, which had a higher wage index.

Lawrence sought to enjoin the Secretary and MGCRB from applying the reclassification rule to its application.
The district court in December 2013 denied Lawrence a preliminary injunction, finding the hospital was unlikely to succeed on the merits that the regulation was invalid. *Lawrence Mem'l Hosp. v. Sebelius*, No. 3:13cv1495(JBA) (D. Conn. Dec. 6, 2013).

The district court granted summary judgment to the Secretary in December 2014. Reversing, the Second Circuit found the reclassification rule violated the Medicare Act because the statute unambiguously required MGCRG to review Section 401 hospitals according to the standards applied to hospitals geographically located in a rural area.

Although the Second Circuit didn’t remand the case to the agency, it is common for appeals courts to remand cases to the lower court for remand to the agency, the court here said.


**U.S. Court in Massachusetts Says Secretary Improperly Denied Medicare Coverage for Test Strips**

The U.S. District Court for the District of Massachusetts found May 12 the Medicare Appeals Council improperly deferred to a Medicare Policy Article in denying a beneficiary coverage for glucose test strips. The court said the Article was not due deference and remanded to the Department of Health and Human Services Secretary for further consistent proceedings.

Medicare beneficiary Patricia Finigan, who has type 1 diabetes, requested coverage for supplies for her Continuous Glucose Monitoring System (CGMS) from her Medicare Advantage plan, AARP Medicare Complete.

The insurer rejected the claim, and Finigan appealed all the way up to the Medicare Appeals Council, which affirmed the rejection.

Looking for guidance as to whether the CGMS should qualify as durable medical equipment (DME) that would be covered under Medicare Part B, the government relied on one relevant Local Coverage Determination (LCD). The LCD did not directly address the question, but referred to a Policy Article asserting that CGMS is "considered precautionary and therefore non-covered under the [DME] benefit."

Finigan argued the Council erroneously deferred to the Policy Article and that the medical evidence in the record constituted "substantial evidence" that supported "a finding that [Finigan's CGMS] is reasonable and [n]ecessary."

The court agreed that it was “legal error” for the Council to treat the Policy Article as an LCD entitled to substantial deference.

A Policy Article is not an LCD “because it does not make reasonable-and-necessary determinations,” the court said.

The Secretary argued that, even if deferring to the Policy Article was erroneous, remand was unnecessary because, under Centers for Medicare & Medicaid Services guidance—which is due substantial deference—the CGMS did not qualify as DME.

The court agreed with Finigan that neither the Council nor the hearing officer advanced this argument and therefore it could not serve as the basis for affirming the Secretary’s decision.
Patient Privacy/Medical Records

U.S. Court in Arkansas Applies HIPAA Whistleblower Exception to Plaintiffs Alleging Wrongful Termination

A federal district court in Arkansas held that the “whistleblower exception” to the Health Insurance Portability and Accountability Act (HIPAA) applied to two former hospital workers who handed over protected health information (PHI) to their attorney as part of a lawsuit alleging they were wrongfully terminated for raising concerns about the facility’s billing practices.

The court also refused, at the summary judgment stage, to deny plaintiffs Pam Howard and Eben Howard whistleblower status under the False Claims Act (FCA).

Both plaintiffs alleged Arkansas Children’s Hospital terminated their employment after they raised concerns about its billing practices. Plaintiffs alleged their termination violated the First and Fourteenth Amendments, 42 U.S.C. § 1983, Section 504 of the Rehabilitation Act of 1973, the FCA, and Arkansas law.

In the course of their duties, plaintiffs received PHI for a number of hospital patients, which they kept after their termination and later disclosed to an attorney in anticipation of the instant lawsuit.

The hospital alleged plaintiffs violated HIPAA by acquiring and disclosing to their attorney the PHI. Plaintiffs argued, however, that the HIPAA whistleblower exception, 42 C.F.R. § 164.502(j)(1), applied.

The U.S. District Court for the Eastern District of Arkansas agreed with plaintiffs. Specifically, the court noted that the hospital is a “covered entity,” plaintiffs were members of its workforce or business associates before their termination, and they acquired the PHI in the course of their duties with the hospital.

