

Hospitals & Health Systems Rx

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Corporate Leaders in the Cross Hairs: Exclusions and Other Government Enforcement Trends Converge Against Individuals

Richard Blake, Esquire
Claire Turcotte, Esquire
Bricker & Eckler LLP
Cleveland and Cincinnati-Dayton, OH

Healthcare executives—beware. The government is looking at you in a different light. Gone are the days when criminal indictments and government exclusions were generally limited to rogue employees, owners of small companies, and career criminals engaged in blatantly fraudulent activities, such as operating sham providers or billing for services that were never furnished. The government has now turned its sights to healthcare corporations’ owners, directors, senior executives, and in-house counsel, and has increasingly been holding these individuals responsible for the misconduct of their organizations, even when they had no direct involvement.

Recent statements by the U.S. Department of Justice (DOJ) and the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) officials illustrate the government’s increasing interest in holding these individuals personally responsible for corporate misconduct. Similarly, in several recent cases, the government has been seeking both criminal indictments and exclusion from federal healthcare programs against these individuals. As part of this effort, DOJ’s increasing penchant for charging in-house counsel with obstruction of justice, as well as its use of the “Responsible Corporate Officer Doctrine”¹ against corporate executives, suggests that these highly placed individuals can expect the enforcement heat to be focused on them personally when their corporations come under government scrutiny. The confluence of these trends is a clear wake-up call to these individuals that they should remain vigilant in their efforts to combat fraud within their organizations.



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—from a declaration of the American Bar Association

OIG's Permissive Exclusion Authority

Section 1128(b)(15)(A)(ii) of the Social Security Act permits OIG to exclude an individual owner, officer, or managing employee of a sanctioned entity (i.e., an entity that has been convicted of certain offenses or excluded from participation in federal healthcare programs) from participation in the federal healthcare programs. OIG may exclude those individuals who have an *ownership or control interest* in a sanctioned entity if they *knew or should have known* of the conduct that led to the sanction.² However, OIG may also exclude *officers and managing employees* based solely on their position within the entity.³

In recent guidance,⁴ OIG has outlined a number of informal and nonbinding factors it will consider in deciding whether to exercise its permissive exclusion authority in a specific case, including the circumstances of the misconduct, seriousness of the offense, how much authority the individual has and their role in the company, and how they acted in response to the misconduct. Although OIG has emphasized that the presence or absence of any or all of these factors will not be the sole basis for determining whether OIG will pursue exclusion, it is important to carefully consider these nonbinding factors in advising clients and evaluating the potential risk of an individual's exclusion in connection with corporate misconduct.⁵

The effect of an OIG exclusion from federal healthcare programs is that no federal healthcare program payment can be made for any items or services furnished by an excluded individual or entity, including for administrative or management services. Moreover, federal program participating entities may be sanctioned for employing or entering into contracts with excluded individuals.⁶ As a practical matter, an individual who is excluded from the federal healthcare programs cannot be employed by or contract with a healthcare provider that receives reimbursement, directly or indirectly, from any of the federal healthcare programs. "Because of its scope and effect, the risk of exclusion creates a strong incentive to comply with the programs' rules and requirements."⁷

Recent Government Statements

Recent testimony of OIG officials sends a clear message that OIG intends to pursue individuals whose companies are involved in healthcare fraud. On March 9, 2011, HHS Inspector General Daniel Levinson testified that in the past fiscal year, OIG opened more than 1,700 healthcare fraud investigations, resulting in more than 900 criminal and civil actions, and more than \$3 billion in expected investigative recoveries and \$1 billion in audit receivables.⁸ Despite its increasing fraud enforcement efforts, the government has in fact rarely brought actions against directors, management, or counsels who were not directly responsible for fraud or other misconduct. That is until recently. In his recent testimony, Levinson stated that although OIG had excluded corporate officials in more than thirty cases since 1996 under its permissive exclusion authority,⁹ OIG has in the past:

typically applied this exclusion authority to individuals who controlled smaller companies, such as pharmacies, billing services, and DME companies and not to execu-

tives of large complex organizations such as a drug or device manufacturer.¹⁰

More recently, however, DOJ and OIG have made it known that they are actively pursuing responsible individuals for the fraudulent misconduct of large corporate healthcare entities. Both Levinson and Chief Counsel Lewis Morris have expressed concerns that because some hospital systems, pharmaceutical manufacturers, and other providers play such a critical role in the delivery of healthcare services, those entities may believe they will never be excluded. Presumably, excluding them would pose too great a risk of harm to the health of program beneficiaries. According to OIG, so long as the profits from the fraud exceeds any criminal or civil fines imposed by the government, corporations will view the fines as the price of doing business, and abusive corporate behavior will likely continue.

Faced with what they see as a "too important to fail" mentality by such organizations, the government has decided to focus on individual executives. By punishing individual executives while permitting the organizations to continue operation, the government believes it can influence corporate behavior without putting patient access to care at risk.

One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access at risk. . . . [Moreover, even if OIG decides that] 'exclusion of a major health care entity is not in the best interest of federal health care programs and their beneficiaries, we may decide that executives in positions of responsibility at the time of the fraud should no longer hold such positions with entities that do business with the programs.'¹¹

According to Levinson:

[o]nce we determine that an individual or entity has engaged in fraud or abuse or provided substandard care, OIG can use one of the most powerful tools in our arsenal: the authority to exclude that provider from participating in Federal health care programs. Program exclusions bolster our fraud-fighting efforts by removing from Federal health care programs those who pose the greatest risk to our programs and their beneficiaries.¹²

Responsible Corporate Officer Doctrine

In addition to OIG's exclusion authority, the government has been applying the Responsible Corporate Officer Doctrine to individual corporate officers to hold them accountable for corporate misconduct. Any corporate officer who has responsibility or authority to prevent violations of laws, such as the federal Food, Drug, and Cosmetics Act,¹³ may be criminally liable for the corporation's violations of law. Notably, the successful

application of the doctrine does not require that the officers had criminal intent, personal knowledge, or even reckless disregard of the violation. Moreover, the only viable defense to this charge, termed the “impossibility defense,” is that the corporate officer could not possibly have stopped the violation, such as the misbranding in the KV Pharmaceuticals (KV) case (discussed further below). To date, the government has applied this theory to healthcare only in pharmaceutical and medical device cases, as in the KV case. However, executives across the entire healthcare industry should be bracing to face the possible application of this theory against them if their corporations become involved in government investigations of misconduct.

Recent Cases

Exclusions of Executives Under OIG’s Exclusion Authority and Use of the Responsible Corporate Officer Doctrine

Recent OIG exclusions of corporate executives reflect its increased use of personal accountability to curtail corporate fraud and abuse. In December 2010, the federal District Court for the District of Columbia (DC) sided with OIG, ruling that a twelve-year exclusion of three former senior executives of the Purdue Frederick Company was reasonable.¹⁴ The case originated in May 2007, when the U.S. Attorney’s Office for the Western District of Virginia entered into a settlement with the Purdue Frederick Company and Purdue Pharma LP, in which the three executives entered guilty pleas to misdemeanor misbranding charges under the “Responsible Corporate Officer Doctrine.”¹⁵

After their sentencing, OIG excluded the executives for fifteen years, but the HHS Appeals Board ultimately reduced the exclusions to twelve years.¹⁶ In October 2009, the executives filed a complaint in the federal DC District Court challenging the exclusions. Among other things, the executives argued that they were not eligible for exclusion because they did not personally commit fraud. In finding against the executives, the DC District Court disagreed that the executives did not personally commit fraud, holding that their characterization of the role they played in the misbranding of OxyContin was inconsistent with their earlier guilty pleas of misbranding and related statement of facts.

