CHAPTER 1

YEAR IN REVIEW

John E. Steiner, Jr., Esq.
Daniel J. Avants
Michelle Garvey, M.Ed.
Edgar T. Staren
Joseph Van Leer

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§ 1.01 ANTITRUST

[A] Reverse Patent Settlements

Pharmaceutical patents protect the significant research and development investments companies make every year. Because patents prevent competitors from developing "generic" drugs that are later sold for a cheaper price, pharmaceutical companies earn higher profits. Generic drugs are the bioequivalent of brand-name drugs and require considerably less investment. The public can benefit from generic drugs because essential pharmaceuticals are then available to the general population at a more affordable price. Ideally, there is a proper balance between the public interest and incentivizing innovation.

In 2004, the Hatch-Waxman Amendments[1] to the federal Food, Drug, and Cosmetic Act of 1938 sought to do just that by providing a framework for patent litigation. The legislation allows generic companies to submit abbreviated new drug applications (ANDAs) in order to bring bioequivalent drugs to market. As part of the ANDA, the generic company must certify that (1) the branded manufacturer did not file the required patent information, (2) the patent expired, (3) the patent will expire, or (4) the patent is invalid or not infringed.[2] If a generic company alleges, as part of the ANDA, that a patent is invalid or not infringed, the branded company must file suit within 45 days of receiving notice. Upon filing suit, the Food and Drug Administration (FDA) stays approval of the generic version for 30 months, unless the FDA finds the branded patent invalid or not infringed or the patent expires.[3] Parties often resolve these suits through patent settlements that set a market entry date for the generic drug and schedule payments from the branded manufacturer to the generic. These payments are called "reverse payments."

The reverse payments associated with pharmaceutical patent settlements are debated extensively among those in the antitrust community. Some antitrust scholars believe that these payments are a disguised method of delaying entry of a generic, less costly drug. Put another way, companies that have a monopoly on a particular drug are paying another company to refrain from obtaining a license to sell that drug. On its face this appears problematic, but patents should, and do, protect innovation for a reasonable period of time. Accordingly, many antitrust scholars contend that the settlements actually enable generic drugs to enter the market quicker. Many circuits agree, commonly upholding reverse payment settlements.[4]

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[1] Drug, Price, Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[2] 21 U.S.C. § 355(j)(2)(A)(vii) (2009).

[3] 21 U.S.C. § 355(j)(2)(A)(vii).

[4] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1060 (11th Cir. 2005); *In re* Ciproflaxin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1331 (Fed. Cir. 2008); Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294, 1304, 1306-07, 1309, 1311-12 (11th Cir. 2003); *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 386 (2d Cir. 2005).

The United States District Court for the Northern District of Georgia recently did so. Solvay (branded company) owned the pharmaceutical patent on AndroGel, a prescription gel used to treat men with low levels of testosterone.[5] The patent was set to expire in August 2020. In May 2003, two companies (generic companies) submitted ANDAs for a generic version of AndroGel. Again, ANDAs request the approval of a bioequivalent to a previously approved drug, enabling companies to rely on that drug's initial FDA approval.[6] Thus, the branded company responded to the ANDAs by filing patent infringement actions against the two companies. Because the branded company timely filed, the FDA stayed approval of the ANDAs for 30 months.

Before the court decided the infringement actions, the branded and the generic companies settled. The branded company agreed to dismiss the infringement action, and the generic companies agreed not to market generic AndroGel for nearly seven years. Additionally, the branded company agreed to share profits with the companies. In response to the settlement, the Federal Trade Commission (FTC) and individual consumers filed a class action suit alleging violation of the federal antitrust laws.[7]

The court examined (1) the scope of the patent's exclusionary potential, (2) whether the agreements exceeded that scope, and (3) the resulting anticompetitive effects.[8] The court found that the settlements did not exceed the scope of the patent because they only excluded generic AndroGel, the exclusion was five years less than the patent, and it applied only to the settling companies. Thus, there was no antitrust violation.[9] This decision illustrates the continued support for reverse settlements, with the rationale that they potentially allow market entry prior to patent expiration; however, the FTC continues its opposition to such settlements.

§ 1.02 TORT REFORM

The installment of statutory limitations on malpractice damages is one of the more disputed practices in tort reform. Statutory malpractice caps are currently the most direct method of limiting frivolous lawsuits brought against physicians. They attempt to reduce malpractice insurance costs, which are passed on to consumers in the form of higher health care rates. These statutes generally limit the amount of damages awarded but vary widely. Some cap non-economic damages only, while others limit all damages. Some statutes are even applied differently depending on whether the defendant is a physician or a provider.

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[5] *In re* Androgel Antitrust Litig., __ F. Supp. 2d __, 2010 WL 668291 (N.D. Ga. 2010).

[6] *In re* Androgel, __ F. Supp. 2d __, 2010 WL 668291, *2.

[7] *In re* Androgel, __ F. Supp. 2d __, 2010 WL 668291, *4.

[8] *In re* Androgel, __ F. Supp. 2d __, 2010 WL 668291, *5.

[9] *In re* Androgel, __ F. Supp. 2d __, 2010 WL 668291, *7.

[A] Illinois Supreme Court Strikes Down Cap on Non-Economic Damages

In early 2010, the Illinois Supreme Court, in a 4-2 decision, struck down a legislative cap on non-economic malpractice damages.[10] The statute, Public Act 94-677, imposed a $500,000 cap on claims against physicians and a $1,000,000 cap on claims against hospitals.[11]

The case stemmed from numerous permanent injuries to Frances Lebron's baby, Abigaile, during delivery.[12] In 2006, Lebron, on behalf of her daughter, filed a medical malpractice and declaratory judgment action in the Cook County Circuit Court against the defendants, Gottlieb Memorial Hospital, Inc., the delivering physician, and a registered nurse. In addition to the malpractice claims, the plaintiffs sought a judicial determination of their rights with respect to the legislative cap on non-economic damages. The plaintiffs alleged that the limitation on damages violated the separation of powers clause in the Illinois Constitution[13] by permitting the legislature to encroach on the judiciary's authority under the doctrine of remittitur.

[1] Illinois Tort Reform History

Historically, Illinois courts have been reluctant to accept tort reform through damage limitations. The Illinois judiciary has struck down three attempts to limit damages. The first came after the General Assembly passed Illinois Public Act 79-960, which capped compensatory damages in medical malpractice cases at $500,000, in 1973.[14] The statute also required a medical review panel of one practicing attorney, one practicing physician, and a circuit court judge to preside over a nonbinding hearing after a plaintiff filed a medical malpractice panel. The Illinois Supreme Court struck down the law two years later.[15] It found that the cap violated the special legislation section of the Illinois Constitution because it arbitrarily classified and unreasonably discriminated against victims of serious medical malpractice injuries while placing special privilege on victims with minor injuries.[16] The court also found that the malpractice review board performed an inherently judicial function and violated the right to trial by jury.

Nevertheless, the General Assembly attempted to enact comprehensive legislation again with Illinois Public Act 89-7. At the crux of this legislation was another $500,000 cap on non-economic damages. The reform also removed joint and several liability and limited punitive damages to three times economic damages. Two years later, the Illinois Supreme Court struck down the law in *Best v.*

[10] Lebron v. Gottlieb, 930 N.E.2d 895 (Ill. 2010).
[11] 735 ILCS 5/2-1706.5 (West 2008).
[12] *Lebron*, __ N.E.2d __, *1.
[13] Ill. Const. 1970, art. II, § 1.
[14] Ill. Rev. Stat. 1975, ch. 73, par. 1013(a); Or. Public Act 79-960 (1975).
[15] Wright v. Central Du Page Hosp. Ass'n, 347 N.E.2d 736 (Ill. 1976).
[16] *Wright*, 347 N.E.2d 736, 741.

Taylor Machine Works.[17] As in *Wright v. Central Du Page Hospital Association*, the court found that the cap violated the special legislation clause by discriminating against those most seriously injured. It also found that the law violated the separation of powers by permitting the legislature to reduce excessive awards, which was a role typically reserved for the judiciary through remittitur. Remittitur is "the process a court requires either that the case be retried, or that the damages awarded by the jury be reduced."[18] The court struck down the Act in its entirety because the invalid provisions of the Act were integral to the statute and could not be independently severed.

The legislature attempted once more to enact comprehensive tort reform through Illinois Public Act 94-677, which did not last much longer than other attempts. On November 13, 2007, the Circuit Court of Cook County declared the Act unconstitutional. The circuit court determined that, like *Best*, the statutory cap on non-economic damages operated as a legislative remittitur in violation of the separation of powers clause.[19] The defendants appealed directly to the Illinois Supreme Court pursuant to Rule 302.[20] Two years later, the Illinois Supreme Court handed down its decision, once again striking down a cap on non-economic damages.[21]

[2] *Lebron* Decision

For a fourth time, the Illinois Supreme Court found that the statute's limitation on damages violated the separation of powers clause because it functioned as a legislative remittitur.[22] The court relied heavily on the analysis in *Best*, which explained that the purpose of the separation of powers clause "is to ensure that the whole power of two or more branches of government shall not reside in the same hands."[23] Although the doctrine of remittitur has no constitutional basis, Illinois courts have employed it for more than a century.[24] In *Best*, the court reasoned that a cap on damages disregards the careful determinations made by a jury because it is mandatory.

The defendants in *Lebron* argued that the separation of powers analysis in *Best* did not apply because it was unnecessary to the disposition of the case; thus, it was *dicta*.[25] Although the court conceded that the discussion was *dictum*, it found that it was judicial *dictum*, which is an expression of opinion upon a point in a case argued by the counsel and deliberately passed upon by the court, though not essential to the disposition of the case. A judicial *dictum* is entitled to much weight and should be followed unless found to be erroneous.[26] Thus, the court relied upon *Best* in its separation of powers analysis.

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[17] 689 N.E.2d 1057 (Ill. 1997).
[18] Blacks Law Dictionary (8th ed. 2004).
[19] Lebron v. Gottlieb, 2007 WL 3390918 (Ill. Cir. 2007).
[20] Ill. Sup. Ct. R. 302(a).
[21] *Lebron*, __ N.E.2d __, *21.
[22] *Lebron*, __ N.E.2d __, *18.
[23] *Best*, 689 N.E.2d 1057, 1078.
[24] *Lebron*, __ N.E.2d __, 2010 WL 375190, *7, *32.
[25] *Lebron*, __ N.E.2d __, 2010 WL 375190, *8.
[26] *Lebron*, __ N.E.2d __, 2010 WL 375190, *8.

Additionally, the defendants argued that Illinois Public Act 94-677 was considerably less broad than that at issue in *Best*. Although the court agreed that the statute was not nearly as broad, it found that the cap's encroachment upon the judiciary's inherent power was analogous to that in *Best*.[27] The court reasoned that the cap acted as a legislative remittitur because it encroached upon the judicial function by requiring courts to override the jury's deliberative process and reduce any non-economic damages in excess of the statutory cap, regardless of *the particular facts and circumstances*.[28] Justice Karmeier's dissent strongly opposes the court's application of the doctrine of remittitur as an essential component of the judicial power granted by the Illinois Constitution of 1970.[29] He disagrees that caps on damages are the equivalent of a remittitur because a reduction of an award on the basis that it exceeds a cap does not act as a substitution of the jury but merely determines that a higher award is not permitted by law.