In addition, plaintiffs believed the hospital behaved unlawfully, violated professional or clinical standards, or was endangering patient safety.

Finally, the disclosure was to their attorney for purposes of determining legal options for their concerns, the court said. “Therefore, the plaintiffs have met their burden of showing that they qualify as whistleblowers under the HIPAA regulations.”


New York Court Drastically Slims Down Claims Allowed Against Hospitals for Negligence in Protecting Patients’ Personal Health Data

The New York Supreme Court August 14 dismissed all but two claims asserted against multiple defendants after the protected health information of numerous plaintiffs was stolen by third parties. Among its findings, the trial court said no private right of action exists under the Health Information Technology for Economic and Clinical Health Act (HITECH) or the Health Insurance Portability and Accountability Act (HIPAA). Plaintiffs in the case are 13 patients, or relatives of patients, who allegedly received medical services at facilities owned or operated by defendants North Shore-Long Island Jewish Health System, Inc. (Health System), North Shore-Long Island Jewish Medical Care, PLLC, (Medical Care), North Shore-LIJ Network, Inc. (Network), and North Shore University Hospital (NSUH).
According to plaintiffs, on or before Fall 2010 and continuing at least through 2012, medical record face sheets and unencrypted computer network data were stolen from defendants.

Plaintiffs allege that the stolen data contains private, personal information, including but not limited to protected health information as defined by HIPAA, Social Security numbers, medical information, and other information of hundreds of patients.

Plaintiffs further allege that the defendants were aware of the thefts and security breaches and that they failed to notify patients within 60 days of the breach; that defendants failed to timely notify the Department of Health and Human Services, and that defendants failed to maintain a written log of security breaches since 2007, on an annual basis.

The complaint alleges 11 causes of action. Defendants moved to dismiss the complaint.

The court first dismissed claims asserting state law negligence per se under three different statutes, finding no private right of action in the statutes.

The court also found no private right of action existed for plaintiffs' negligence per se claims under HIPAA and HITECH.

In addition, the court granted motions to dismiss based on breach of contract and breach of fiduciary duty.

The court did, however, find the complaint sufficiently stated a claim for negligence against defendants Health Systems and NSUH, although it dismissed the claim as to all other defendants.

The court also dismissed a claim based on the duty of good faith and fair dealing, finding “such a claim may not be used as a substitute for a nonviable claim of breach of contract.”

For plaintiffs' eleventh cause of action for misrepresentation, the court said the claim must also be dismissed because fraud claims "asserted against multiple defendants must include specific and separate allegations for each defendant," and the plaintiffs failed to do that here.


U.S. Court in New York Allows Claims Alleging Plaintiffs Overcharged for Copies of Medical Records

The U.S. District Court for the Western District of New York allowed September 16 a group of plaintiffs to proceed with their claims that health care providers and their contractor that provides copies of medical records improperly profited from the copying fee. Named plaintiffs, on behalf of themselves and others similarly situated, sued Verisma Systems, Inc., Strong Memorial Hospital, Highland Hospital, and the University of Rochester.

Verisma contracts with the health care provider defendants to provide medical records to patients of those entities.

Plaintiffs, who were patients of the health care defendants, claimed that charges for copies of their medical records were excessive in violation of the New York Public Health Law. They also asserted unjust enrichment and deceptive trade practices claims.

The court found all claims survived dismissal under Fed. R. Civ. P 12(b)(6).
The New York Public Health Law allows providers to impose a "reasonable charge" for copies, as long as the charge (1) does not exceed "the costs incurred by such provider" to make the copies; and (2) does not exceed "seventy-five cents per page" of records.

Plaintiffs argued that pursuant to the statute, Verisma could only charge the amount of its costs, capped at seventy-five cents per page. Verisma, on the other hand, argued that the statute sets seventy-five cents as a presumptively reasonable price, so that a health care provider whose actual costs incurred were less still may charge seventy-five cents per page.