In a similar case in March 2011, majority stockholder, KV Chief Executive Officer, Director, and officer of Ethex (a majority stockholder of KV) Marc Hermelin pleaded guilty to two counts of criminal misbranding of morphine sulfate. Applying the Responsible Corporate Officer Doctrine, in its indictment the government alleged that Hermelin “had the power, authority, and responsibility to either prevent drug manufacturing problems in the first instance and the ability to promptly correct the violation of the Food, Drug, and Cosmetic Act that did occur at KV and Ethex.”¹⁷ According to the indictment, while Hermelin was a responsible corporate officer of KV, KV introduced and delivered into interstate commerce morphine sulfate that was misbranded. In November 2010, OIG excluded Hermelin using its permissive exclusion authority, seemingly in an effort to avoid the exclusion

of KV, which settled with DOJ. Assistant HHS Inspector General Gregory Demske offered his prediction describing OIG’s exclusion of Hermelin as a “preview of things to come.”¹⁸

Criminal Indictments of Corporate Counsel

Recent criminal indictments of senior executives also reflect the government’s focus on pursuing individuals for corporate wrongdoing. The Federal Criminal Code prohibits individuals from obstructing any federal agency proceeding and specifically prohibits certain conduct, including knowingly making false statements to the government; intentionally omitting information or concealing material information or documents or misleading the government; obstruction of criminal investigations of healthcare offenses; and destruction, alteration, or falsification of records in federal investigations.¹⁹

The government used its power to bring obstruction charges in the November 2010 indictment of GlaxoSmithKline’s former Vice President and Associate General Counsel Lauren Stevens, who was indicted for obstruction of a U.S. Food and Drug Administration (FDA) proceeding. The indictment alleged that Stevens concealed requested documents and provided false statements in a series of letters regarding alleged off-label use of the drug Wellbutrin.²⁰

According to the indictment, Stevens agreed to voluntarily collect and produce to FDA relevant materials from the company and third parties, even if the company did not create or maintain the materials. The government alleged that Stevens withheld some of the materials she obtained and lied to FDA by stating that the company had not developed a program or activity to promote off-label use. Significantly, there was no allegation that Stevens or anyone destroyed materials, or that any court order had been violated.

The Stevens indictment demonstrates the government’s willingness to charge individuals with obstruction when prosecutors believe the intent is to mislead investigators. In its November 9, 2010, press release, DOJ Civil Division Assistant Attorney General Tony West stated that when appropriate, “the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations.” Carmen Ortiz, the U.S. Attorney for the District of Massachusetts, added that “[t] here is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth,” and that federal agencies cannot protect public health if the “entities and individuals they regulate provide false information and conceal the true facts.”²¹

The government’s willingness to criminally charge corporate counsel with obstruction when counsel is responding on behalf of the company is particularly disturbing. Counsel has an obligation to advise company executives about all legal options available. To the extent that the government may view some options or strategies that corporate clients elect to pursue in their defense as criminal obstruction by their counsel may have a chilling effect on counsel’s exploration of various options or strategies. Counsel may understandably fail to offer or advise against certain options because of their very real concern for their own potential criminal

liability. Similarly, this enforcement trend may force in-house counsel to more frequently seek the advice of outside counsel to ensure they have a good-faith “advice of counsel defense” in an effort to avoid future charges of obstruction or exclusion. In relying on the advice-of-counsel defense, of critical concern is whether the in-house counsel sought outside counsel’s advice with the intent that the in-house counsel’s acts should be lawful. In that case, the in-house counsel cannot be convicted of a crime requiring unlawful intent, even if the outside counsel’s advice is inaccurate.

In the conclusion of an earlier case against former Tenet General Counsel Christi Sulzbach, alleging violation of the False Claims Act, federal District Court Judge Kenneth Marra granted summary judgment in early 2010. In its 2007 complaint, DOJ alleged that Sulzbach had falsely certified that Tenet was in compliance with Medicare requirements in 1997 and 1998. The government alleged that Sulzbach (then the associate general counsel and director of Tenet’s Corporate Integrity Program) knew about, but failed to disclose illegal employment contracts with physicians at the North Ridge Medical Center in Fort Lauderdale. A *qui tam* action involving the North Ridge contracts was filed in 1997 and Tenet ultimately paid \$22.5 million to settle that lawsuit. According to the government, however, prosecutors did not learn until 2006, when Tenet provided numerous documents in connection with a \$900 million settlement that Sulzbach had received a report from outside legal counsel advising Tenet that its physician employment contracts were problematic.

In granting the summary judgment to Sulzbach, Judge Marra agreed with Sulzbach that the government’s lawsuit against her was filed after the statute of limitations had expired. Had the matter gone to trial, Sulzbach’s attorney maintained that the report of outside counsel was a draft that never reached Sulzbach’s desk. As with the Stevens case, the Sulzbach case raises concerns about how increased government enforcement against corporate counsel may negatively impact corporate counsels’ ability to advise their clients.²²

What to Expect?

In light of the government’s statements and the recent cases discussed above, healthcare organizations can expect the government to continue to focus its enforcement efforts on pursuing individual owners, executives, board members, and counsel who may be held accountable for corporate misconduct. The industry can also expect the government to apply one or more of its enforcement tools used in the above cases, including obstruction of justice, the Responsible Corporate Officer Doctrine, and OIG’s exclusion authority.

In all likelihood, the industry will also face continued scrutiny of corporate counsel’s actions in their roles as legal advocates, such as government attempts to characterize their efforts as obstruction, including intentional omitting information or misleading the government. Owners, executives, board members, and counsel alike should beware and take great care when dealing with matters relating in any way to the government. What today may

appear to be prudent advice and appropriate actions for organizations to take may one day be viewed by government prosecutors and regulators as obstruction and/or a violation of one’s corporate responsibility. One thing is clear—individuals in positions of authority within healthcare organizations are more vulnerable than ever before. Unfortunately, it appears that this trend will not end anytime soon.