Furthermore, the court rejected the defendants' arguments that the statute was rationally related to a legitimate government interest and that it did not burden one class of plaintiffs because such inquiries are not relevant to separation of powers analysis. The court determined that the key question is whether the statute unduly encroaches on the judiciary's "sphere of authority."[30] The rational basis test and the potential burden on a particular group are not part of the determination.

Finally, the defendants argued that it was within the legislature's power to repeal or change the common law, as it did here. Although the court conceded that point, it noted that the legislature must exercise those changes within constitutional bounds, which it failed to do in this case. The court distinguished precedents limiting or prohibiting punitive damages. It reasoned that, unlike the cap on non-economic damages, punitive damages do not recompense an individual, and any act barring punitive damages merely establishes a public policy that, in certain cases, such damages should not be awarded.

Interestingly enough, the court declined to comment on the constitutionality of similar statutes limiting common law liability. Nevertheless, it did distinguish the Innkeeper Protection Act, which limits a hotel's liability for damage or loss to guest property because it allows the parties to contract around the statutory limit.[31] Although potentially unintended, this may indicate a willingness to uphold statutes that allow certain victims of malpractice to contract around the limitation on damages.

In concluding its opinion, the court noted that although the entire Act was struck down because it contained an inseverability provision, the legislature is free to reenact the provisions not addressed by the court. It remains to be seen

[27] *Lebron*, __ N.E.2d __, 2010 WL 375190, *10.
[28] *Lebron*, __ N.E.2d __, 2010 WL 375190, *10.
[29] *Lebron*, __ N.E.2d __, 2010 WL 375190, *33.
[30] *Lebron*, __ N.E.2d __, 2010 WL 375190, *11.
[31] *Lebron*, __ N.E.2d __, 2010 WL 375190, *16.

whether tort reform that includes a cap on damages will ever hold in Illinois, but it appears unlikely with its delicate past.

[B] *Estate of McCall v. United States*[32]

This case arose after the death of a mother (Michelle Evette McCall), following the delivery of her son, while in the care of the U.S. Air Force. Her estate filed an action against the United States, pursuant to the Federal Tort Claims Act.[33] Among their claims, the plaintiffs challenged the constitutionality of Florida's cap on non-economic damages in medical malpractice actions.[34] Florida law limits the amount of non-economic damages to $500,000 per claimant but allows claimants left in a permanent vegetative state to receive non-economic damages up to $1,000,000. Also, damages recoverable by all claimants may not exceed $1,000,000 in the aggregate. Plaintiffs claimed that the statue was unconstitutional because it violated the equal protection clause, the right of access to the courts, and the right to fair compensation, and the statutes acted as a legislative remittitur.

Unlike the court in *Lebron*, the court here rejected the plaintiffs' claim that the cap was unconstitutional under the separation of powers because it acted as a legislative remittitur.[35] The court found that limiting the amount of non-economic damages available in malpractice actions does not equate to directing the outcome of the case.[36] The statute still permits courts to grant remittitur if appropriate.

Additionally, plaintiffs argued that the non-economic damages cap violated their right to fair compensation. As listed in the Florida Constitution, the right to fair compensation provides that in medical malpractice claims where there is a contingent legal fee, the plaintiff may receive no less than 70 percent of the first $250,000 in all damages received and 90 percent of all damages in excess of $250,000.[37] Plaintiffs argued that the provision entitled them to the specified percentages of all damages available and that the cap on damages, therefore, was unconstitutional.[38] However, proceeding with the presumption that a statute is constitutional, the court rejected the plaintiffs' argument because a plain reading shows that the provision is a restriction on the collectable amount of attorney's fees rather than a definition of what amount of damages are recoverable.[39] Also, the fact that the statute was in place prior to passage of the fair compensation provision led the court to believe that had the Florida Supreme Court addressed the case, it would uphold the cap.[40]

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[32] 663 F. Supp. 2d 1276, 1296 (N.D. Fla. 2009).

[33] Federal Tort Claims Act, 28 U.S.C. § 1346(b) (2010).

[34] *See* Fla. Stat. § 766.118.

[35] *Estate of McCall*, 663 F. Supp. 2d 1276, 1307.

[36] *Estate of McCall*, 663 F. Supp. 2d 1276, 1297.

[37] Fla. Const. art. I, § 26(a).

[38] *Estate of McCall*, 663 F. Supp. 2d 1276, 1297.

[39] *Estate of McCall*, 663 F. Supp. 2d 1276, 1298.

[40] *Estate of McCall*, 663 F. Supp. 2d 1276, 1298.

Plaintiffs also claimed that the cap violated their right to access the courts, as guaranteed by the Florida Constitution.[41] The legislature may abolish the right to access the courts, which existed prior to adoption of the state constitution, only "upon demonstration of (1) a reasonable alternative to protect the right to redress for injuries or (2) a legislative showing of both an overpowering public necessity for the abolishment of the right and that no alternative method of meeting the public necessity can be shown."[42] The legislature failed the first prong because there is no reasonable alternative to protect plaintiffs with non-economic damages exceeding the cap. It did, however, satisfy the second prong by showing extensive legislative findings as to the need for a cap on non-economic damages. The court gave these findings substantial deference, reasoning that policy decisions are best left to the legislature.

The plaintiffs further argued that the cap on non-economic damages violated the equal protection clause of both the U.S. Constitution[43] and the Florida Constitution. Equal protection requires that persons similarly situated be treated similarly. The government has broad discretion to make classifications in legislation; however, in doing so, it may discriminate against a particular class. Here, the court reviewed the statute under the rational basis test because the statute did not involve a suspect classification (e.g., race, nationality) or a fundamental right.[44] The rational basis test requires a statute to serve a legitimate governmental purpose and that the legislature reasonably believes the challenged classification would promote that purpose. The court found that the cap was rationally related to the legislative purpose of reducing malpractice premiums and making Florida more attractive to physicians. Accordingly, because the court rejected the plaintiffs' constitutional arguments, it denied the motion for partial judgment.

[C] *Atlanta Oculoplastic Surgery, P.C. v. Nestlehutt*[45]

On March 22, 2010, the Georgia Supreme Court found that non-economic damages caps in OCGA § 51-13-1 violated the constitutional right to trial by jury.[46] The case stemmed from a malpractice suit brought by the plaintiff and her husband against the attending surgeon. Complications arose after surgery, resulting in Nestlehutt's permanent disfigurement. The trial court returned a verdict of $1,265,000, $1,150,000 of which was for non-economic damages. The statute would have reduced the non-economic damages to the statutory limit of $350,000. As a result, the plaintiffs moved to have it declared unconstitutional because the cap violated the Georgia Constitution's guarantee of the right to trial

[41] Fla. Const. art. I, § 21.

[42] *Estate of McCall*, 663 F. Supp. 2d 1276, 1299.

[43] U.S. Const. amend. XIV; Fla. Const. art. I, § 2.

[44] *See Estate of McCall*, 663 F. Supp. 2d 1276, 1303.

[45] No. S09A1432, 2010 WL 1004996 (slip copy, Ga. Mar. 22, 2010).

[46] *Atlanta Oculoplastic Surgery*, No. S09A1432, 2010 WL 1004996.

by jury. The trial court granted the motion and entered judgment for the plaintiffs in the full amount awarded by the jury. The defendants appealed.

Typically, the Constitution guarantees such a right only with respect to cases in which the right to trial by jury existed at common law. This includes medical malpractice cases. The court reasoned that this right applies to damage caps because the determination of damages rests "peculiarly within the province of the jury."[47] Accordingly, the court found that the cap undermined the jury's basic function as a finder of fact by requiring a court to reduce non-economic damages that exceed the statutory limit. Thus, it declared the cap unconstitutional. Also, the decision applies retroactively and overturns awards previously reduced by the cap.

§ 1.03 ANTI-KICKBACK STATUTE

[A] The Patient Protection and Affordable Care Act Modifies the Anti-Kickback Statute

The Patient Protection and Affordable Care Act (PPACA) of 2010 modifies the knowledge requirement under the federal anti-kickback statute,[48] which some federal courts interpreted as requiring specific knowledge that the activity violated the anti-kickback statute. Such a strict interpretation made obtaining a conviction very difficult. PPACA states that "a person need not have actual knowledge of [the anti-kickback statute] or specific intent to commit a violation of [the anti-kickback statute]."[49] PPACA also clarified that an anti-kickback statute violation can result in a False Claims Act violation.[50]

[B] Hospital–Physician Jointly Owned Ambulatory Surgical Centers

The anti-kickback statute provides a specific safe harbor for any payment that is a return on investment from ownership in ambulatory surgical centers (ASCs).[51] The safe harbor applies to four types of ASCs: (1) surgeon-owned, (2) single specialty, (3) multi-specialty, and (4) hospital–physician ASCs. Brief analysis of the hospital–physician safe harbor is appropriate for the purposes of the case discussed below.

The safe harbor's requirements include:

(1) At least one investor must be a hospital, and all of the remaining investors must be physicians who meet the requirements of the surgeon-owned ASC, single-specialty ASC, or multi-specialty ASC.

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[47] *Atlanta Oculoplastic Surgery*, No. S09A1432, 2010 WL 1004996, *3.

[48] 42 U.S.C. § 1320a-7b (2010).

[49] Pub. L. No. 111-148, 124 Stat. 119, Section 6402(f).

[50] Pub. L. No. 111-148, 124 Stat. 119, Section 6402(f).

[51] 42 C.F.R. § 1001.952(r).

(2) The investment terms must not be related to previous or expected volume of referrals to be generated from investor.

(3) The surgeon/investor must not receive loaned funds or guarantees from the entity or other investors.

(4) The return on investment must be directly proportional to the amount of capital investment.

(5) All ancillary services performed at the ASC must be directly and intricately related to the primary procedure performed at the ASC.

(6) The entity and all surgeons/investors must treat Medicare/Medicaid patients in a nondiscriminatory manner.

(7) The ASC may not use space or equipment owned by the hospital unless such space/equipment meets the Equipment/Leased Space Safe Harbor.

(8) The hospital investor may not include any cost related to the ASC on its cost report or any other claim for payment from Medicare/Medicaid.

(9) The *hospital may not be in a position* to make or influence referrals directly or indirectly to any investor or the ASC.[52]

[1] Significance of Opinion

On July 29, 2009, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released Advisory Opinion No. 09-09[53] addressing the co-ownership of an ASC by a hospital and seven orthopedic surgeons. The OIG found that the arrangement did not violate the anti-kickback statute,[54] although it did not qualify for the ASC safe harbor.