The court agreed with plaintiffs, finding Verisma’s argument "misreads the statute."

The court also rejected defendants’ argument that plaintiffs’ claims were foreclosed pursuant to the voluntary payment doctrine, which "bars recovery of payments voluntarily made with full knowledge of the facts, and in the absence of fraud or mistake of material fact or law." *Dillon v. U--A Columbia Cablevision of Westchester, Inc.*, 760 N.Y.S.2d 726 (2003).

But the court said dismissing plaintiffs' claims under the voluntary payment doctrine “would be premature” at this stage of the litigation.


**Georgia Appeals Court Says Lower Court Erred in Finding All Plaintiff’s Medical Records Privileged**

The Georgia Court of Appeals reversed October 23 a lower court’s determination that all of a plaintiff's medical records were privileged in an action against her medical providers after her daughter was injured during delivery. Instead, the appeals court said the lower court should have determined which records were privileged and which were not.

Plaintiff Courtney Howard sued various medical providers, alleging they were negligent during the delivery of her daughter.

During discovery, the medical providers sought all of Howard's medical records from age ten to the present, and requested she identify all treatment she received from psychologists, psychiatrists, clinics, and all other medical providers. Howard objected to the request.

During discovery, Howard admitted that she previously received mental health and substance abuse treatment at Cobb Recovery Center (CRC) and had taken "drug classes" there. In addition, medical documents produced from other sources showed that Howard tested positive for marijuana on one or more occasions during her pregnancy.

After the deposition, the medical providers requested that Howard provide a Health Insurance Portability and Accountability Act-compliant authorization that would allow CRC to produce Howard's records.

Howard refused, and the medical providers moved to compel production of the CRC records. After the trial court found the CRC records privileged, the appeals court granted the providers’ motion for interlocutory appeal.

The medical providers contended the trial court erred by concluding that all of the CRC records other than the billing records were privileged.
The appeals court agreed. Although many of the documents produced were “obviously not relevant to the present proceedings,” some could be both relevant and non-privileged, the appeals court noted.

On remand, the appeals court instructed the lower court to conduct an in camera review to separate privileged versus non-privileged information and provide a redacted copy.


**Ninth Circuit Says Hospital May Use Patient Records in Counterclaim Against Medical Practice**

A radiation oncology practice suing a hospital for unfair trade practices wasn’t entitled to an injunction barring the hospital from using certain medical records to assert its counterclaim that the practice improperly transferred patients to a competing facility, the Ninth Circuit held December 22, 2015. The Ninth Circuit affirmed the lower court’s denial of injunctive relief because the hospitals’ alleged violations of the Health Insurance Portability and Accountability Act (HIPAA) and the Hawaii Constitution were unrelated to the underlying action for unfair trade practices and other state law claims.

Plaintiffs Pacific Radiation Oncology, LLC (PRO), a group of physicians who specialize in radiation oncology, provided services to patients at The Queen’s Medical Center (Queen’s), among other hospitals. Queen’s is the only Nuclear Regulatory Commission-licensed facility on Oahu, HI with an operating room.

In 2011, Queen’s decided to transition to a closed-facility model allowing only employed physicians privileges to use its facilities. According to Queen’s, the move was intended to improve quality and patient safety and ensure continuity of care.

Queen’s offered PRO physicians employment, but they did not accept, due in part to requirements that they stop providing services at competing facilities.

PRO sued Queen’s asserting claims for violating their substantive and procedural due process rights and unfair, deceptive, anti-competitive, and illegal trade practices.


Queen’s subsequently asserted a counterclaim against PRO, alleging its physicians improperly steered patients from Queen’s to a competing facility in which they had a financial interest.

Queen’s identified 133 patients from its own electronic medical record system that initially consulted with a PRO physician at Queen’s but did not return there for radiation therapy. Queen’s sought to subpoena these patients’ records from the competing facility and mistakenly posted an unredacted list of patient information on the public docket, which was restricted and sealed a day after the error.