- 1 *United States v. Dotterweich*, 320 U.S. 277 (1943). See also 21 U.S.C. § 301 *et seq.*,
- 2 Social Security Act § 1128 (b)(15)(A)(i); 42 U.S.C. § 1320a-7(b)(15)(A)(i). (Emphasis added). For owners, exclusion requires that the evidence support a finding that the owner *knew or should have known* of the conduct, in which case OIG will presume that exclusion should occur. This presumption can be overcome, however, if OIG finds that significant factors weigh against exclusion. By contrast, for officers and managing employees, the Act does not require any knowledge of the wrongdoing. As a result, OIG may exclude every officer and managing employee of a sanctioned entity, although OIG has stated it does not intend to do so. Nevertheless, as with owners, if OIG finds evidence supporting that a managing employee *knew or should have known* of the conduct, OIG will presume that exclusion should occur. Again, this presumption can be overcome by evidence that significant factors weigh against exclusion.
- 3 Social Security Act § 1128(b)(15)(A)(ii); 42 U.S.C. § 1320a-7(b)(15)(A)(ii). Generally, “managing employees” include any individual who exercises operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity. Social Security Act § 1126 (b); 42 U.S.C. § 1320a-5(b). (Emphasis added).
- 4 OIG Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act (October 20, 2010). See also OIG Special Advisory Bulletin on the Effect of Exclusion (September 1999).
- 5 *Id.* at 2-4. OIG’s factors include:
 - (1) Circumstances of the misconduct and seriousness of the offense. (For example, what was the nature and scope of the misconduct of the sanctioned entity or any other relevant misconduct? Did the misconduct occur at the entity headquarters or in a peripheral area? What type and amount of penalty was issued against the sanctioned entity? Whether the misconduct resulted in actual or potential harm to beneficiaries or others or financial harm to any federal healthcare program or other entity. Whether the misconduct was an isolated occurrence or part of a pattern or wrongdoing.)
 - (2) Individual’s role in the entity and at the time of the misconduct. (Particularly the degree of managerial control or authority the individual had by virtue of their position during the misconduct.)
 - (3) Individual’s Actions in Response to the Misconduct. (For example, whether the individual attempted to stop the misconduct or mitigate its harmful effects, such as by disciplining responsible individuals, whether these actions predated the individual’s knowledge of a government investigation, and whether the individual cooperated with the government. A factor against exclusion is that the individual exercised extraordinary care, but yet could not prevent the exclusion.)
 - (4) Information about the entity. (Such as whether the entity has previously been convicted of a crime or been found liable, or has been involved in a civil or administrative case with the federal or any state government, and if so, the nature of that prior misconduct. The size of the entity, the number of employees, and its corporate structure and reporting relationships among subsidiaries is also relevant.)
- 6 Social Security Act § 1128A (a)(6); 42 U.S.C. § 1320a-7a(a)(6); 42 C.F.R. § 1003.102(a)(2).
- 7 Testimony of HHS Inspector General Daniel Levinson, Senate Committee on Homeland Security and Governmental Affairs (March 9, 2011), pg. 8.
- 8 *Id.* at 2. See also Testimony of Chief Counsel to the Inspector General, Lewis Morris, House Ways and Means Committee, Subcommittee on Oversight (March 2, 2011).
- 9 *Id.* at 8. See also *supra* Note 2.
- 10 *Id.* See also *supra* Note 4.
- 11 *Id.* at 8-9. See also Testimony of Lewis Morris at Note 8.
- 12 *Id.* at 7. See also *supra* Note 4. Another tool OIG can and has used against healthcare executives is to enter into civil monetary penalties settlements, as it did with Michael Bakst, PhD, in October 2000, who paid \$64,000 to settle allegations that while he was executive director and compliance officer of

- Community Memorial Hospital in Ventura, CA, he violated the Stark Law by personally negotiating noncompliant contracts with physicians.
- 13 21 U.S.C. § 301 *et seq.*
- 14 *Friedman v. Sebelius*, 2010 U.S. Dist. LEXIS 131465 (D.D.C. 2010). The executives were the company's president and chief executive officer, the executive vice president and chief legal officer, and former executive vice president and chief scientific officer.
- 15 *Id.* The 2007 settlement resolved government allegations that the companies had improperly marketed the pain reliever, OxyContin, as less addictive and less likely to cause withdrawal symptoms than other pain relievers, even though the companies had no evidence to support the claims. In addition to the misdemeanor guilty pleas, HHS imposed a twelve-year exclusion from federal healthcare programs on each of the three executives.
- 16 *In the Case of: Paul D. Goldenheim, M.D., Howard R. Udell, Michael Freidman v. Inspector General*, DAB No. 2268, 2009 WL 2957956 (HHS Aug 28, 2009). Note that the Purdue executives were not excluded under OIG's permissive exclusion authority, but rather its authority to exclude individuals for fraud convictions. See 42 U.S.C. § 1320a-7(b)(1).
- 17 *United States v. KV Pharmaceutical Co.*, CR 95-0179 (Dist. M.D., 1995). The government also alleged that the drug's labeling was false and misleading because it stated the drug was a specified strength when in fact it was oversized and contained excess active ingredients. KV had earlier pled guilty to misdemeanor charges involving the misbranding of drugs and failure to file required reports with FDA. KV was also involved in three drug forfeiture lawsuits by FDA, in 1993 and 2008, respectively, and had received warning letters about deviations from FDA manufacturing regulations. In 2009, KV and Hermelin executed a civil consent decree with FDA, placing the company's drug manufacturing activities under FDA supervision. *United States v. KV Pharmaceutical Co.*, 4:09-CV-334 RWS (E.D. M.O. 2009).
- 18 *Exclusion of K-V Pharmaceutical Executive Previews 'Things to Come,' OIG Official Says*, BNA HEALTH LAW REPORTER, Volume 15, Number 234 (December 8, 2010).
- 19 18 U.S.C. §§ 1501-1520.
- 20 *United States v. Stevens*, No. 8:10-CR-00694-RWT (D.M.D. 2011). The case was being prosecuted by Washington DOJ and the U.S. Attorney's Office for the District of Maryland. On March 23, 2011, the district court dismissed without prejudice the indictment against Stevens due to its finding that federal prosecutors had improperly instructed the Grand Jury regarding Stevens' "advice of counsel defense." In that regard, Stevens argued successfully that Grand Jury transcripts should be disclosed to show that the government had improperly instructed the Grand Jury, and also persuaded the court that the advice of counsel defense is not an affirmative defense, but rather the required *mens rea* element of the charged offense. The court found that a proper instruction to the Grand Jury on the advice of counsel defense would have stated that if Stevens relied in good faith on the advice of counsel, after fully disclosing to counsel all relevant facts, then she would lack the wrongful intent to violate the law and could not be indicted for the crimes charged in the indictment. Therefore, to the extent that Stevens sought the advice of counsel with the intention that her acts should be lawful, she cannot be convicted of a crime that required willful and unlawful intent, even where the counsel's advice may be incorrect. On April 13, 2011, the government re-indicted Stevens on essentially the same charges. DOJ Press Release, Former Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements (April 14, 2011). On May 10, 2011, the court granted Stevens' motion for Rule 29 judgment of acquittal. The court stated that "[o]nly with a jaundiced eye and with an inference of guilt that's inconsistent with the presumption of innocence could a reasonable jury ever convict" Stevens. *United States v. Stevens*, 10-CR-00694-RWT, TR at 8. The court concluded that "it would be a miscarriage of justice to permit this case to go to the jury." *Id.* at 9.
- 21 DOJ Press Release, Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements (November 9, 2010). According to a motion of Stevens that was unsealed at a pre-trial hearing on March 17, 2011, prosecutors misled the grand jury that indicted her for allegedly lying to regulators about off-label marketing of Wellbutrin. Stevens relied on an advice-of-counsel defense based on advice she received from outside counsel. *Stevens* at Documents 119-1, 119-9.
- 22 In another recent case holding corporate executives and counsel responsible for corporate wrongdoing, on March 2, 2011, the U.S. Attorney's Office for the Middle District of Florida indicted five former executives of WellCare Health Plans Inc., including its former general counsel, on charges of submitting false statements and healthcare fraud in connection with WellCare's reporting of expenditures for behavioral healthcare services to the Florida Medicaid

program. The indictment alleges that the former executives inflated medical expenses used to calculate premium refunds owed by WellCare to Florida's Medicaid program. WellCare was required to spend at least 80% of the capitation payments the company received on the provision of behavioral healthcare services, or return the difference to the state. WellCare had previously entered into a deferred prosecution agreement with the government in 2009 and agreed to pay \$80 million in restitution and forfeiture as a result of the company's actions. WellCare issued its own press release on March 2, 2011, stating that the company had conducted an internal investigation in 2009 and is pursuing legal claims against a number of the former executives. *United States v. Farha*, CV 8-11-Cr-115-T-30MAP (M.D. Fla. 2011).