Under the proposed arrangement, the surgeons would own an equal portion of a limited liability company. The hospital would develop a single hospital operating room bordering the ASC. Then the parties would establish a new entity to operate a two-room ASC and contribute their respective assets, plus any cash necessary to equalize values, to the entity.

Although the OIG determined that the entity would not meet the relevant safe harbor, it found that the agreement included sufficient safeguards to minimize the likelihood of fraud and abuse. The hospital could not meet the safe harbor requirements because it was in a position to make or influence referrals directly or indirectly to the ASC;[55] however, the hospital certified that employees would not refer patients to the ASC, would not track referrals, and would refrain from any

[52] 42 C.F.R. § 1001.952(r)(4) (emphasis added).
[53] HHS, OIG, Adv. Op. No. 09-09.
[54] 42 U.S.C. § 1320a-7b (2010).
[55] 42 C.F.R. § 1001.952 (r)(4)(viii) (2010).

action encouraging its medical staff to refer to the ASC.[56] These safeguards sufficiently constrained the ability of the hospital to direct referrals to the ASC.

Additionally, although the safe harbor requires physicians to hold their investment interests in the ASC directly or through a group practice, the use of a "pass through" entity (LLC) to hold the physicians' interest reduced the OIG's concern that an intermediate investment entity would be used to redirect revenues to reward referrals. Furthermore, the fact that both the surgeon group and the hospital would receive a proportional interest based on their respective capital investments reduced the likelihood that physicians were rewarded for their referrals through disproportional investment interests.[57] Also, valuation of the assets contributed to the ASC would not take into account past or anticipated referrals but would be based solely on the tangible assets. Accordingly, the OIG found that although the joint venture failed to meet the safe harbor, it involved minimal risk of abuse because it contained sufficient safeguards.

As a result, this opinion provides some guidance regarding structuring hospital–physician joint ventures in compliance with relevant fraud and abuse laws. The emphasis on taking into account the valuation of the tangible assets rather than intangible assets demonstrates the OIG's continued view that payments for intangible assets are easily disguised as payments to induce referrals.

§ 1.04 STARK LAW

[A] Whole Hospital Exception

The Stark law prohibits physicians from referring Medicare and Medicaid patients to any entity with which the physician (or any immediate family member) has a financial relationship, unless an exception applies.[58] The "whole hospital" exception permits physician ownership of a hospital as long as the physician owner (1) has an interest in the whole hospital, (2) is authorized to perform services at the hospital, and (3) is actually expected to perform the services.[59] Section 6001 of the PPACA changes this by prohibiting hospitals from increasing the total percentage of the total value of physician ownership interests.[60] The law, however, "grandfathers" in hospitals that have agreements in place prior to December 31, 2010. In addition, the PPACA enhances compliance requirements for grandfathered hospitals to ensure that physicians are *bona fide* owners of the hospital. These requirements include the following:

1. Each hospital must establish procedures that require referring or treating physician–owners to inform patients of ownership interests;

2. The hospital must publicly disclose physician ownership interests; and

[56] HHS, OIG, Adv. Op. No. 09-09 *4.
[57] HHS, OIG, Adv. Op. No. 09-09 *5.
[58] 42 U.S.C. § 1395nn *et seq.*
[59] 42 C.F.R. § 411.356(c).
[60] Pub. L. No. 111-148, 124 Stat. 119, Section 6001.

3. The hospital must disclose all ownership interests to the Centers for Medicare & Medicaid Services (CMS).

[B] Self-Referral Disclosure Changes

The PPACA also changes the rules that enable self-disclosure of violations of the Stark law[61] by requiring HHS to develop a self-referral disclosure protocol that allows providers to disclose Stark violations.

The PPACA permits HHS to reduce amounts due for violations by considering:

(1) the nature and extent of the improper or illegal practice;

(2) the timeliness of such self-disclosure;

(3) the cooperation in providing additional information related to the disclosure; and

(4) such other factors that the Secretary considers appropriate.[62]

Previously, providers could not disclose Stark law violations unless there were also anti-kickback statute violations.[63] Also, the OIG refused to settle any disclosed violation for less than $50,000. The change made by the PPACA allows significant enhancement of HHS responsibility regarding Stark violations and may increase its enforcement ability.

[C] In-Office Ancillary Services Changes

The PPACA also changes the requirements of the in-office ancillary services exception for self-referrals. Beginning on January 1, 2010, the law requires a physician referring a patient to the physician's own group practice or office for magnetic resonance imaging (MRI), positron emission tomography (PET), or computed tomography (CT) to inform the patient, in writing, that he or she may obtain services from a physician other than the referring physician.[64] Also, the referring physician must provide the patient with a list of providers furnishing the service in the area in which the patient resides. This change gives patients greater flexibility in receiving care from a physician that did not refer to his or her own practice.

§ 1.05 TAX EXEMPTION

The basis of tax exemption in favor of charitable organizations rests on the assumption that such organizations confer a benefit on the public and help relieve the burden of the government.[65]

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[61] 42 U.S.C. § 1395nn.

[62] Pub. L. No. 111-148, 124 Stat. 119, Section 6004(b).

[63] *See* HHS, David R. Levinson, Inspector General, An Open Letter to Health Care Providers (Mar. 24, 2009), *available at* <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> (last accessed July 2010).

[64] Pub. L. No. 111-148, 124 Stat. 119, Section 6003.

[65] Sch. of Domestic Arts & Sci. v. Carr, 153 N.E. 669, 671 (Ill. 1926).

There are a number of different standards used for granting health care entities tax exemptions. The federal standard, which applies to federal income taxation, embraces a "community benefit" model that does not require charity care to patients outside the emergency setting,[66] although this was not always the case. Revenue Ruling 69-545 shifted the federal standard from requiring charity care to a broader test of community benefit, enabling tax-exempt organizations to engage in a plethora of strategies to retain their tax-exempt status. This policy shift was largely due to the passage of Medicare and Medicaid legislation. Many exempt hospitals argued that there would be insufficient demand for charity care to meet the federal standard. Thus, the current federal standard employs a broader policy that simply requires hospitals to promote a community benefit. A community benefit can include maintaining a community board and an open medical staff, operating an emergency room, and treating Medicaid and Medicare patients.[67]

By contrast, Illinois adheres to one of the most restrictive standards to qualify for state and local tax-exempt status.[68] Tax-exempt organizations in Illinois must meet a certain level of charity to demonstrate a charitable purpose. Simply providing a necessary service to the community is insufficient. This standard affects state and local tax exemption, which is particularly important given the impact on property taxes. There is no explicit statutory standard for hospitals or health care facilities in Illinois, however. The Illinois Supreme Court instituted the state's first common law test in its 1968 decision in *Methodist Old Peoples Home v. Korzen*. The test states:

> (1) the institution bestows benefits upon an indefinite number of persons for their general welfare, or the benefits in some way reduce the burden on government; (2) the institution has no capital, capital stock, or shareholders and does not profit from the enterprise; (3) the funds of the institution are derived mainly from private and public charity and are held in trust for the purposes expressed in the charter; (4) charity is dispensed to all who need it and apply for it; (5) the institution puts no obstacles in the way of those seeking the charitable benefits; and (6) the primary use of the property is for charitable purposes.[69]

This test indicates that tax-exempt status rests largely on some kind of charitable program. However, establishing what constitutes charity care is no easy task, although most courts find that writing off bad debt does not represent charity care,[70] and even if it did, it is extremely difficult to measure. For example, many

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[66] *See* Rev. Rul. 69-545, 1969-2 C.B. 117 (1969).

[67] *See* Rev. Rul. 69-545, 1969-2 C.B. 118.

[68] *See, e.g.*, Methodist Old Peoples Home v. Korzen, 233 N.E.2d 537 (Ill. 1968).

[69] *Methodist Old Peoples Home*, 233 N.E.2d 537, 541-42; Eden Ret. Ctr., Inc. v. Dep't of Rev., 821 N.E.2d 248 (Ill. 2004) (listing the requirements in *Methodist Old Peoples Home*); Alivio Med. Ctr. v. Dep't of Rev., 702 N.E.2d 189, 193 (Ill. App. Ct. 1998).

[70] Highland Park Hosp. v. Dep't of Rev., 507 N.E.2d 1331, 1336 (Ill. App. Ct. 1987).

hospitals measure charity care using charges rather than costs. This inflates figures because health care charges are significantly higher than actual costs and reimbursement rates established by Medicare and Medicare and private payors.

The Illinois Supreme Court intensified scrutiny of tax-exempt status with its recent decision in *Provena Covenant Medical Center v. Department of Revenue*.[71] This leaves many organizations questioning the amount of charity care they provide and puts nearly every tax-exempt organization in Illinois at risk.

[A] *Provena Covenant Medical Center*

On March 18, 2010, the Illinois Supreme Court decided a case that significantly impacts tax exemption in Illinois and the United States. In a plurality decision, the court upheld the Illinois Department of Revenue's withdrawal of Provena Covenant Medical Center's property tax-exempt status.

The legislature may exempt property from taxation that is used for a charitable purpose.[72] Under Section 15-65 of the Property Tax Code,[73] the property in question must be *actually and exclusively* used for charitable purposes and owned by an institution of public charity. Historically, courts interpret "exclusively" organized and operated for charitable purposes as meaning "primarily."[74]

In applying the test set forth in *Methodist Old Peoples Home*, the court found that Provena met the first factor for determining whether an organization can be considered a charitable institution: it has no capital, capital stock, or shareholders. Provena also satisfied the fourth factor: it does not provide gain or profit in a private sense to any person connected with it. Nevertheless, the court found that Provena failed to meet the remaining factors.

[1] Source of Funds Analysis

The court found that Provena was not charitably owned. In this case, Provena failed to meet the source of funds provision in *Methodist Old Peoples Home*, which states that "the funds of the institution are derived mainly from private and public charity and are held in trust for the purposes expressed in the charter." The court noted that only $6,938 of Provena's overall revenue came from charitable donations. Provena derived the remainder from fees for patient care. This analysis may be the most indicative of the potential fate of tax-exempt health care organizations. In general, nonprofit hospitals receive less than 2 percent of revenues from charitable donations.[75] Prior to this case, most courts did not find failure to meet the source of funds criterion determinative of failing the *Methodist Old Peoples Home* test as a whole.[76] It appears this is no longer the case.

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[71] __N.E.2d __ , 2010 WL 966858 (slip copy, Ill. Mar. 18, 2010).

[72] Ill. Const., art. IX, § 6.

[73] 35 ILCS 200/15-65 (West 2002).

[74] Community Health Care, Inc. v. Ill. Dep't of Rev., 859 N.E.2d 1196 (Ill. App. Ct. 2006).

[75] John D. Colombo, *Hospital Property Tax Exemption in Illinois: Exploring the Policy Gaps*, 37 Loy. U. Chi. L.J. 493, 520 (2006).

[76] *See* Am. Coll. of Surgeons v. Korzen, 224 N.E.2d 7 (Ill. 1967).