PRO then moved for a TRO or preliminary injunction challenging Queen’s right to review its own medical records as well as the records it sought through the subpoena. According to PRO, Queen’s violated HIPAA and the Hawaii Constitution.
The district court denied PRO’s motion because the group’s underlying complaint did not allege improper review and use of confidential patient information in violation of HIPAA and the Hawaii Constitution, and therefore could not form the basis for granting injunctive relief.

Adopting the Eighth Circuit’s reasoning in Devose v. Herrington, 42 F.3d 470 (8th Cir. 1994), the Ninth Circuit held that an injunction was not appropriate where the relief sought was unrelated to the underlying complaint.

“PRO’s motion for injunctive relief is based on potential misconduct entirely unrelated to its unfair trade practices claim,” the Ninth Circuit observed. “PRO’s complaint relates only to the retention of hospital privileges and collection of damages from unfair competition and related theories,” not the improper review and use of confidential patient information in violation of HIPAA and state law.

The Ninth Circuit said PRO instead could have sought leave to amend its complaint to include a claim that patients’ privacy was violated, or brought a separate suit against Queen’s for the alleged misconduct. But PRO could not respond to Queen’s discovery request by seeking injunctive relief for claims unrelated to the original lawsuit, the appeals court said.


Virginia Appeals Court Says Hospital Employee Did Not Violate Law in Accessing Ex-Husband’s Medical Records

The Virginia Court of Appeals dismissed February 2 a hospital’s arguments that an employee’s actions in accessing her ex-husband’s medical records at his request violated the law or hospital policy.

Susan Jordan worked as a registered nurse at the University of Virginia’s Medical Center. Her ex-husband, Kurt Jordan, also worked at the hospital and was being treated there for an advanced stage of multiple myeloma.

Kurt executed a number of documents to provide Jordan with the authority to gain access to his medical records, including a durable power of attorney and an advanced medical directive.

Jordan accessed Kurt’s medical records at his request on four occasions. After an internal computer audit revealed that Jordan gained access to Kurt’s medical records, the Medical Center sought to fire Jordan on the basis of “serious misconduct” for multiple violations of policy, which it alleged precluded this kind of access.

Jordan filed a grievance to challenge the Medical Center’s action. The hearing officer ruled in her favor. The Medical Center appealed the hearing officer’s conclusions on matters of policy to the Department of Human Resources Management (DHRM), which also ruled in Jordan’s favor. The Medical Center then appealed to the circuit court, which affirmed.

Because Jordan was acting as an agent on Kurt’s behalf when she pulled his medical record for his benefit, “both the hearing officer and the circuit court committed no error in concluding that the access was attributable to Kurt, because Kurt obtained access to his medical record through his agent,” the appeals court found.

The appeals court found no violation of the Health Insurance Portability and Accountability Act privacy rule because the access was authorized under the statute.
Virginia law also “clearly specifies that the Medical Center is required to disclose Kurt Jordan’s health records to him and that it may do so to an agent appointed under his power of attorney,” the appeals court noted.


**U.S. Court in Massachusetts Tosses Claims Against State Attorney General for Improper Accessing of Medical Records**

The U.S. District Court for the District of Massachusetts dismissed a physician’s claims against various state officials, including the state Attorney General, that they improperly accessed computer records for the purpose of falsely accusing him of Medicaid fraud.

The court found the evidence provided by the physician—who was representing himself pro se—failed to state a claim under any of the cited statutes.

Plaintiff Dr. Bharanidharan Padmanabhan filed a criminal complaint against a host of defendants, including the Attorney General of the Commonwealth of Massachusetts, the Deputy Chief of the Medicaid Fraud Division at the Office of the Attorney General, and other state officials.

Plaintiff alleged that defendants unlawfully accessed the protected Prescription Monitoring Program computer database to obtain a list of 16 of his patients who received Medicaid benefits, and then falsely accused him of committing Medicaid fraud.

The court granted defendants' motion to dismiss the claims.

Plaintiff alleged defendants violated the Computer Fraud and Abuse Act, which prohibits an individual from (1) intentionally accessing a computer without authorization or exceeding authorized access and (2) obtaining information from any federal department, federal agency, or protected computer.