Practice Groups Staff

Trinita Robinson

Vice President of Practice Groups
(202) 833-6943
trobinson@healthlawyers.org

Magdalena Wencel

Senior Manager of Practice Groups
(202) 833-0769
mwencel@healthlawyers.org

Denis Vidal

Practice Groups Administrator
(202) 833-0782
dvidal@healthlawyers.org

Crystal Taylor

Practice Groups Coordinator
(202) 833-0763
ctaylor@healthlawyers.org

Brian Davis

Practice Groups Editorial Coordinator
(202) 833-6951
bdavis@healthlawyers.org

Ramon Ramirez

Practice Groups Web Assistant
(202) 833-0761
rramirez@healthlawyers.org

Graphic Design Staff

Mary Boutsikaris

Art and Design Director
(202) 833-0764
mboutsik@healthlawyers.org

Ana Tobin

Graphics Assistant
(202) 833-0781
atobin@healthlawyers.org

Assessing Intangible Value in a Physician Practice Acquisition*

Mark O. Dietrich, CPA/ABV
Mark O. Dietrich CPA PC
Framingham, MA

Gregory D. Anderson, CPA/ABV, CVA
HORNE LLP
Hattiesburg, MS

Carol Carden, CPA/ABV, ASA, CFE
W. James Lloyd, CPA/ABV, ASA, CBA, CFE
Pershing Yoakley & Associates PC
Knoxville, TN

J. Gregory Endicott, CPA/ABV, ASA, MBA
Strategic Value Group LLC
Los Angeles, CA

Todd J. Sorensen, AVA
VMG Health
Nashville, TN

Reed Tinsley, CPA
Houston, TX

Kathie L. Wilson, CPA, CVA
Millbrae, CA

Introduction

Due in large part to concerns over healthcare reform and declining reimbursement rates, physicians are increasingly looking for opportunities to sell their practices to hospitals and work as employees. Similarly, hospital systems are interested in acquiring key practices to solidify or expand their provider networks. These transactions are clearly subject to the regulatory restrictions of commercial reasonableness and Fair Market Value (FMV) imposed by the Stark Law¹ and the Anti-Kickback Statute (AKS),² as well as the Internal Revenue Code Section 501(c)(3) regulations if the hospital is a nonprofit entity. Many practices have very low or sometimes negative projected post transaction earnings after adjusting for the physician's anticipated post transaction compensation. Accordingly, an Income Approach valuation methodology, such as the Discounted Cash Flow (DCF) method, will generally result in zero or a very low value for the practice. In such cases, the Cost Approach will be utilized instead. However, the problem arises when the Cost Approach results in substantial values being attributed to intangible assets,³ such as physician workforce, that are not supported by an appropriate level of net cash flow needed to provide an economic return to the hypothetical buyer.

This paper addresses the appropriateness of assigning substantial value to intangible assets such as physician workforce, under the FMV standard, and going concern premise of value, without such amounts being appropriately supported by net cash flow under the Income Approach.

The paper first defines the key terms used and describes typical intangible assets, then looks at the theoretical underpinning of the Cost Approach as described in accepted valuation texts and court cases, then examines, critiques, and ultimately dismisses the sole use of the Cost Approach to value physician workforce as both a violation of professional standards and the regulatory structure for FMV.

Key Concepts & Definitions

The following key concepts and definitions are important for understanding the analysis and conclusions expressed in this paper.

Commercial Reasonableness

Transactions between hospitals and physicians with the ability to refer designated health services (DHS) must be commercially reasonable. The Stark regulations explain commercial reasonableness as: "An arrangement will be considered commercially reasonable, in the absence of referrals, if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential designated health services referrals."⁴

Accordingly, the commercial reasonableness requirement means the transaction must make good business sense *without* the potential of future referrals from either party.

Fair Market Value

The most widely used definition of FMV is: "*The price at which property or service would change hands between a willing buyer and a willing seller, neither being under a compulsion to buy or sell and both having reasonable knowledge of the relevant facts.*"⁵

The Stark regulations define FMV similarly as: "The value in arm's length transactions, consistent with the General Market Value." General Market Value (GMV) is defined as: "The price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of the acquisition of the asset or at the time of the service agreement."⁶

Strategic Value

In contrast to FMV, strategic value is the value to a particular buyer rather than to a hypothetical buyer. There are a variety of strategic considerations that a specific buyer may employ in determining strategic value, some of which would likely not violate



the Stark Law and others of which almost certainly would. For example, a tax-exempt hospital would have access to tax-exempt bonds to acquire a practice, providing a low cost of capital and a correspondingly higher multiple of value. It would also not pay any income tax on income from the practice if the transaction were properly structured resulting in a higher cashflow and strategic value. Although they do not violate the Stark law, these two items likely violate the anti-inurement rules. When compared to a hypothetical nonhospital buyer, a hospital obtains various inpatient referrals from a physician practice, of course, but consideration of these referrals directly or indirectly is prohibited.

Income Approach Valuation Methodology

The Income Approach is a general way of determining an indication of value based on the future income (benefits) expected to be generated by the asset. This approach is based on the fundamental valuation principle that an asset's worth is directly related to the present value of the future benefits of ownership. The most common Income Approach methodology is the DCF method, which discounts anticipated future net cash flow to present value by using a discount rate that reflects the time value of money and the risk associated with the asset.

The Income Approach is generally used to value operating companies that produce positive cash flow under the going concern premise of value.

Cost Approach Valuation Methodology

The Asset Approach, which is also commonly referred to as the Cost Approach,⁷ is a general way of determining an indication of value based on the entity's underlying assets and liabilities. This approach is based on the theory that an asset's worth is directly related to the amount that would be required to reproduce or replace it. The Cost Approach generally results in an upper limit of value for assets that can be easily replaced or reproduced, since no prudent investor would pay more for an asset than the cost to create a comparable one. Similarly, no prudent investor would pay to create an asset that would not generate an income return under the regulatory structure commensurate with the outlay that is allowed.

Intangible Asset

Intangible assets are non-physical assets, such as trademarks, patents, securities, contracts, and goodwill that have rights and provide economic benefits to the owner.⁸

Goodwill

Goodwill is a type of intangible asset that is related to the entity's name, reputation, customer loyalty, and similar factors not separately identified.⁹ Assembled workforce is generally considered to be an integral part of goodwill and not identifiable as a separate asset.¹⁰

Typical Physician Practice Assets—Least Controversial to Most Controversial

1. Furniture & Equipment
2. Accounts Receivable
3. Leasehold Improvements
4. Trade Name
5. Telephone Numbers
6. Patient Charts
7. Non-Physician Workforce
8. Physician Workforce

The Context for Valuing Physician Workforce

While the proper premises of value to apply may be debated, there is little argument that tangible assets such as furniture and equipment and accounts receivable have some value in this context. Reasonable minds may differ on the proper treatment or value of intangible assets such as trade name and telephone numbers—intangible assets that may often be differentiated because they possess the potential for being both legally protectable and separately marketable.