[2] Charitable Care Analysis

The court in *Provena* did not end its analysis at this point, however. In fact, it established a more restrictive charitable care standard. Again, unlike the federal tax-exemption test, organizations in Illinois must demonstrate a certain level of charity care to qualify as tax-exempt organizations. Prior to this decision, no court had established a specific or minimum quantum of care requirement.

First, the court found not only that Provena provided a "de minimis"[77] amount of charity care but also that its charity care policy was essentially a last resort. Provena did not advertise the availability of charitable care at its facilities. Provena billed patients and referred unpaid bills to collection agencies. Only until the hospital determined that a patient had no insurance coverage and was not eligible for Medicare or Medicaid did it discount or waive charges. The court found this policy indistinguishable from the process through which for-profit institutions write off bad debt. Courts consistently reject this process as "the bestowal of charity within the meaning of [the Illinois property tax code]."[78] The fact that Provena gave discounts to only 302 of Provena's 110,000 patients bolstered this argument.[79] Discounts totaled $1,758,940 in charges ($831,724 in actual cost), a mere 0.723 percent of Provena's revenues. Again, the court found this de minimis.

Additionally, the court rejected the contention that charitable use should take into account Medicare and Medicaid shortfalls. Provena demonstrated that Medicare and Medicaid reimbursements were insufficient to cover the costs of care at Provena. In fact, in 2002, the shortfalls hit $10,523,367.[80] Nevertheless, the court noted that participation in Medicare and Medicaid is not mandatory; increases revenue, albeit at a discount; and enables qualification for favorable treatment under federal tax law.[81] The court also noted that Illinois courts have held that discounted care for Medicaid and Medicare patients is not considered charity. In fact, the court elaborated, saying that gifts must occur without consideration.[82]

[3] Relieving Burden of Government

Additionally, the court discussed that the reason behind exempting some property from taxes arises from the fact that the use of the property tends to lessen the burdens of government. It reasoned that each lost tax dollar equals less money that the government has to spend to meet obligations to the public directly. It is noteworthy that Provena stood to receive $1.1 million in tax benefits from the exemption. Although the court states that Illinois law has never required a dollar-for-dollar correlation, it appears to support a "matching" concept, e.g., providing charitable care equal to the value of the tax exemption. It rejected the argument that Provena lessens the burden of the local taxing body by providing

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[77] *Provena*, __ N.E.2d __, 2010 WL 966858, *14.
[78] *Provena*, __ N.E.2d __, 2010 WL 966858, *14.
[79] *Provena*, __ N.E.2d __, 2010 WL 966858, *5.
[80] *Provena*, __ N.E.2d __, 2010 WL 966858, *3.
[81] *Provena*, __ N.E.2d __, 2010 WL 966858, *16.
[82] *Provena*, __ N.E.2d __, 2010 WL 966858, *16.

valued health care services because providing services for value does not relieve a burden.

[4] Religious Exemption

The court also rejected Provena's claim that it qualified for the religious exemption because, although there was a religious component to its mission, advancing religion is not identified as its dominant purpose. Property tax exemption does not rest solely on the beliefs or motives of the owner but also on whether the building is used primarily for a religious purpose.[83] The record established that the primary purpose for the Provena property was to provide medical care to patients for a fee.

§ 1.06 EMPLOYEE RETIREMENT INCOME SECURITY ACT

[A] *Conkright v. Frommert*:[84] Reinforcing a Deferential Standard of Review

In this case, the U.S. Supreme Court addressed whether a benefits plan administrator's interpretation of a plan is entitled to deferential review where the administrator made a "single honest mistake" in administering and interpreting a plan. When courts use deferential review, they yield to the opinions of governmental or other agencies with unique expertise and authority. The Court found no error in the district court's refusal to defer to Xerox Corporation's interpretation of provisions in its pension plan. In reversing the Second Circuit, the Court held that "a single honest mistake in plan interpretation" does not justify stripping the administrator of deferential review in subsequent interpretations of the plan.[85] Using principles of trust law to shape its decision, the Court reinforced the basic points of other cases related to this issue: (1) that deferential review is to be applied and (2) that deferential review is necessary to balance employee rights on the one hand and employer-provided benefits on the other. The five justices joining in the majority decision agreed that deference promotes efficiency by encouraging resolution of benefits disputes through internal administrative proceedings rather than litigation.

Justice Breyer dissented, arguing that the majority was wrong in finding that courts are required to defer to a plan administrator's "second attempt" at interpreting plan documents, even after the court has determined that the administrator's first attempt was an abuse of discretion. He stated that the "one free honest mistake rule" is not feasible because it requires courts to determine what is "honest," encourages appeals, and delays proceedings.

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[83] *Provena*, __ N.E.2d __, 2010 WL 966858, *20.

[84] No. 08-810, __ S. Ct. __ , 2010 WL 1558979 (Apr. 20, 2010).

[85] *Conkright*, 2010 WL 1558979, *1.

Although this case involved the administration of a pension plan, it applies in a health benefits context as well since the standard of review does not depend on the type of plan at issue. The decision gives lower courts guidance after the Court's ambiguous ruling in *Metropolitan Life Insurance Co. v. Glenn*, a 2008 decision in which the Supreme Court held that courts should consider conflicts of interest when reviewing the administration of benefits plans.[86] Because *Glenn* did not provide any standards for review, the *Conkright* decision logically follows by indicating that courts must use the basic rules that govern benefits plans when reviewing administrative decisions.

[B] *Connecticut State Dental Association v. Anthem Health Plans, Inc.*:[87] Determining ERISA Preemption

In this case, the court determined whether ERISA completely preempted one or more of the plaintiffs' state law claims, causing the case to be heard in federal court. The plaintiffs, two dentists practicing in Connecticut, and the Connecticut State Dental Association (CSDA), filed separate complaints in Connecticut state court. The dentists' complaint alleged breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment, and violation of the Connecticut Unfair Trade Practices Act (CUTPA) that resulted in underpayment of dentists for services rendered. The CSDA's complaint alleged that the defendant, Anthem Health Plan, violated the CUTPA. The defendant removed the claims to federal court on the basis of ERISA preemption. The district court denied the motion to remand the case to state court, and the Eleventh Circuit found that ERISA completely preempts some portions of the dentists' state law claims but does not preempt the CSDA's state law claim.

ERISA's civil enforcement provision falls under § 502(a) of the statute, which has such "extraordinary" preemptive power that it "converts an ordinary state common law complaint into one stating a federal claim for the purposes of the well-pleaded complaint rule."[88] Thus, any cause of action within the scope of § 502(a) is removable to federal court. In this case, the Eleventh Circuit applied the two-part test from *Aetna Health, Inc. v. Davila* to determine whether ERISA preempted the state law claims.[89] The *Davila* test requires that (1) the plaintiff could have brought its claim under § 502(a) and (2) no other legal duty supports the plaintiff's claim.

In *Connecticut State Dental Association*, the court found that the dentists' claim was a hybrid claim, part within § 502(a) and part beyond the scope of ERISA. The court first noted that provider claims generally are not subject to complete preemption because health care providers are not considered "beneficiaries" or

[86] Metro. Life Ins. Co. v. Glenn, 554 U.S. 105, 128 S. Ct. 2343 (2008).
[87] 591 F.3d 1337 (11th Cir. 2009).
[88] Metro. Life Ins. Co. v. Taylor, 481 U.S. 58, 107 S. Ct. 1542, 1547 (1987).
[89] Aetna Health, Inc. v. Davila, 542 U.S. 200, 124 S. Ct. 2488 (2004).

"participants" under ERISA. Here, however, the court found that claims forms authorizing payment of dental benefits to the plaintiffs *were* sufficient to establish standing. The court determined that the dentists' claims implicated ERISA because they involved the "right of payment" (in addition to the "rate of payment") and improper denials and reductions of reimbursement services.[90] The court relied on the Fifth Circuit's reasoning in *Davila* that claims involving "rate of payment" are not preempted, while claims involving "right of payment" may be preempted.

In analyzing the second prong of the *Davila* test, the court found that the plaintiffs' claims strayed from the boundaries of the provider agreements into "ERISA territory" by asserting improper denials of medically necessary claims.[91] Thus, portions of the plaintiffs' claims arose under ERISA rather than any independent legal duty.

The court ultimately concluded that the dentists' state law claims were completely preempted by ERISA and that the action was properly removed to federal court. The court remanded the CSDA's complaint, finding that the state law claim on behalf of its members was not completely preempted because the trade association lacked standing to sue under ERISA.

The Eleventh Circuit's decision signals that trade associations such as the CSDA do not have standing to sue under ERISA if the claims asserted require the participation of individual members in the lawsuit. Moreover, the court's discussion of "rate of payment" and "right of payment" provides useful guidance for assessing ERISA preemption of health care provider claims.

[C] *Standard Insurance Co. v. Morrison*:[92] Challenging Discretionary Clauses

In *Standard Insurance Co. v. Morrison*, the U.S. Court of Appeals for the Ninth Circuit answered the question whether the state of Montana could prohibit insurers from including discretionary clauses in ERISA plans. Throughout 2008 and 2009, Montana and several other states stepped forward to ban discretionary clauses that allow ERISA plan administrators to gain deferential court review if participants file a lawsuit to challenge a claim denial. Some states prohibit discretionary clauses to allow courts to give de novo review to ERISA plan administrators' decisions.

In this case, the court held that ERISA does not bar states from prohibiting insurers from including "discretionary clauses" in insurance plans. Here, Morrison, the Montana state insurance commissioner denied Standard Insurance's application for approval of proposed disability insurance forms that contained discretionary clauses. The commissioner based his decision on Montana law,

[90] *Conn. State Dental Ass'n*, 591 F.3d 1337, 1349.

[91] *Conn. State Dental Ass'n*, 591 F.3d 1337, 1353.

[92] 584 F.3d 837, 840 (9th Cir. 2009).

which provides that the commissioner must disapprove of any insurance form that contains any "inconsistent, ambiguous, or misleading clauses or . . . conditions."[93] The plaintiff insurance company argued that ERISA preempted the commissioner's actions. The district court granted summary judgment, and the Ninth Circuit affirmed. Standard Insurance filed a petition asking the U.S. Supreme Court to review the Ninth Circuit's decision, but no action has been taken as of the time of publication.

The Ninth Circuit joins the U.S. Court of Appeals for the Sixth Circuit in holding that ERISA does not bar states from banning discretionary clauses in insurance documents. The rulings are significant for ERISA plan administrators who often depend on discretionary clauses to gain deferential court review for their decisions denying claims.

§ 1.07 MANAGED CARE

[A] *Thomas v. Blue Cross & Blue Shield Association*:[94] Barring Physician's Claims by Settlement of Class Action Lawsuit

This case from the U.S. Court of Appeals for the Eleventh Circuit addressed whether a prior settlement of a class action lawsuit, brought by physicians against a medical plan provider, bars a participating physician's individual lawsuit. In this case, physicians brought a class action lawsuit alleging that medical plan providers had engaged in a conspiracy to delay, reduce, and deny payments to them. The parties entered a settlement, and the physicians agreed to release the provider from all claims arising from the class action. A physician who was a member of the class then sued the provider for claims including tortious interference with contractual relationships, tortious interference with prospective economic advantage, and defamation. The provider moved to hold the physician in contempt of the injunction because his individual claims were within the scope of the settlement. The district court denied the provider's motion with respect to the tort claims but found that the physician's contract claim had been released in the settlement. The provider appealed, and the physician cross-appealed.