Dismissing the claim, the court agreed with defendants that the patient consulting costs, legal fees, and professional injuries plaintiff alleged did not qualify as losses under the statute.

Plaintiff also failed to allege that the purportedly accessed information was protected by the Stored Communications Act, the court said in dismissing that claim as well.

The court also denied plaintiff equitable relief, finding his “[c]onclusory allegations that defendants falsely accused plaintiff of Medicaid fraud, seized his medical records despite a ‘total absence of real evidence’ and engaged in witness intimidation and tampering do not, in the absence of supporting factual assertions, state a valid claim under the Fourth Amendment.”

General and vague statements that the alleged conduct violated unidentified federal statutes “also do not suffice to set forth a plausible claim for relief,” the court held.


**Ohio Supreme Courts Says Physical Location Doesn’t Determine Medical Record Contents**

Data kept by the risk management department may be considered part of the medical record under Ohio law if a health care provider decided to maintain the information and it relates to a patient’s
medical history, diagnosis, prognosis, or medical condition, the state’s highest court ruled March 23. The high court rejected a hospital’s contention that the physical location of the information—i.e., whether it was maintained by the medical records department—determined whether the data were part of the medical record.

Reversing the lower courts’ decisions, the Ohio Supreme Court said under applicable state law the term “medical record” includes any data that a health care provider decides to keep or preserve in the process of treating a patient.

The case was before the high court over a dispute as to whether Aultman Hospital produced the entire medical record in a medical malpractice action brought by a deceased patient’s daughter. At issue were certain cardiac monitoring strips from shortly before the patient died.

Both the trial court and the appeals court agreed with the hospital that “medical record,” as used in Ohio Rev. Code § 3701.74, which sets forth access procedures, only includes information that is “maintained” by the medical records department.

According to the hospital, the strips were printed from the electronic monitoring equipment at the request of the risk management department after the patient’s discharge. The director of medical records previously testified, however, that information is deleted from the monitoring equipment unless a physician orders the data to be saved.

Under Section 3701.74(A)(8), “medical record” is defined as “data in any form that pertains to a patient’s medical history, diagnosis, prognosis, or medical condition and that is generated and maintained by a health care provider in the process of the patient’s health care treatment.”

The high court acknowledged that a “medical record” under the statute doesn’t include all patient data. But the high court also noted the statutory definition didn’t limit a medical record to physical location—something other state laws have specifically done.

The high court rejected the hospital’s argument that “maintain” as used in the statute depends on a managerial decision to keep or preserve the data in a discrete location or file. Instead, the high court adopted the “ordinary and common” meaning “that the healthcare provider has made a decision to keep or preserve the data.”

Reversing the decisions below, the high court remanded for further proceedings to determine whether the cardiac monitoring strips at issue were saved at the direction of a physician, which would mean that they fell under the “medical record” definition.

A dissenting opinion argued that records generated for and maintained by a hospital’s risk management department for risk-management purposes after a patient’s death are not “medical records” under Section 3701.74(A)(8).

Another dissenter said the underlying wrongful-death claim had been settled and the appeal should be dismissed on that basis.


New York High Court Allows Breach of Confidentiality Claim Against Hospital That Allowed Filming

A hospital and its former chief surgical resident must face a claim that they breached physician-patient confidentiality when they allowed a film crew to record a patient’s treatment and subsequent
death without consent, the New York Court of Appeals held March 31. The high court’s decision revives a lawsuit against New York and Presbyterian Hospital and physician Sebastian Schubl who treated the decedent, Mark Chanko, in the emergency room following an automobile accident.

The complaint alleged the hospital and Schubl allowed an ABC News crew to film Chanko’s treatment, the declaration of his death, and the moment the family was informed of his death without their knowledge.

Chanko’s widow more than a year later saw an episode of NY Med and recognized her husband, although his image was blurred out and he wasn’t identified by name.

Plaintiffs, Chanko’s widow and other family members, also sued ABC News.