Other intangible assets or economic phenomena that may not meet the definition of an intangible asset are of particular concern as you move further along in the list. Some appraisers make the mistake of not only assigning value to these items in the absence of cash flows, but also in attaching value to something that may

not be an asset in the first place. In their book, “Valuing Intangible Assets,” Robert Reilly and Robert Schweihs note that, in order for an intangible asset to exist from a valuation perspective, it must include the following:

1. It should be subject to specific identification and recognizable description.
2. It should be subject to legal existence and protection.
3. It should be subject to the right of private ownership, and the private ownership should be legally transferable.
4. There should be some tangible evidence or manifestation of the existence of the intangible asset (e.g., a contract, a license, a registration document, a computer diskette, a listing of customers, a set of financial statements, etc.).
5. It should have been created or have come into existence at an identifiable time or as the result of an identifiable event.
6. It should be subject to being destroyed or to a termination of existence at an identifiable time or as the result of an identifiable event.¹¹

It is in this area that we see some valuations incorrectly assign value to phenomena such as a workforce in place where no legal right exists, such as in the case of a physician without an employment agreement or the non-physician workforce of a physician practice in an at-will employment state.

The disparity of treatment and the rather large magnitude in associated value, however, approaches darker shades of gray as you approach the physician workforce in place. Our attempt here is not to minimize the need to properly treat each of the tangible and intangible asset classes, but the most controversial asset in this context also happens to be the item that some appraisers are attaching the greatest magnitude of value to—the physician workforce.

When practice acquisition valuations based on the Cost Approach imply intangible value attributable to physician workforce in the observed range of \$50,000 to more than \$400,000 per physician, there is cause for concern over the validity of the valuation analysis and the intentions of the parties.

Example

The argument for the attachment of significant value to the physician workforce in place arises out of a legitimate business consideration for hospitals in some scenarios. The scenario goes something like this:

Hospital X's CEO in a two-hospital town relies almost exclusively on Heart Group, the only cardiology group of substance in the area, to generate volume (i.e., referrals) for Hospital X's cardiology line of business. Heart Group currently splits business between Hospital X and Hospital Y. Heart Group informs

both Hospital X and their competitor, Hospital Y, that they want to entertain the sale of their practice and employment. Faced with the potential loss of the cardiologists that generate all of the volumes in the cardiology lines of business at his hospital, Hospital X's CEO argues that if he doesn't buy Heart Group, he'll have to recruit and employ physicians to practice at Hospital X—absorbing recruiting costs and significant losses in the process. To further complicate the fact pattern, Hospital Y has retained a valuation firm that values these costs to recreate the physician workforce at \$300,000 per physician despite that firm's analysis that there will be little to no cash flow from the cardiology practice after paying the cardiologists' salaries. Hospital X's CEO is really left with no choice, they feel they must at least match their competitor's offer.

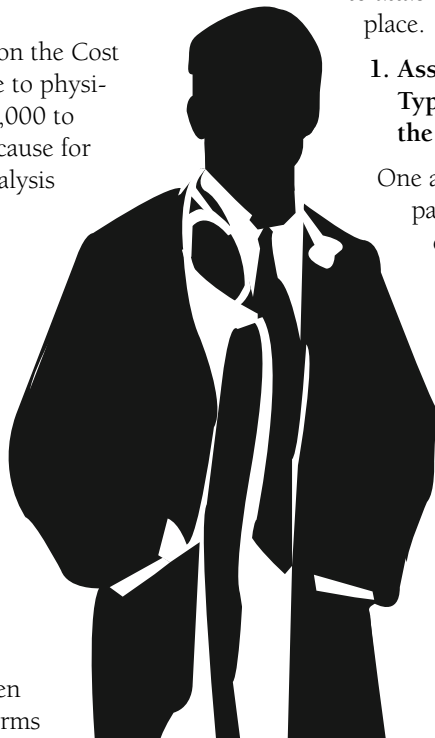
As is explained in more detail on the coming pages, the sole reliance on the Cost Approach to value intangible assets is generally inappropriate. Whether the intangible assets are related to payments for physician workforce, non-compete agreements, or compensation, they must be viewed in the context of an even exchange between the parties with no benefit, directly or indirectly, ascribed to referrals. In the absence of an expectation of income from the acquired physician practice, the only source of income necessary to meet the FMV standard is from future referrals associated with that practice.

A Review of the Significant Issues

Among the many problems with relying solely on the Cost Approach to value intangible assets related to an ongoing business enterprise is that it is inconsistent with valuation theory and the valuation guidance offered by the Stark Regulations. While not necessarily exhaustive, the following is a list of the significant issues that would all need to be resolved favorably in order to attach significant value to the physician workforce in place.

1. Assuming a Hospital Can Be Considered the Typical or Likely Buyer is Inconsistent With Both the Classical and Regulatory Definitions of FMV

One argument often cited as a reason for hospitals paying for a physician workforce is the avoidance of costs related to recruiting and employing such physicians in order to meet their community need. The momentum of many of the concepts associated with healthcare reform such as bundled payments and accountable care organizations (ACOs) generates additional support for the business case for hospital employment of physicians. Given that hospitals will likely need to employ physicians and provided there are strong contractual relationships in place to secure it, there is little question or argument that securing a physician workforce in place brings strategic value (as distinguished earlier herein from FMV) to a hospital in that it allows a hospital to precede the costs associated with recruiting and ramping up a



physician workforce. However, this is inconsistent with both the classical and regulatory definitions of FMV in the context of the acquisition of the assets of a physician practice since those assets must be shown to generate income and that income must not be proscribed by applicable regulations. For business appraisals performed in the context of hospitals purchasing physician practices, healthcare regulations and statutes require any transaction to occur at FMV.

As stated earlier, FMV is classically defined as the price at which an asset would exchange between a willing buyer and a willing seller, neither being under compulsion to buy or sell, each having reasonable knowledge of all relevant facts, and with equity to both. Based on the guidelines established by the Stark II regulations, we typically expand our definition of FMV to encompass GMV, which is the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement (42 C.F.R. 411.351), and where the compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals and where the arrangement would be commercially reasonable even if no referrals were made to the employer.¹²

Given the definition of FMV, the practice of simply assuming that a hospital is avoiding a significant cost by simply paying for a physician workforce or that a hospital should be considered the most likely buyer of the physician practice appears to be somewhat inconsistent with the classical definition of FMV in that there is some compulsion for hospitals to buy physician practices. Even if one is somehow able to get comfortable with being consistent with the classical definition of FMV, the assumption that a hospital is the only typical or likely buyer of a physician practice appears to be even more directly inconsistent with the further restrictions under Stark II that the assumed buyer not be in a position to benefit from the business generated by the seller.

2. Replication Cost as a Valuation Methodology Has Significant Weaknesses, and Its Use to Value the Physician Workforce is Inconsistent With All Premises of Value Other Than Going Concern

A book looked upon as an authoritative text in the valuation profession is *Valuing a Business: The Analysis and Appraisal of Closely Held Businesses*.¹³ Chapter 14 provides guidance to appraisers in conducting the Cost Approach. According to the authors, conducting the Cost Approach requires the appraiser to not only choose the proper standard of value, but also to choose the proper premise of value. The four premises of value delineated include:

- Value in continued use as part of a going concern;
- Value in place as part of a mass assemblage of assets;
- Value in exchange, as part of an orderly disposition; and

- Value in exchange, as part of a forced liquidation.