The Eleventh Circuit determined that it lacked jurisdiction over the physician's cross-appeal because the order instructing the physician to withdraw his claim was not a final order and was not subject to any exception allowing for jurisdiction. In addressing the provider's appeal, the court reasoned that the physician's individual allegations were related to matters in the class action. The physician's individual allegations asserted that the provider "engaged in practices to deny and delay payments . . . and that these actions caused [the physician] to lose existing patients as well as referral[s]."[95] The Eleventh Circuit reversed the trial court's decision and remanded the case for further proceedings. This decision reinforces the rule that class members who fail to opt out of a class

[93] *Standard Ins. Co.*, 584 F.3d 837, 840.
[94] 594 F.3d 814 (11th Cir. 2010).
[95] *Thomas*, 594 F.3d 814, 822.

action settlement are barred from raising future claims covered by matters in the settlement. Accordingly, physicians should consider carefully decisions to participate in class action settlements.

[B] *Northern Michigan Hospitals, Inc. v. Health Net Services, LLC*:[96] Requiring Plaintiffs to Exhaust Administrative Remedies Before Bringing Cases in Federal Court

In this case, the U.S. Court of Appeals for the Third Circuit decided whether four non-network participating providers could pursue breach of contract and improper reimbursement claims against two TRICARE program contractors prior to exhausting administrative remedies. The TRICARE program is a managed care program that covers active members of the uniformed services and their dependents. Here, Health Net and Triwest, two support contractors for the program, were responsible for underwriting the delivery of health services and establishing networks of health care providers to offer services to TRICARE beneficiaries. The plaintiff hospitals were non-network participating providers that claimed they were not adequately reimbursed for the use of their facilities.

The district court held that plaintiffs must exhaust administrative remedies prior to bringing cases in federal court because administrative review enables regulatory expertise and produces a detailed factual record for subsequent judicial review. On appeal, the hospitals argued that the district court erred because the issues raised in the complaint did not involve a factual dispute.

The Third Circuit upheld the district court, finding that the dispute involved factual issues concerning the nature of the facility charges. The court found that the real issue was "whether the hospitals are entitled to more money, because the regulations have not been properly applied to their claims for reimbursement."[97] Thus, the plaintiffs' legal claims required factual determinations that were proper for administrative review. The Third Circuit ultimately concluded that exhaustion of administrative remedies was appropriate because the plaintiffs did not clearly show that administrative review would be futile given the nature of their claim. This decision may prove persuasive for courts evaluating claims commonly raised under the administrative review process.

[C] *AlohaCare v. Hawaii, Department of Human Services*:[98] Rejecting Plaintiff's Right to Remedies Under § 1983 of the Civil Rights Act for Alleged Violation of Medicaid Act

In this case, the U.S. Court of Appeals for the Ninth Circuit addressed whether AlohaCare, a consortium of federally qualified health centers (FQHCs), could sue the state of Hawaii for Medicaid Act violations under 42 U.S.C. § 1983. In 2007, the Hawaii Department of Human Services (DHS) issued a request for proposals for qualified health care plans to provide managed care under QEXA,

[96] 344 Fed. App'x 731 (3d Cir. 2009).
[97] *N. Mich. Hosps.*, 344 Fed. App'x 731.
[98] 572 F.3d 740 (9th Cir. 2009).

an expanded version of the statewide managed care model. QEXA allows the state to contract with health maintenance organizations (HMOs) to provide health care coverage to populations outside the reach of Medicaid. AlohaCare submitted a proposal to provide managed care to Medicaid-eligible aged, blind, and disabled individuals. DHS awarded the contract to two other health plans, and AlohaCare protested that its proposal was not evaluated properly. DHS denied the protest, and AlohaCare filed a request for reconsideration with the State Procurement Office. Before the state responded, AlohaCare brought suit against DHS in federal court. AlohaCare argued that DHS violated five provisions of the Medicaid Act by "awarding contracts in violation of the statute's requirements for managed care organizations (MCOs)"; "failing to assure that the MCOs had capacity to serve the relevant population"; "providing rebates to those awarded contracts"; "imposing managed care on the under 19 population"; and "restricting the number of entities eligible for managed care contracts."[99]

The Ninth Circuit held that the Medicaid Act does not create rights that are enforceable under § 1983 of the Civil Rights Act. Although the Medicaid Act defines the term "Medicaid managed care organization" and outlines state reimbursement under the Medicaid program, it does not discuss the rights of FQHCs such as AlohaCare. According to the Supreme Court's decision in *Gonzaga*, lawsuits may be brought under § 1983 only when there is an underlying statute with "rights-creating" language.[100] Thus, there was no basis for AlohaCare's claim in this case. The court similarly rejected AlohaCare's argument that HHS regulations demonstrate that Congress intended to confer a right of eligibility on FQHCs and that AlohaCare had associational standing to assert the rights of its FQHC members. Therefore, the Medicaid Act did not confer a federal right to contract eligibility on AlohaCare that could be remedied under § 1983.

§ 1.08 HITECH ACT

The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted on February 17, 2009, as a part of the American Recovery and Reinvestment Act of 2009,[101] to promote the adoption and meaningful use of electronic health records (EHRs).[102] The Office of the National Coordinator (ONC) issued an interim final rule on December 30, 2009, with the purpose of setting standards, certification criteria, and implementation specifications with respect to Stage 1 of the meaningful use incentive program.[103] A public comment period followed, which ended on March 15, 2010.[104] CMS will release a final rule upon review of these comments.

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[99] *AlohaCare*, 572 F.3d 740, 744.

[100] Gonzaga Univ. v. Doe, 536 U.S. 273, 283 (2002).

[101] Pub. L. No. 111-5, 123 Stat. 115.

[102] Health Information Technology: Standards & Certification Interim Final Rule, 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).

[103] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).

[104] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).

There are currently 23 meaningful use criteria for hospitals and 25 criteria for eligible professionals (EPs).[105] Although subject to modification per the final requirements, the Stage 1 EHR meaningful use criteria should include the following:[106]

- Use computerized physician order entry (CPOE) (80 percent of orders for EPs, 10 percent of orders for hospitals);
- Implement drug-drug, drug-allergy, drug-formulary checks;
- Maintain active medication and allergy lists;
- Record demographics and vital signs;
- Implement five clinical decision support rules;
- Send reminders to patients for appointments and follow-up care;
- Provide patients with an electronic copy of their health records;
- Provide summary care record for each transition of care and referral; and
- Protect EHR technology through the implementation of appropriate measures.

These Stage 1 requirements become effective in 2011, at which point EPs and eligible hospitals will begin receiving incentive payments. For the first year of the program, hospitals and EPs need only demonstrate meaningful use of their EHRs for a 90-day period to qualify for an incentive payment in the 2011 payment year. Additionally, that period may be any 90 consecutive days beginning on October 1, 2010, the first day of the federal fiscal year. For hospitals, the 2011 payment year ends with the federal fiscal year on September 30, 2011; therefore, the last day a hospital may begin demonstrating meaningful use of EHRs is July 3, 2011.[107] For EPs, the 2011 payment year ends with the calendar year on December 31, 2011; therefore, the last day they may begin demonstrating meaningful use of EHRs is October 2, 2011.[108]

Beginning in 2012, and continuing through the duration of the program, hospitals and EPs must demonstrate meaningful use for the entire year (fiscal for hospitals and calendar for EPs).[109] Though not yet finalized, Stage 2 requirements will take effect in 2013, and Stage 3 requirements will take effect in 2015.[110]

There will be penalties for hospitals and EPs that fail to meet the meaningful use requirements. The Medicare fee schedule amount for services provided by an

[105] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).
[106] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).
[107] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).
[108] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).
[109] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).
[110] 75 Fed. Reg. 2015 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).

EP who was not a meaningful EHR user for the year will be reduced,[111] and there will be a market basket reduction for eligible hospitals.[112]

Throughout 2010, the Health Information Technology Standards Committee and the Health Information Technology Policy Committee, both established by the HITECH Act, will continue to advise the ONC on the meaningful use requirements.[113] The committees will assist eligible hospitals and EPs to meet these requirements in order to receive incentive payments as quickly as possible.[114]

In addition to improving the EHR infrastructure, the HITECH Act also serves to protect patients' privacy and security with respect to the improved technology. As a result, the ONC stresses the importance of compliance with numerous existing laws, including the Privacy Act of 1974, the Freedom of Information Act, and the Health Insurance Portability and Accountability Act. The importance of privacy and security also can be seen in some of the meaningful use requirements.

As part of this increased focus on privacy and security, the HITECH Act requires enhanced reporting of large data breaches to HHS and to the public.[115] Entities must report breaches when more than 500 records of protected health information are lost, stolen, or compromised;[116] however, there are safe harbors for this requirement, exempting certain information. With the new rules, many more entities, including patient safety organizations and subcontractors, must comply with breach notification rules imposed on business associates. The rules also set forth stricter requirements for storage and disposal of EHRs. Most notably, the Act considers encrypted files protected, and therefore breaches of such files do not need to be reported to HHS or the public. However, HHS has removed this final rule from review and will issue a new rule in the coming months. Nevertheless, the rule will remain in effect until a new one is issued.

§ 1.09 MEDICAL STAFF DEVELOPMENTS

[A] Peer Review/Health Care Quality Improvement Act Immunity

In peer review cases, courts continue to favor the Health Care Quality Improvement Act (HCQIA) immunity presumption for hospitals. To overcome this presumption, physicians must show a clear failure to meet the immunity requirements or negligence.

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[111] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).

[112] 75 Fed. Reg. 2014 (proposed Jan. 13, 2010) (to be codified at 45 C.F.R. Pt. 170).

[113] HHS, Health IT Standards Committee, *available at* <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=6&mode=2>.

[114] HHS, Health IT Standards Committee, *available at* <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=6&mode=2>.

[115] HHS, Breaches Affecting 500 or More Individuals, *available at* <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html>.

[116] HHS, Breaches Affecting 500 or More Individuals, *available at* <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html>.