The trial court dismissed several claims except the causes of action asserting breach of physician-patient confidentiality against the hospital and Schubl and intentional infliction of emotional distress against ABC, the hospital, and Schubl. The appeals court, however, dismissed the entire complaint.

The New York Court of Appeals found that plaintiffs stated a claim for breach of physician-patient confidentiality under state law.

In so holding, the high court rejected defendants’ argument that the disclosed medical information must be embarrassing or something the patient would want to keep secret to be actionable.

“[W]hether the confidentiality inherent in the fiduciary physician-patient relationship is breached does not depend on the nature of the medical treatment or diagnosis about which information is revealed,” the high court said.

The high court also was not persuaded that the fact Chanko’s image was blurred and his name omitted from the episode meant no confidential information was disclosed. Even if no one recognized him from the broadcast, which plaintiffs argued was not the case, “the complaint expressly alleges an improper disclosure of medical information to the ABC employees who filmed and edited the recording.”

Plaintiffs should be allowed to continue with the breach of confidentiality cause of action including discovery of the raw footage beyond the three minutes that actually aired to help demonstrate any damages, the high court held.

The high court did find, however, that plaintiffs failed to allege a claim for intentional infliction of emotional distress, finding the conduct wasn’t “extreme and outrageous.”

The broadcasting of a patient’s last moments of life without consent “would likely be considered reprehensible by most people, and we do not condone it,” the high court said. “Nevertheless, it was not so extreme and outrageous as to satisfy our exceedingly high legal standard.”

Specifically, the high court noted that the broadcast footage did not include decedent’s name, his image was blurred, and the episode included less than three minutes devoted to Chanko.


New Jersey Appeals Court Says Arbitration Clause in Medical Records Processor’s Invoice Unenforceable
A New Jersey appeals court held April 22 that a hospital’s medical records processor may not enforce a mandatory arbitration clause that it included in its invoice to a patient's attorney in response to a request for records. The Superior Court of New Jersey, Appellate Division, said that because the hospital, and the processor acting as its agent, had a pre-existing legal duty under federal and state law to provide the records, the alleged bargain to arbitrate was unsupported by consideration, and therefore was unenforceable.

Defendant Medical Records Online, Inc. (MRO) is a third-party processor of requests for medical records submitted to hospitals and physicians, including Kennedy Memorial Hospitals.

Plaintiff Bernetich, Hatzell & Pascu, LLC (BH&P) is a personal injury law firm that submitted a records request to Kennedy Hospitals on behalf of a prospective client.

In response to the request, MRO sent BH&P an invoice for $204.19 for the records. The invoice contained an arbitration clause.

BH&P filed a complaint on behalf of itself and a putative class, alleging that MRO overcharged BH&P and other records requesters. According to BH&P, patients and their authorized agents are legally entitled to obtain their medical records, and health care providers may only charge a cost-based fee. BH&P alleged that MRO's per page fee was unrelated to, and far exceeded, its actual costs in retrieving electronically stored medical records and transferring them onto digital media in violation of the New Jersey Consumer Fraud Act.

MRO moved to compel arbitration. The trial court denied the motion.

On appeal, MRO contended that BH&P accepted the arbitration provision, and waived any objection to its terms, by paying the invoice.

The appeals court noted that MRO had a pre-existing duty as the hospital’s agent to provide requested medical records. Under state and federal law, a patient has a qualified right to inspect or obtain copies of his medical records under the Health Insurance Portability and Accountability Act of 1996.

State law requires that a "reasonable fee" must be a "fee based on actual costs," and may not exceed established ceilings. A hospital may even be constrained to accept less than a cost-based fee, as the regulation sets a $200 maximum for an entire record requested by a patient or the patient's legally authorized representative, the court noted.

Applying basic principles of contract law, the court said consideration generally may not be furnished by fulfilling a pre-existing legal duty.

In this case, MRO's pre-existing duty arises from statute and regulation. “[I]n exchange for assent to the arbitration provision, MRO did not promise BH&P anything it was not already obliged to provide,” the appeals court said.