Based on generally accepted interpretations of the guidance provided by this authoritative text, the only of the four premises of value above that would ultimately result in any significant value for the physician workforce in place is value in continued use as part of a going concern. According to the authors, “Under this premise, it is assumed that the subject assets are sold as a mass assemblage and as part of an *income producing* (emphasis added), business enterprise.”¹⁴ The assumption that the practice is income producing is in complete contradiction to the reasoning used to rely exclusively on the Cost Approach. As previously discussed, relying exclusively on the Cost Approach is a function of the fact that considering the proposed compensation arrangement with the physician(s), there is either no income or at least not enough income to justify any value over and above the value of the tangible assets.

The weaknesses of the Cost Approach in differentiating what has value and what does not have value are not limited to physician workforce. Michael Crain, CPA/ABV, ASA, CFA, a well-known and highly regarded member of the appraisal community observes:

“Some criticize the Cost Approach by arguing that the evidence of a relationship between cost and price is weak and, thus, the Cost Approach is not a reliable way to estimate the value of something. One example of weak relationships is the decline in real estate prices in the late 2000s. It is conceivable that the costs of building some homes were higher than their market prices. Further, these downward price movements were weakly correlated with the costs of building a home. *A closely-related argument is that the Cost Approach is overly simplistic and can violate the first principle of valuation that says the value of something is the expected future benefits expected from it, discounted to the present. This principle links value to future returns whereas the Cost Approach has strictly a historical perspective.*” (Emphasis added)

“Another argument criticizing the Cost Approach is that it assumes that if a firm develops something, it is valuable. We know from theory and observation that firm managers use trial and error in their operations. Simply put, some things managers do work and some do not. *The Cost Approach is unable to distinguish between the costs of successful and unsuccessful efforts.*”¹⁵ (Emphasis Added)

The 2008 Tax Court case *Derby*¹⁶ specifically addresses the Cost Approach issue for tax-exempt hospitals and related entities. Although the valuation in that case was a misuse¹⁷ of the Income Approach, the principle that FMV constitutes an even exchange between hypothetical buyer and seller is the same.

“The Dutcher appraisal takes no account of the \$35,000 ‘Physician Access Bonus’ payable to each SWMG physician over the initial two years of the affiliation. Ignoring these payments when computing distributable earnings that SWMG would generate results in an overstatement of those earnings and a corresponding overstatement of the value of SWMG’s intangible assets (since, under Mr. Dutcher’s analysis, intangible asset value equals present value of future distributable earnings, less tangible assets and implied working capital).”

The point here, of course, is not limited to the physician access bonus. Any transaction involving the purchase of a medical practice must consider all the elements of that transfer in determining whether the transaction meets the FMV standard, as modified by the Stark law. This includes post-transaction compensation in addition to the purchase price and contractual terms.

“Petitioners have not shown that the value of what they transferred to SMF exceeded the value of the benefits they received in return. As noted above, those benefits included, in the first instance, employment that was compensated with shares of revenue (47 to 57.75 percent) that significantly exceeded the median share of revenue (45.18 percent) devoted to physician compensation in petitioners’ specialties; a \$35,000 ‘Physician Access Bonus’ for each SWMG physician, including petitioners; an absence of restrictions on establishing a competing medical practice in the event of cessation of employment with SMF; and greater economic security in the managed care environment.”

3. Financial Reporting, Court Cases, and Other Guidance Point to Allocating Value to Workforce in Place, Not Separately Valuing It

Similarly, it should be noted that while using replication costs to estimate the value of the workforce in place is widely accepted in valuation texts and other sources of guidance when *allocating value*, it is not necessarily sanctioned as proper for assigning value in the *Cost Approach*. Nowhere is this more clear than in the application of the Financial Accounting Standard Board’s Statements on Financial Accounting Standards (SFAS). Citing SFAS 141, Valuation for Financial Reporting notes that, “SFAS 141 specifically prohibits the recognition of assembled workforce as an intangible asset apart from goodwill” (Michael J. Mard, 2002). The IRS has also offered several pieces of guidance regarding the valuation of physician practices. One of the often referenced pieces of guidance used for valuation of physician practices is *Valuing Physician Practices* (Charles F. Kaiser, 1996). It should be noted that while this article discusses at length the value of various tangible and intangible assets such as equipment, trade name, patient charts, and workforce in place utilizing cost to recreate in an the *Cost Approach*, the context is clearly one of *allocating the value obtained from the Income Approach* (DCF method) and not one of using the *Cost Approach* in isolation.

4. Ability to Terminate Without Cause May Limit Ability to Protect Value

In the previous phase of physician practice transactions, many of the employment agreements included terms of five or more years without the ability for either party to terminate without cause. In addition, many of the employment agreements included trailing covenants not to compete, that combined with inability to terminate without cause, made it not only virtually impossible for either party to terminate the agreement during the initial term, but also extremely difficult for the physicians to remain in a community following the initial term, absent employment with the hospital. One feature in the current phase of physician practice transactions that distinguishes it from the previous phase

is that, in many cases, the employment agreements permit either party to terminate the employment agreement without cause with only ninety to 180 days notice, with no restrictions on future competition. This is certainly not always the case. However, if the subject employment agreements include the ability to terminate without cause and permit a physician to remain in the community, the potential inability to legally protect the physician workforce beyond the rolling ninety to 180-day virtual term of the employment agreements should be considered.

The Tax Court case *Derby* specifically addresses this issue for tax-exempt hospitals and related entities. Failure to follow these principles raises the specter of the Intermediate Sanctions Provisions and anti-inurement provisions of the Internal Revenue Code, particularly with the post-reform emphasis on disclosure in Form 990—and the public access to those forms, including by potential qui tam plaintiffs and their attorneys.

“There is no adjustment for the fact that the SWMG physicians were not required to execute noncompete agreements. Mr. Dutcher treated each SWMG physician as transferring an allocable share of SWMG’s intangibles, including goodwill, which was not treated as diminished in any way by the physicians’ not having executed noncompete agreements with respect to SWMG or SMF. However, in *Norwalk v. Commissioner, T.C. Memo. 1998-279*, we found that there is no transferable or salable goodwill where a company’s business depends on its employees’ personal relationships with clients and the employees have not provided covenants not to compete . . . We also believe that, under the willing buyer/willing seller standard of FMV enunciated in *Rev. Proc. 59-60, 1959-1 C.B. 237*, to which Mr. Dutcher purportedly adhered, a willing buyer of SWMG on the transaction date would have insisted on a significant discount with respect to the value of the entity’s intangible assets, precisely on account of the absence of noncompete agreements from the SWMG physicians. Indeed, the SWMG physicians not only did not execute noncompete agreements; they had the benefit of the ‘free to compete’ provision in the PSA which facilitated their reclaiming their patients in the event they decided to cease working for WMG/SMF. Mr. Dutcher’s failure to account for the risk to his estimated five-year stream of earnings posed by SWMG physicians’ departing with their patients is contrary to well-established valuation principles and common sense, and results in an inflated value for the SWMG physicians’ goodwill.” (Emphasis added)

“. . . and rather than a noncompete agreement, the ‘free to compete’ provision, which secured for each petitioner the express right, upon his or her termination of employment with SWMG/SMF, to have his or her patients as of the date of affiliation with SMF notified of the departure and given the option of having the patient’s medical records transferred to the departing physician. In addition, when petitioners’ circumstances before the transaction are considered, a second tier of benefits they secured in the transaction with SMF becomes apparent. First, petitioners solved their core economic problem arising from the advent of managed care; namely, the risk of loss from having patients requiring extraordinary care. After the transaction, by virtue of

the minimum compensation guaranties, this risk was largely transferred to SMF, which could better manage it given SMF's greater patient population and resources. Second, as a result of their affiliation with a relatively large health care organization, petitioners secured the benefits of greater leverage in negotiating contracts with HMO's and greater efficiencies in providing care, with any resulting enhancement in revenues inuring to their benefit by virtue of SWMG's compensation being determined as a percentage of net revenues. In sum, by transferring their practices to SMF in the transaction at issue, petitioners ensured for themselves the continued ability to maintain or improve their accustomed level of earnings from the practice of medicine—something they had concluded was not likely to be possible had they continued to maintain solo or small group practices.”