A recent decision in the Northern District of Ohio affirmed the immunity presumption trend for hospitals.[117] The defendant hospital suspended the plaintiff physician's endoscopic privileges as a result of two negative patient outcomes.[118] Following this suspension and plaintiff's multiple outbursts directed at medical staff, the hospital asked the plaintiff to sign a code of conduct and submit to a psychological evaluation.[119] During this time, the plaintiff was self-medicating for Cushing's syndrome with steroids and pain relievers.[120] The psychological evaluation also revealed that the plaintiff suffered from Dysthymic Disorder and that he was not abusing any medication.[121]

In the months following his suspension, the plaintiff retained general clinic privileges at the hospital; however, he continued to act rudely and aggressively toward the medical staff.[122] Upon review of these incidents and meeting with the plaintiff and his counsel, a hospital review committee terminated the physician's staff privileges for violation of the code of conduct.[123] The plaintiff brought suit under the Americans with Disabilities Act (ADA) and HCQIA.[124] The court held that the physician's physical ailments did not qualify him under the ADA.[125] Further, the court found the physician's violation of the code of conduct sufficient grounds for dismissal, even though it was signed after the initial suspension.[126]

When determining whether to grant a physician's application for medical staff privileges, the hospital relied on a peer review report issued by another medical facility.[127] The physician argued that since the hospital failed to communicate with any members of the previous medical facility's staff or corroborate any facts contained in the report, the hospital should not be immune under the HCQIA.[128] However, the Indiana Appellate Court held that a hospital's reliance on a peer review report issued by a medical facility at which a physician had previously obtained privileges was reasonable, and thus, upon denial of application, the hospital was entitled to immunity.[129] Also, the court said that the hospital was not statutorily required to conduct its own fact-finding investigation to corroborate the accuracy of facts found by a previous facility's peer or disciplinary review proceedings, as the physician had accepted the prior disciplinary measures without challenge and nothing indicated that the report's findings and conclusions were unreliable or suspect.[130]

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[117] Badri v. Huron Hosp., ___ F. Supp. 2d ___, 2010 WL 582652 (N.D. Ohio, Feb. 10, 2010).

[118] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[119] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[120] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[121] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[122] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[123] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[124] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[125] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[126] *Badri*, ___ F. Supp. 2d ___, 2010 WL 582652.

[127] W.S.K. v. M.H.S.B., 922 N.E.2d 671 (Ind. Ct. App. 2010).

[128] *W.S.K.*, 922 N.E.2d 671.

[129] *W.S.K.*, 922 N.E.2d 671.

[130] *W.S.K.*, 922 N.E.2d 671.

During the review of a summary judgment, a New Mexico Appellate Court found that the hospital's fact-finding procedures created a significant preponderance of the evidence to deny its motion for summary judgment on the issue of HCQIA immunity.[131] Relying particularly on two patient accounts when making its decision, the hospital suspended the physician's psychiatric privileges for using inappropriate, sexually explicit language with female patients.[132] The court ultimately held that the hospital failed to demonstrate a reasonable fact-finding effort because one of the two patient altercations was based solely on the handwritten notes of the patient's case manager.[133] The hospital made no effort to acquire additional facts.[134] As a result, the court determined that the hospital's decision was predominantly based on the account of one patient and that it was insufficient to succeed on a motion for summary judgment.[135]

[B] Medical Staff By-Laws: Standard MS.01.01.01

In April 2010, the Joint Commission approved a revised version of old Standard MS.1.20 with respect to medical staff by-laws.[136] New Standard MS.01.01.01 helps ensure patient safety and improved quality of care by determining the content of medical staff by-laws, establishing a method for proposed changes, and creating a conflict resolution process.[137] Changes to the Standard include:[138]

- Flexibility to place associated details in medical staff by-laws, rules and regulations, or policies;
- Recognition of medical staff's role in creating by-laws;
- Establishment of a conflict resolution process; and
- A list of medical staff officer positions in by-laws.

The new Standard is effective in March 2011.

§ 1.10 FALSE CLAIMS ACT

Congress decided that, in addition to lowering payments to providers, focusing on fraud prevention is key for controlling the costs of health care. The focus is no longer simply on punishing practitioners for erring in their reporting; the aim is to prevent these issues from occurring in the first place. This is not just a federal goal; states are also initiating significant efforts in this regard. In fact, in

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[131] Summers v. Ardent Health Servs., LLC, 226 P.3d 20 (N.M. Ct. App. 2010).

[132] *Summers*, 226 P.3d 20.

[133] *Summers*, 226 P.3d 20.

[134] *Summers*, 226 P.3d 20.

[135] *Summers*, 226 P.3d 20.

[136] Joint Comm'n, Standard MS.01.01.01, *available at* <http://www.jointcommission.org/NR/rdonlyres/30AB87C7-D717-4949-8627-91F3E4BF4730/0/MS_01_01_01.pdf> (last accessed July 2010).

[137] Joint Comm'n, Standard MS.01.01.01, *available at* <http://www.jointcommission.org/NR/rdonlyres/30AB87C7-D717-4949-8627-91F3E4BF4730/0/MS_01_01_01.pdf> (last accessed July 2010).

[138] Joint Comm'n, Standard MS.01.01.01, *available at* <http://www.jointcommission.org/NR/rdonlyres/30AB87C7-D717-4949-8627-91F3E4BF4730/0/MS_01_01_01.pdf> (last accessed July 2010).

2009, agencies in Florida collected approximately $287 million from Medicaid overpayments and prevented nearly $19 million in improper payments. These funds came from home health firms, pharmaceutical companies, and HMOs within the state. U.S. Senator Grassley of Iowa has warned that states need to update their respective state False Claims Acts (FCAs) to include the new federal FCA changes.[139]

Recent amendments to the FCA are making it easier for government agencies to enforce the Act, creating hundreds of pending FCA-related cases. In 2009, nearly $3 billion was recovered from just 65 settlements. President Barack Obama increased the scope of liability within the FCA by signing the Fraud Enforcement Recovery Act (FERA) in late May 2009,[140] so that health care providers may now be liable for not returning any payment which they should reasonably know is, in fact, a government overpayment. In addition, the PPACA, signed into law in 2010 mandates the return of government overpayment within 60 days.

Prosecutors are also using the FCA to enforce billing and fiduciary duty violations stemming from poor quality of care. In addition, OIG prosecutions under the FCA for Stark law violations are increasing. Also, the PPACA should increase significantly the number of *qui tam*, also known as whistleblower, complaints that survive motions to dismiss.[141]

The government will use large recoveries from fraud and whistleblower cases to fund various aspects of health care reform, so organizations must continue to implement effective policy and procedure initiatives. While proponents note the regulatory advantages of the FCA, critics argue that changes to the FCA are only inflating the health care system, which is causing a drastic increase of costly false claims investigations.

Some of the significant cases and settlements under the FCA are discussed in the following sections.

[A] *United States v. Sulzbach*[142]

In this case, Sulzbach, Tenet Healthcare Corporation's former general counsel and compliance officer, signed the corporate integrity agreement but did not report ongoing kickbacks given by the corporation. The Department of Justice prosecuted Tenet under the FCA. Although the judge overseeing the case issued

[139] Letter from Sen. Charles Grassley to Inspector Gen. Daniel Levinson & Att'y Gen. Eric Holder (Apr. 28, 2010), *available at* <http://grassley.senate.gov/about/upload/042810-Letter-to-IG-Levinson-and-AG-Holder.pdf> (last accessed July 2010).

[140] False Claims Act of 1863, ch. 67, 12 Stat. 696 (1863), 31 U.S.C. § 3729-3733 (amended by Pub. L. No. 111-21, 123 Stat. 1621).

[141] Pub. L. No. 111-148, 124 Stat. 119, Section 10104(j)(2).

[142] Motion for Summary Judgment, United States v. Sulzbach, No. 07-61329 (S.D. Fla. Oct. 30, 2009).

a summary judgment to the defendant on April 16, 2010, the case continues to make clear that the OIG will expect certifications from all compliance employees or oversight committee members and potentially will expose such individuals to personal liability if they fail to follow corporate integrity standards.

[B] Chiropractors

[1] Chiropractor and Assistant Indicted for Fraudulent Blue Cross Claims (Pennsylvania)

A Pennsylvania chiropractor and his assistant were indicted on January 26, 2010, for filing approximately $1 million of health care insurance claims to Blue Cross for treatment and services that were not rendered. Charges include health care fraud, mail fraud, and making false statements. If convicted, both face significant prison terms, large fines, and restitution.[143]

[2] Chiropractor and Doctor Indicted for Submitting False Claims (Illinois)[144]

On March 11, 2010, a chiropractor, a physician, and an administrative staffer were indicted for federal health care fraud at an Illinois clinic. They were charged with billing for false and highly inflated insurance claims to the federal Workers' Compensation Office. The physician and chiropractor signed and forged false documents in support of these false claims. Each count of the health care fraud carries up to 10 years' imprisonment in addition to $250,000 in fines.

[C] Clinics

[1] Clinic and Physician False Claims Act Settlement (Florida)[145]

Melbourne Internal Medicine Associates Cancer Center (MIMA) and Dr. T. Scarbrough allegedly submitted false claims to Medicare, TRICARE (the U.S. military health care program), and other government payors in violation of the FCA and settled with the U.S. government for $12 million. MIMA allegedly inflated claims and conspired to conceal these falsified activities; the oncology services billed for were allegedly unsupervised, repeats, unnecessary, and not performed; and the center purportedly billed for procedures that were more expensive than those actually given to patients. Members of upper management

[143] Press Release, Dep't of Justice, Chiropractor and Assistant Charged in Health Care Fraud Scheme (Jan. 26, 2010), *available at* <http://philadelphia.fbi.gov/dojpressrel/pressrel10/ph012610a.htm>.

[144] Bonnie L. Cook, *Chiropractor, Assistant Indicted in Fraud*, Philly.com, *available at* <http://www.philly.com/philly/news/pennsylvania/20100127_Chiropractor__assistant_indicted_in_fraud.html> (last accessed May 20, 2010).

[145] Press Release, Dep't of Justice, Florida Health Care Provider & Individual Physician to Pay $12 Million to Settle False Claims Act Allegations (Mar. 23, 2010), *available at* <http://www.justice.gov/opa/pr/2010/March/10-civ-299.html> (last accessed July 20, 2010).

were aware of these ongoing incidents but did not attempt to stop them. The whistleblower, the former radiation oncology director at MIMA, received $2.64 million from the settlement with the government.

[2] Clinic and Physician False Claims Act Settlement (Detroit, Michigan)[146]

On March 11, 2010, a physician was fined more than $18 million and convicted of 13 counts of Medicare fraud based on conspiracy to commit health care fraud, substantive health care fraud, and conspiracy to launder the proceeds of the fraudulent scheme. The clinic owner co-conspired in the Medicare fraud by creating falsified therapy files for services not rendered. In addition, the clinic owner and physician bribed physical and occupational therapists to sign these fictitious documents. Moreover, the physician signed therapy prescriptions and certified the need for therapy services without patient evaluation. The physician also profited from home visits that did not, in fact, occur. The clinic owner pled guilty to conspiracy of health care fraud and money laundering. The physician faces sentencing for up to 30 years' imprisonment and $500,000 in fines based on the two counts.

[3] Clinic Falsified Billing for Physicians (Missouri)[147]

In Perryville, Missouri, on March 18, 2010, Convenient Healthcare Clinic (CHC) was sentenced to a five-year probation and $17,500 in fines for health care fraud charges. The clinic improperly billed Medicare and Medicaid for physicians no longer employed in addition to improperly billing labor union benefit funds. A separate civil settlement for nearly $200,000 was reached with the federal government. The U.S. District Court sentenced the office manager to three years' probation.