The court also refused to find that plaintiffs waived the right to object to arbitration. “The purported waiver was the product of a threat to withhold the requested medical records for an indeterminate period of time while the dispute was referred to arbitration,” the appeals court observed.

Tax and Nonprofit

U.S. Court in Florida Hands Hospital Victory on Medical Resident FICA Claims

The U.S. District Court for the Middle District of Florida dismissed with prejudice October 21 a former medical resident's claims against his hospital employer for allegedly breaching its fiduciary duty related to Federal Insurance Contributions Act (FICA) refunds. Dr. Bryan Reuss, who currently is employed by Orlando Health, Inc as a surgeon, worked at the hospital as a medical resident during the relevant time period—July 1, 2000 to June 30, 2005. During his residency, the hospital withheld FICA taxes from Reuss' wages in accordance with the requirements of the Internal Revenue Service (IRS).

In 2004, after some confusion as to whether medical residents are subject to the FICA tax, the IRS issued a new regulation providing that an employee who performs services of a "full-time employee" is not a "student" exempt from FICA taxation, essentially clarifying that medical residents are subject to the FICA tax.

Despite the 2004 regulation, in 2010, the IRS decided that it would honor claims for FICA tax refunds filed before April 1, 2005 on behalf of medical residents under the student exception.

Many hospitals, including the hospital here, filed so-called “protective FICA tax refund claims” in case the IRS decided to change its policy and classify medical residents as students. The hospital filed a protective FICA tax refund claim in 2004 on behalf of itself and its medical residents for FICA taxes paid in the year 2000, but it did not file protective claims for itself or its residents for the years 2001-2005.

Reuss sued the hospital, claiming it breached a fiduciary duty by failing to either file a FICA tax refund claim on behalf of him and others for 2001-2005 or advise them of their opportunity to seek a FICA tax refund.

The court found no fiduciary duty existed between the hospital and Reuss that would require the hospital to file FICA tax refund claims on Reuss' behalf or to notify him of the refund opportunity, noting the cases he cited were “clearly distinguishable.”

The court also found Reuss' claims time-barred. Reuss' cause of action for breach of fiduciary duty accrued, at the latest, on April 16, 2009, when he was no longer able to file for a FICA tax refund claim for the year 2005.

“Generally speaking, a request for a FICA tax refund from the IRS must be filed within three years from the time that the employer filed its quarterly federal tax return,” the court said. Because Reuss filed his complaint on May 18, 2015—more than four years after April 16, 2009—his claims are time-barred.

In addition, the court said because “Reuss's claim is, at its core, a claim for a tax refund” it is also preempted by 26 U.S.C. § 7422, which provides for civil actions for tax refunds.


Illinois Appeals Court Strikes Down Statutory Hospital Property Tax Exemption
An Illinois statute that provides a property tax exemption for hospitals violates the state’s constitution because it doesn’t require that the property be used “exclusively” for charitable purposes, a state appeals court ruled January 5. At issue in the case was Section 15-86 of the Property Tax Code, which provides a property tax exemption for hospitals whose total amount of charity care (services and activities) equals or exceeds their estimated property tax liability in a given year.

The state legislature enacted Section 15-86 in 2012 following the Illinois Supreme Court’s high-profile decision in Provena Covenant Med. Ctr. v. Department of Revenue, No. 107328 (Ill. Mar. 18, 2010), which held Provena failed to show it qualified for either the charitable or religious exemption to the state property tax.

In this case, Carle Foundation Hospital sought to claim an exemption retroactively under Section 15-86 on four parcels of property from 2004 through 2011.

A trial court held Section 15-86 applied to the hospital’s claims of exemption and granted summary judgment in its favor. State and local taxing authorities, including the Illinois Department of Revenue, appealed that decision.

The Illinois Appellate Court, Fourth District, reversed, finding Section 15-86 was unconstitutional. Specifically, the appeals court cited Article IX, Section 6, of the Illinois Constitution, which provides: “The General Assembly by law may exempt from taxation only . . . property used exclusively . . . [for] charitable purposes.”