The example described earlier of a hospital relying upon a single heart group for admissions parallels to a large extent the recent qui tam case *Bradford Regional Medical Center* in which the Federal District Court for Western Pennsylvania granted summary judgment to the qui tam plaintiffs on violations of the Stark Law. That case involved the “lease” of a nuclear medicine camera from two internists who were responsible for a significant share of the hospital's high tech imaging, inpatient and outpatient referrals. There, the hospital was confronted with the loss of the nuclear medicine scans which severely restricted its ability to recruit a cardiologist. Further risk apparently existed with respect to the possibility that the physicians might acquire their own MR or CT scanner, both of which have cardiac applications.

Part of the court's analysis was that the record indicated that the defendant hospital had clearly considered the volume and value of referrals in the price paid for the nuclear medicine camera sublease, which price included a noncompete agreement. As such, the valuation prepared in connection with that sublease was irrelevant, since the FMV exception could only be used if the sublease did not consider referrals in the first instance. Further, the valuation also discussed loss of referrals, and there the definition of FMV was not consistent with the modifications of the Stark law.

5. Lack of Any Evidence Indicating Hospitals Could Sell Physician Workforce Back for Any Significant Value

Another key to valuing physician practices is consistent treatment of controversial items, regardless of which party is on the buyer side and which party is on the seller side. We believe collectively performing hundreds of valuations for both potential purchases from physicians and sales to physicians provides a balanced perspective to approaching these issues. We are not aware of a single instance, even in situations where enforceable employment agreements and covenants exist, where hospitals have successfully sold a physician workforce to the physicians. The accepted method for establishing the value of a noncompete covenant is to use the Income Approach.

6. Analyses Typically Include No Consideration for Physician Age, Need to Amortize the Asset

Like #4, another concept that may often be ignored in assigning value to physician workforce is that of inevitability—it is inevitable that eventually the physician workforce must be replenished and

the employer will incur the costs associated with recruitment and ramp up. In this sense, any cost to recreate the physician workforce is simply a present value exercise. Ignoring the other five factors or even assuming an appraiser is comfortable with their ability to successfully navigate the mine field, this must be considered.

Conclusion

Under the FMV standard of value, there is no basis for exclusive reliance on the Cost Approach in valuing intangible assets in general and physician workforce in particular when there is no expectation of income from the underlying assets of a going concern. The professional literature of valuation theory that serves as the basis for FMV provides no support. Additionally, the commercial reasonableness requirement under the Stark law that a transaction make sense in the absence of referrals would almost assuredly be violated by paying for physician workforce without such values being adequately supported by cash flows under the Income Approach. Given that both the economic value and the FMV of an asset is the present value of expected future benefits of ownership, implicit in the use of the Cost Approach—and in our view explicitly assumed—is income from the referrals to be received.

**This article was originally published as a white paper by HORNE LLP in February 2011. The statements herein represent general principles of valuation. The specific circumstances present in a given engagement may affect the extent of their application.*

1 42 U.S.C. Sec. 1395nn.

2 42 U.S.C. Sec. 1320a-7b.

3 There are certain specifically identifiable assets (such as a Certificate of Need or EMR systems) that may have value even in the absence of DCF value to the existing owner.

4 69 Fed. Reg. 16093 (March 26, 2004).

5 Estate Tax Reg. 20.2031.1-1(b); Revenue Ruling 59-60, 1959-1, C.B. 237.

6 420 CFR 411.351. See also Section 1877(h)(3) of the Social Security Act.

7 The terms are used interchangeably.

8 Hitchner, James R., *Financial Valuation Applications and Models*, John Wiley & Sons, Inc., 2003, p. 13.

9 *Ibid.*

10 See Financial Accounting Standards Board Accounting Standards Codifications 958-810, Not-for-Profit-Entities, and 954-810, Health Care Entities. IRS may recognize assembled workforce as a separate intangible when there is a DCF value to support it.

11 *Valuing Intangible Assets*. Reilly, Robert F. and Schweihs, Robert P. McGraw-Hill (New York, 1999), p. 5.

12 42 C.F.R. 411.351 and 42 C.F.R. 411.357(c).

13 *Valuing a Business: The Analysis and Appraisal of Closely Held Businesses*, Shannon P. Pratt, 4th Edition 14 *Ibid.*, Chapter 14, page 314.

14 *Ibid.*, Chapter 14, page 314.

15 Michael A. Crain, “Study Guide, Business Valuation for Forensic Accountants” (working paper, School of Accounting, Florida Atlantic University, 2010), used with permission.

16 T.C. Memo. 2008-45.

17 Given the court's detailed rejection of the assumptions utilized.

Trends in Catholic Healthcare

*Sandra M. DiVarco, Esquire**

Kerrin B. Slattery, Esquire

McDermott Will & Emery LLP

Chicago, IL

Introduction

Catholic hospitals comprise more than 12% of all hospitals in the United States,¹ making the unique issues relevant to those facilities relevant for all health lawyers and advisors to understand. This article discusses background on Catholic hospitals and identifies three major trends impacting this important industry segment. These trends arise with a backdrop of the changing demographic of Catholic healthcare sponsors, the orders of women and men religious who started healthcare ministries. In many cases, these ministries were started in the late 1800s and continue today. The demographics of sponsoring congregations and orders are changing as the average age of members increases and some congregations consolidate and merge. These changes have impacted both the sponsors and the organizations they sponsor, as they face increasing challenges directing and overseeing Catholicity for their sponsored ministries. In addition, the healthcare industry itself has been subject to overhaul and change.

First, the article explores the complexities of compliance with the *Ethical and Religious Directives for Healthcare Organizations* (ERDs),² both in recently publicized cases and in day-to-day operations. The role of sponsors, boards of directors, and management of Catholic organizations in ensuring compliance with the ERDs will be highlighted. The article includes suggestions on steps to take to memorialize the obligation to comply with the ERDs and make recommendations regarding audit and enforcement of compliance for Catholic hospitals or non-Catholic operators who have committed to operate as a “Catholic” hospital.

Second, the article identifies ways in which civil law changes, such as the establishment of state laws recognizing civil unions and the increasing requirements prescribed for insurance coverage as part of healthcare reform, pose particular challenges for Catholic hospitals in their role as major employers in many communities. Moreover, as Catholic facilities, Catholic hospitals are subject not only to civil laws, but also to Canon law, which is the Church-created law that governs Catholic entities and operations. (In civil legal terminology, Canon law is akin to “statutes” and ERDs would be an example of “regulations” derived from those statutes).