[D] Dentists

[1] Dentist: Medicaid Fraud[148]

On January 4, 2010, a former dentist was sentenced, after pleading guilty, for defrauding Kentucky's Medicaid Program, as well as on three separate counts of drug trafficking. The dentist overbilled the Kentucky Medical Assistance Program for unperformed or unnecessary operations. He also overprescribed pain medication and supplied it to drug-seeking clients while still billing for dental services.

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[146] Press Release, Dep't of Justice, Detroit-Area Doctor Convicted in Medicare Fraud Scheme (Mar. 11, 2010), *available at* <http://detroit.fbi.gov/dojpressrel/pressrel10/de031110a.htm> (last accessed July 20, 2010).

[147] Press Release, Office of the U.S. Attorney Southern District of Illinois (Mar. 30, 2010), *available at* <http://www.justice.gov/usao/ils/press/2010/Mar/03302010_CHC_press%20release.htm> (last accessed Aug. 6, 2010).

[148] Press Release, Office of the Attorney General (Kentucky), Former Eastern Kentucky Dentist Pleads Guilty to Medicaid Fraud & Drug Trafficking (Nov. 18, 2009), *available at* <http://migration.kentucky.gov/newsroom/ag/ralstonpleads.htm> (last accessed July 20, 2010).

The recommendation was the maximum five years' imprisonment for each count, and the dentist was ordered to pay nearly $5,000 for Medicaid restitution and $3,000 for the investigation costs to the state.

[E] Durable Medical Equipment

[1] Dialysis Services/Supply Firm: Medicare Fraud[149]

On March 22, 2010, a federal judge issued an order against Renal Care Group (RCG), Renal Care Group Supply Co. (RCGS), and Fresenius Medical Care Holdings Inc. to pay nearly $20 million for Medicare fraud. The case stemmed from a whistleblower suit in 2005, which the U.S. Attorney General's office joined in 2007. While many employees complained about the Medicare billing activities, the firm showed a "reckless disregard" for the statutes and regulations within Medicare. Allegedly, RCG created RCGS as a shell corporation in order to improperly receive 30 percent extra on dialysis supplies.

[2] Medical Equipment Company: Health Care Fraud (Florida)[150]

The former president and owner of a medical equipment firm, Atenas Medical Equipment, Inc., in the state of Florida was convicted of 10 counts of health care fraud on February 2, 2010. The firm, which provides durable medical equipment (DME) to Medicare beneficiaries, allegedly billed fraudulent Medicare claims of more than $1.4 million for DME used in treatment of chronic disease, incontinence, and other illnesses. The providers allegedly failed to prescribe or distribute the DME to patients and forged prescriptions, medical necessity certification, and receipts of delivery to fraudulently represent various beneficiaries of Medicare and physicians. The former president and owner of the company faces up to 10 years in prison for each count of health care fraud in violation of the FCA.

[3] Durable Medical Equipment Company: Medicare Fraud and Kickback Scheme (Pennsylvania)[151]

On December 10, 2009, Robert and Sheila Saul, along with R&V Medical Supplies, LLC, were indicted for conspiracy to commit Medicare fraud. They allegedly submitted more than $1.2 million in fraudulent claims for DME reimbursement. The different counts include health care fraud, mail fraud, and paying illegal kickbacks for Medicare referrals. The medical office employees sold to the

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[149] Robert Patrick, *Fresenius Ordered to Repay Government $19 Million*, St. Louis Post-Dispatch (Mar. 24, 2010), *available at* <http://www.stltoday.com/business/article_90d59053-e037-5a15-a6ab-e91ad056ffe9.html?print=1> (last accessed Aug. 6, 2010).

[150] Press Release, Dep't of Justice, Former President and Owner of Atena's Medical Equipment, Inc. Convicted on Health Care Fraud Charges (Feb. 2, 2010), *available at* <http://miami.fbi.gov/dojpressrel/pressrel10/mm020210d.htm> (last accessed Aug. 6, 2010).

[151] Press Release, Dep't of Justice, Durable Medical Equipment Company, Six Others Charged in Medicare Fraud and Kickback Scheme (Dec. 10, 2009), *available at* <http://philadelphia.fbi.gov/dojpressrel/pressrel09/ph121009.htm> (last accessed Aug. 6, 2010).

aforementioned individuals identities of patients covered by a certain health care benefit program. Then the defendants forged signatures and charged for DME that was not prescribed by a physician or necessary for the patients. As a result, the Medicare beneficiaries received equipment that they had no knowledge of. If convicted, the maximum sentence for each count of conspiracy is five years' imprisonment; for each count of health care fraud, 10 years' imprisonment; for each count of mail fraud, 20 years; for each count of illegal kickback payment, five years; and for each count of obstruction of justice, 20 years.

[F] Fraud Enforcement and Financial Recovery Act Changes and Increased Litigation[152]

FERA, signed by President Obama on May 20, 2009, drastically alters the existing FCA and will continue to increase litigation and damages against health care entities under the FCA since FERA provides incentives for potential whistleblowers to file suit against an entity. First, under the new amendments, companies are liable for any fraudulent claims against public or private companies, as long as there is some governmental connection. Second, FERA overturns a Supreme Court decision, *Allison Engine Co. v. United States ex rel. Sanders*,[153] mandating that a defendant have the *intention* of defrauding the government to violate the FCA. There is no longer an intent requirement so claims are easier to justify under the FCA. Third, FERA extends liability to practices not currently covered under the FCA, including failure to return government overpayment, underpayment to the government or government-reimbursed organization, and conspiracy to commit a fraudulent act under the FCA. FERA permits the mutual sharing of information and evidence between the government and private parties. Also, the government may become a co-plaintiff even after the statute of limitations, assuming the private plaintiff filed the complaint in a timely manner. Coupled with this, states such as Nebraska have recently extended their statutes of limitations, thus exposing health care entities to liability for a greater period of time. Whistleblowers who are contractors or agents may not file suit for retaliation under FERA.

[G] Health Care Systems: *United States ex rel. Wendy Buterakos v. Ascension Health and Genesys Health System*[154]

In late December 2009, Central Michigan's Genesys Health System settled with the Department of Justice for nearly $700,000 based on Medicare overbilling allegations. The company, part of Ascension Health, purportedly billed Medicare for more services than the cardiology patients received. The settlement encourages whistleblowers to come forth given that the case's whistleblower was a hired

[152] Pub. L. No. 111-21, 123 Stat. 1621.
[153] 553 U.S. 662 (2009).
[154] Civil Action No. 06-10550 (E.D. Mich.).

auditor who received nearly 20 percent of the settlement. The settlement did not include an admission of liability by the health system.[155]

[H] Home Health Care: *United States and the State of Michigan v. Visiting Physicians Association*[156]

Visiting Physicians Association (VPA), a Michigan-based home health care firm, settled whistleblower lawsuits for $9.5 million. VPA allegedly submitted claims to Medicare, Medicaid, and TRICARE for unnecessary visits to patients' homes, procedures, exams, advanced evaluations, and management services. The OIG is currently working with VPA to establish a successful compliance program that continually trains employees and audits the firm to encourage compliance with all state and federal regulations. The four whistleblowers in the case split $1.7 million, a big incentive for potential whistleblowers to come forward in the future.[157]

[I] Hospitals

[1] Texas Health Arlington Memorial Hospital: Blood Gas Lab Tests False Claims

On January 5, 2010, the Texas Health Arlington Memorial Hospital settled with the U.S. Attorney General's office for $1 million for false claims violations. The hospital immediately came forward to the OIG when it discovered, during contract renewal reviews, that a physician group contract may have violated the FCA. In this case, the hospital supposedly paid incorrect sums of money to the physician groups for lab tests and pulmonology-related activities, whereupon Medicare reimbursed the Texas hospital for the tests.[158]

[2] Delaware-Based Health System: False Claims Violations Are Largest in State's History

On March 12, 2010, Christiana Care Health System, the largest health care provider in Delaware, settled with the federal government and the state of Delaware for $3.3 million based on whistleblower suits brought regarding alleged unjust self-referrals with physicians' practices within the state. The *qui tam* suit was brought by Dr. William Sommers and Dr. Lee Dresser, of Wilmington Neurology Consultants. Allegedly, Christiana Care knowledgeably and recklessly compensated physicians' practices to encourage referrals to its system, which violated the Stark law, and then improperly claimed reimbursement from

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[155] Press Release, Dep't of Justice, Michigan Health Care Provider to Pay United States $669,413 to Settle False Claims Allegations (Dec. 28, 2009), *available at* <http://www.justice.gov/opa/pr/2009/December/09-civ-1384.html> (last accessed Aug. 8, 2010).

[156] E.D. Mich. Dec. 23, 2009.

[157] Press Release, Dep't of Justice, Visiting Physicians Association to Pay $9.5 Million to Resolve False Claims Act Allegations (Dec. 23, 2009), *available at* <http://www.justice.gov/opa/pr/2009/December/09-civ-1377.html> (last accessed Aug. 6, 2010).

[158] Chelsey Ledue, *Minnesota, Texas Hospitals Settle Allegations of Medicare Fraud,* Healthcare Fin. News, Jan. 5, 2010, *available at* <http://www.healthcarefinancenews.com/news/minnesota-texas-hospitals-settle-allegations-medicare-fraud> (last accessed July 20, 2010).

Medicare and Medicaid. That being said, Christiana admitted no wrongdoing, despite the settlement, in order to prevent any future litigation costs. Christiana signed a corporate integrity agreement to be monitored by the OIG, the U.S. attorney for the District of Delaware, and the Delaware attorney general. This allegation and eventual settlement typify the aggressive government stance in regard to kickbacks for self-referrals.

[3] Massachusetts Hospital Settles: False Claims Act Violation for Services Not Rendered[159]

On February 19, 2010, Mercy Hospital settled with the U.S. Department of Justice for nearly $2.8 million for violation of the FCA. As disclosed to the OIG, it was alleged that the hospital did not comply with required Medicare guidelines, including providing and documenting a minimum number of rehabilitation services to patients. The government is clearly signaling that it will do its best, through the Medicare payments being made, to ensure that patients receive a certain level of care. The hospital is implementing a system to avoid further problems regarding documentation. This case advises other institutions to immediately report and correct documentation issues to avoid significant fines.

[J] Medical Devices: Legal Risks of Marketing

In January 2010, a series of whistleblowers brought forward a *qui tam* suit, under 31 U.S.C. § 3729, charging top stent and other medical device firms with fraud for marketing their use of off-label biliary stents for the treatment of individuals with cardiovascular disease.[160] While doctors may, in fact, use these devices in their treatment, marketing this application of the devices is illegal and thus is Medicare fraud.