The appeals court held Section 15-86 was facially unconstitutional because it provided a charitable exemption to hospitals without requiring an “exclusively charitable use of the property” as specified in Article IX, Section 6.

Although taking pains to avoid a constitutional question, the appeals court found Section 15-86 invalid “because it purports to grant a charitable exemption on the basis of an unconstitutional criterion, i.e., providing services or subsidies equal in value to the estimated property tax liability . . . without requiring that the subject property be ‘used exclusively . . . for charitable purposes.’”

According to the appeals court, Section 15-86 didn’t require any charitable use of the property at all. “Under section 15-86, a hospital entity can obtain a charitable exemption simply by paying subsidies to community clinics . . . or by paying subsidies to the state or local government.” But under Article IX, Section 6, “[a] property owner cannot buy a charitable exemption,” the appeals court said. Rather, the property itself must be used exclusively for charitable purposes.

Ohio Supreme Court Says Taxing Board Must Consider Whether Lessee Qualifies for Charitable-Use Exception

The Ohio Supreme Court reversed and remanded February 16 a Board of Tax Appeals (BTA) decision granting a charitable-use exemption to property taxes to a facility in Adams County, OH that provides dialysis services. While upholding the BTA’s decision that property owner—Rural Health Collaborative of Southern Ohio, Inc.—was a charitable institution, the high court found the BTA failed to fully analyze whether the Dialysis Clinic, Inc., which was leasing the property, qualified for a charitable-use exception under the relevant statute, Ohio Rev. Code. § 5709.121.

Rural Health is comprised of several nonprofit hospitals and a nonprofit organization that provides physician services to underserved areas in Ohio. Rural Health has no dedicated staff; its directors
and the staff of the members carry out its activities, which include applying for grant funding to supply free services.

Rural Health owns the property at issue, which Dialysis Clinic, Inc. (DCI) leases to provide dialysis services.

According to DCI’s indigency policy, the dialysis services it provides are “not a charity or gift to patients” and it retains the rights to refuse to admit or treat patients who are unable to pay. DCI said the policy stems from Medicare requirements prohibiting the waiver of co-insurance. In practice, DCI said, patients who are unable to pay are not turned away.

Rural Health sought a property tax exemption in October 2006. Relying on a previous Ohio Supreme Court opinion, Dialysis Clinic, Inc. v. Levin, No. 2010-OHIO-5071 (Ohio Oct. 26, 2010), the commissioner denied the exemption, citing the anti-charity language of DCI’s indigency policy. In Dialysis Clinic, the Ohio Supreme Court held DCI was not entitled to a charitable-use property tax exemption for one of its facilities.

The BTA reversed, saying under Ohio Rev. Code § 5709.121(A)(2), which applies to leased property, the instant matter was distinguishable from the Dialysis Clinic decision because the question here was whether Rural Health, as the owner of the property, was a charitable institution, not whether DCI, as the lessee, was.

Specifically, Section 5709.121(A) provides that real property belonging to a charitable institution is considered to be used exclusively for charitable purposes if it (1) is used by the institution “or by one or more other such institutions . . . under a lease . . . for charitable purposes” or (2) “is made available under the direction or control of such institution . . . for use in furtherance of or incidental to its charitable . . . purposes and not without the view to profit.”

The high court found the BTA did not abuse its discretion in determining that Rural Health was a charitable institution.

But the high court said the BTA erred in applying Section 5709.121(A)(2) to grant the exemption, because there was no evidence that Rural Health exerted any direction or control over DCI.

At the same time, the high court refused to rule out that an exemption could still be had under Section 5709.121(A)(1). On remand, the BTA should consider whether DCI, as lessee, could qualify as a charitable institution and whether DCI’s provision of services onsite qualified as charitable.

The tax commissioner argued that the Dialysis Clinic case foreclosed any argument that DCI was a charitable institution, but the high court disagreed.

The high court’s ruling in Dialysis Clinic “merely affirmed the BTA’s finding of fact, the BTA was free to evaluate the evidence in the present case and make a fresh determination whether DCI could qualify as a charitable institution for purposes of 5709.121(A)(1).”