[K] Nursing Homes: Omnicare and Nursing Home Chains Settle[161]

In March 2010, nursing home companies, including Mariner Health Care Inc. and SavaSeniorCare Administrative Services LLC, settled with the U.S. Department of Justice for $14 million for kickback claims charged against them. Omnicare, Inc., in contrast, settled with the government for $98 million as a result of alleged kickbacks paid to the drug companies, aforementioned nursing homes, and

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[159] Press Release, Dep't of Justice, Massachusetts Hospital Agrees to Pay U.S. $2.79 Million to Resolve False Claims Act Allegations (Feb. 19, 2010), *available at* <http://www.justice.gov/opa/pr/2010/February/10-civ-164.html> (last accessed July 20, 2010).

[160] Press Release, Dep't of Justice, Nation's Largest Nursing Home Pharmacy and Drug Manufacturer to Pay $112 Million to Settle False Claims Act Cases (Nov. 3, 2009), *available at* <http://www.justice.gov/opa/pr/2009/November/09-civ-1186.html> (last accessed July 20, 2010).

[161] Press Release, Dep't of Justice, Two Atlanta-Based Nursing Home Chains and Their Principals Pay $14 Million to Settle False Claims Act Case (Feb. 26, 2010), *available at* <http://www.justice.gov/opa/pr/2010/February/10-civ-204.html> (last accessed Aug. 6, 2010).

Johnson & Johnson. The kickbacks led to false Medicare and Medicaid claims, among others. The government clearly sent a message: there is no tolerance for kickbacks or false claims, and profits cannot be placed before medical care.

[L] Patient Protection and Affordable Care Act of 2010

In addition to the previously mentioned effects of PPACA, the Act also has had a significant effect on nursing facilities. For example, Section 6121 establishes a background screening program for long-term care providers so that they can review their employees who interact with patients. Also, with the Act's passing, formerly complicated ownership structures are now transparent due to mandatory disclosure. Moreover, more data are available for regulators and consumers to review quality of care, personnel records, and skill-development issues. Under Section 6101 of the PPACA, the ownership and governance of health care entities must now be disclosed. Section 6401 requires HHS to mandate the adoption of compliance programs for health care entities, and Section 6102 requires that operators of health care facilities in fact adopt these compliance programs. Section 6105 asks that the Secretary of HHS develop a standardized complaint form so that patients can easily notify the state governments of existing concerns. One of the goals of the PPACA seems to be the encouragement of integrity in the health care field and compliance departments.

A 2007 case, *Rockwell International Corp. v. United States*,[162] clarified that *qui tam* suits will be dismissed if the claims within the suits are based upon public information, unless the individual bringing the suit is the original source of such information. The PPACA allows the Department of Justice more flexibility in these suits: the government can now *veto* a motion to dismiss even if the motion was based on a public information dismissal. Also, the PPACA explains that the original source may be second-hand information regarding the publicly disclosed information. In addition, Section 6404 of the PPACA reduces the maximum Medicare claim submission period to no longer than one year from the service date. With these changes, it is likely that more FCA cases will be brought and fewer will be dismissed.

[M] Pharmaceutical Marketing That Violates the False Claims Act

On March 16, 2010, Alpharma, Inc., a U.S. pharmaceutical manufacturer, settled with the Department of Justice for $42.5 million based on accusations of FCA marketing violations, specifically with respect to Kadian, a treatment for pain.[163] The company purportedly gave providers kickbacks if they promoted or prescribed the drug; it also misrepresented the drug's safety and effectiveness. The whistleblower in this case received $5.33 million from the settlement. The

[162] 549 U.S. 457 (2007).

[163] Press Release, Dep't of Justice, Alpharma to Pay $42.5 Million to Resolve False Claims Act Allegations in Connection with Promotion of Drug Kadian (Mar. 16, 2020), *available at* <http://www.justice.gov/opa/pr/2010/March/10-civ-269.html> (last accessed Aug. 6, 2010).

government wants doctors' incentives to be based on what is best for the patient, not on illegal kickbacks from pharmaceutical companies. In another example, in early September 2009, Pfizer settled with the federal government for more than $2.3 billion as a result of various alleged FCA violation cases based on illegal marketing of their products. The Pfizer settlement is the largest FCA case settlement in history.[164]

§ 1.11 MISCELLANEOUS DEVELOPMENTS

In the years 2009 and 2010, the health care industry saw many significant developments. Although the majority of these were addressed in earlier sections of this chapter, some developments that fell outside the topics in those sections deserve attention and are discussed below.

[A] Red Flags Rule

The FTC and the National Credit Union Administration implemented the red flags rule as an effort to detect and prevent identity theft. This rule requires financial institutions and creditors to implement programs designed to do so. "Creditors" include any entity that "regularly extends, renews, or continues credit; and any entity that regularly arranges for the extension, renewal, or continuation of credit."[165] A plain reading of this language suggests that it applies to health care entities that extend consumers the option to defer payment or to set up any type of payment plan, which includes nearly all health care providers, although in the past, the definition of "creditor" in similar statutes did not necessarily include these entities.[166] Nevertheless, the FTC stated that health care providers, lawyers, and other professionals are creditors for the purposes of the red flags rule.[167]

The delay of the red flags rule compliance deadline is largely due to the American Medical Association's (AMA's) strong objection. Specifically, the AMA objects to the FTC's interpretation that physician practices are creditors when they accept insurance and bill patients and allow patient payment plans. The AMA wishes to exclude physicians from this program and is lobbying to republish the rule so that there is sufficient time to formally comment. Many other opponents believe that small legal and health care companies should be exempt and hope to voice this opposition in a reopened comment period.

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[164] Press Release, Dep't of Health and Human Services, Justice Department Announces Largest Health Care Fraud Settlement in its History (Sept. 2, 2009), *available at* <http://www.hhs.gov/news/press/2009pres/09/20090902a.html> (last accessed Aug. 6, 2010).

[165] The Red Flags Rule: Frequently Asked Questions ¶ B.1, *available at* <http://www.ftc.gov/bcp/edu/microsites/redflagsrule/faqs.shtm#B> (last accessed July 20, 2010).

[166] *See* Am. Bar Ass'n v. FTC, 671 F. Supp. 2d. 64, 69 (D.D.C. 2009).

[167] The Red Flags Rule: Frequently Asked Questions ¶ B.1, *available at* <http://www.ftc.gov/bcp/edu/microsites/redflagsrule/faqs.shtm#B> (last accessed July 20, 2010).

[B] Labeling

Labeling refers to the packaging of medical products and the written and graphic messages they convey to the consumer. The FDA regulates labeling through the "misbranding" provisions of the Federal Food, Drug, and Cosmetic Act.[168] As a general rule, the FDA enjoys judicial deference to its interpretations of "false or misleading" labeling under the *Chevron* principle of judicial review.[169]

Recently, however, the federal courts have restricted the deference given to the FDA.[170] In early 2009, a federal appeals court held that a federal agency cannot arbitrarily determine the meaning of an ambiguous labeling statement.[171] Even if the agency uses an expert to interpret the label's language, the agency may not authorize a strict interpretation when there is no existing statutory or regulatory provision, guideline, or opinion that defines the terms.[172] Furthermore, the court suggested that in order for the FDA to bring a misbranding claim against a business based on misleading labeling, the FDA must present actual evidence supporting a potential consumer interpretation.[173]

Since the *Farinella* holding, numerous federal cases, primarily from the same federal court, have upheld similar explanations of a federal agency's interpretive powers.[174] While none of these cases relates directly to health care, or even the FDA, the *Farinella* decision signifies a substantial change in the way that consumer products, including those in the health care industry, may be marketed. For example, some practitioners believe that there will be an immediate impact in the way that the FDA handles notices of violation or warning letters issued by the Division of Drug Marketing, Advertising and Communication of the Center for Drug Evaluation and Research in connection with prescription drug advertising and promotion. When there are no FDA provisions relating to specific labeling statements, the FDA must provide empirical evidence proving that the targeted consumer would interpret the label as indicated by the agency.

[C] Fee-Splitting

As a general rule, fee-splitting is illegal. It occurs when a physician receives compensation for services and then shares a portion with a party who did not render that service. Most states indirectly prohibit all fee-splitting variations through administrative laws, practice codes, or other statutory provisions.[175] Due to their broad construction, however, many state laws allow legal fee-splitting arrangements when the fee is provided at fair market value for a service actually

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[169] 21 U.S.C.A. § 331.

[169] Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 468 U.S. 1227 (1984).

[170] United States v. Farinella, 558 F.3d 695 (7th Cir. 2009).

[171] *Farinella*, 558 F.3d 695.

[172] *Farinella*, 558 F.3d 695.

[173] *Farinella*, 558 F.3d 695.

[174] *See*, *e.g.*, United States v. Pulungan, 569 F.3d 326 (7th Cir. 2009).

[175] *See*, *e.g.*, N.Y. Pub. Health Law § 4501(1).

rendered.[176] Nevertheless, some states, including Florida, explicitly prohibit the fee-splitting of Medicaid funds.[177]

On the federal level, percentage-based fee-splitting arrangements are allowed with respect to Medicaid funds as long as the fees are the reasonable compensation for a service actually rendered.[178] However, the OIG has concerns about all percentage-based compensation agreements due to their tendency to produce abusive billing practices.[179] As a result, the OIG issues compliance guidelines to help health care providers prevent fraud and abuse with respect to these compensation arrangements.

Currently, Illinois is the only state that governs fee-splitting arrangements by statute.[180] Enacted in August 2009 and effective beginning January 1, 2011, the Illinois law specifically addresses the issue of fee-splitting, authorizing it under a set of given exceptions while providing grounds for discipline when fees are unlawfully split.[181] Specifically, physicians and their corporate practices may "perform billing, administrative preparation, or collection services based upon a percentage of professional service fees billed or collected, a flat fee, or any other arrangement that directly or indirectly divides professional fees" as long as the practitioner controls the amount of the fees and the fees are paid directly to the practitioner.[182]

Moreover, Illinois law *authorizes* fee-splitting under the following exceptions:

- when practitioners concurrently provide care with the full knowledge of the patient;
- when all the owners of a legal entity are licensed physicians; and
- when the organization is a medical corporation, professional services corporation, professional association, or limited liability company.

The law also *prohibits* fee-splitting for specific circumstances, including health care network negotiations and marketing for physician practices.[183] At this time, no other states appear to be considering similar statutory exceptions to illegal fee-splitting arrangements. It may take some time for the effects of the Illinois law and its applicability to other states to be known.

[176] Preemption of Local Zoning Regulation of Satellite Earth Stations and Restrictions on Over-the-Air Reception Devices: Television Broadcast, Direct Broadcast Satellite and Multichannel Multipoint Distribution Services, 63 Fed. Reg. 71,038-52 (Dec. 23, 1998).
[177] 63 Fed. Reg. 71,038-52 (Dec. 23, 1998).
[178] 63 Fed. Reg. 71,038-52 (Dec. 23, 1998).
[179] 63 Fed. Reg. 71,038-52 (Dec. 23, 1998).
[180] 225 ILCS 60/22.2.
[181] 225 ILCS 60/22.2.
[182] 225 ILCS 60/22.2.
[183] 225 ILCS 60/22.2.