Finally, the article will discuss the special considerations relevant to Catholic hospitals in the era of hospital and healthcare system consolidation and increased transaction activity, the role of Catholicity in such transactions and emerging models that look to address the particular concerns of Catholic hospitals or those with whom they do transactions.

By way of background, the Catholic Church recognizes a number of characteristics as part of the “Catholic identity” of a sponsored ministry. Typically, the sponsoring congregation or order would hold certain reserved powers over the civil law entity that owns and operates the healthcare ministry, creating in effect a “super” governing board for certain powers. The “reserved powers” are those powers required to be held by Canon law (such as approval of Board of Directors, approval of sales or encumbrance of property, etc.).³ Indicia of Catholic identity include:

1. Ensuring compliance with the ERDs;
2. Providing Catholic spiritual care services and chaplaincy;
3. Administering property in accordance with Canon law;
4. Demonstrating Catholic values;
5. Maintaining a chapel (where Catholic mass is held);
6. Displaying Catholic religious symbols within the hospital (crucifixes, statues and icons, stained glass, etc.);
7. Accepting guidance of Catholic authorities (i.e., the diocesan bishop);
8. Maintaining a Catholic “brand” (through naming, use of religious logos, etc.); and
9. Holding the facility or system out to the public as Catholic.

Canon lawyers have summarized the concepts inherent in Catholic identity as four necessary “ingredients”: mission, sponsorship, holistic care, and ethics.⁴ However, recent court cases indicate that the presence of these “ingredients” and the maintenance of a Catholic identity may not be sufficient for civil law recognition of religiosity.⁵

Trend 1—Compliance With ERDs and Church Law

As noted above, Catholic hospitals are required to comply with the ERDs, which are promulgated and approved by the United States Conference of Catholic Bishops and interpreted by the local bishop. ERDs reaffirm the Catholic ethical standards for healthcare and provide guidance on issues that face healthcare providers every day. ERDs address, among other issues, limitations on the performance of specific procedures, provision of spiritual care, care of the poor, the role of the ethics committee, affirmation of the sanctity of life at all stages, end-of-life care, and limitations on partnerships and relationships that pose a heightened risk of actions inconsistent with ERDs.⁶ ERDs do not present a black and white, yes or no answer to every situation. Careful interpretation of ERDs, through consultation with trained Catholic ethicists or moral theologians, may be required in order to assess application to a particular real-life situation.

Given the need to operate in a modern healthcare and insurance delivery system, a small number of ERDs are generally impacted and provide particular challenges. Specifically, those relating to restrictions on birth control, sterilization (tubal ligations and vasectomy), and to lesser degrees, abortion, as well as fertility assistance, are of note.

Cases regarding the revocation or loss of Catholic identity have been detailed in the press with increased frequency over the past few years, often linked to compliance issues where civil matters intersect with the ERD requirements. In Arizona, the ethics committee of a Catholic hospital approved the abortion of a fetus in a case where the mother was very ill. The local bishop was not informed of the matter, and upon discovery several months later, stripped the hospital of its Catholic identity for undertaking “a litany of practices in direct conflict with Catholic teachings over several years.”⁷

In both Oregon and Texas, the performance of tubal ligations led to loss of Catholic identity in the case of one hospital (where the hospital refused to cease providing the procedures after years of negotiations)⁸ and the imposition of remedial action by the bishop to stop the procedures in two others.⁹

It is the ongoing obligation of the Catholic sponsors and the boards of directors and management of a Catholic organization to audit and ensure ERD compliance. To the extent internal audits are not conducted, in this current compliance environment it is likely that someone else will—be it a local bishop, sponsoring congregation, or watchdog group. To the extent that hospital boards and management do not think loss of Catholic identity is enough to cause a public relations embarrassment, they should consider the impact on benefactor support of organization and community relationships, as well as tax-exempt status.¹⁰

Risk also lies in affiliations and “branding” practices, where a Catholic facility lends its name to a program or clinic (such as a retail health clinic in a local grocery store or pharmacy) without oversight of the operations of such program or site to ensure ERD compliance. In addition, the activities of a hospital’s executives in supporting activities in contravention to the ERDs could be problematic, e.g., contraceptives prescribed in Catholic-owned office space or suppression of union activity. Such activities expose the Catholic hospital to the risk of scandal and cooperation in activities that are not compliant with the ERDs.

Validation of Catholic identity has many components, as noted above, but ERD compliance is more nuanced, and a small number of ERDs represent the majority of the issues that arise (e.g., sterilization and birth control, and abortion to a lesser degree for inpatient acute facilities). Of particular importance in today’s integrated healthcare system environment, ERDs are generally interpreted to apply to the Catholic facility or facilities within a system, and not to private physician offices where the physicians are not employees of the Catholic facility (unless those offices are leased from the Catholic facility).

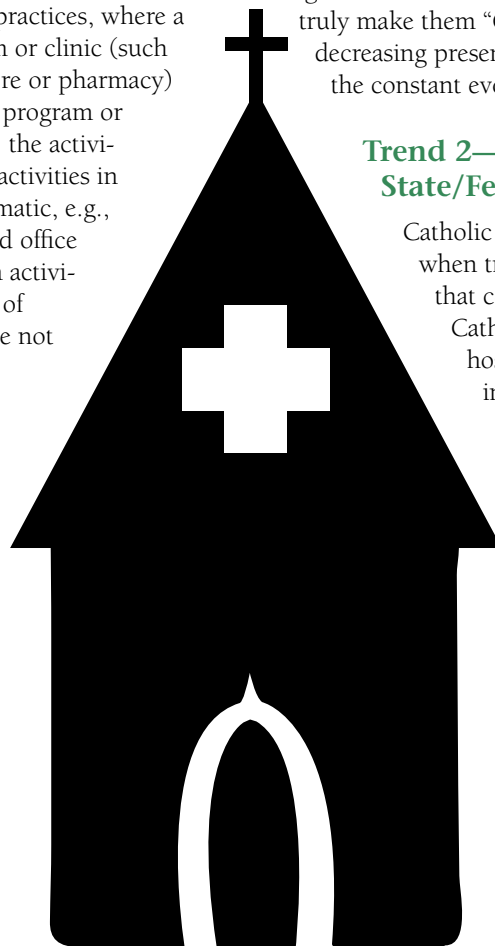
To safeguard Catholic identity in an era of heightened scrutiny, hospitals are increasingly memorializing the obligation to audit Catholic identity/ERD compliance and make recommendations based on the results of an audit. Healthcare organizations are used to frequent monitoring of compliance in connection with healthcare regulatory laws, and Catholic identity and ERD compliance may also be part of that process. Establishing a program that acts like other hospital compliance programs specific to Catholic identity and ERDs and includes auditing, education, and corrective actions can be integrated into ongoing compliance activities. Such a program may include the review of billing records (to identify prohibited procedures), committee minutes (such as medical staff and ethics), and policies and procedures (regarding charity and pastoral care, among others). In addition, staff and physician education should be ongoing. Such audits may identify the need for further training or investigation of areas where noncompliance is identified. A facility may choose to tailor audit activities based on particular board and sponsor concerns. Audits can be overseen by a designated committee of the sponsor, board subcommittee, or a mission-focused executive (such as a vice president or director of mission effectiveness, or pastoral care director) on a quarterly basis or aligned with another regular reporting schedule.

Overall, while Catholic organizations have long been steeped in adhering to their mission in complying with ERDs, Catholic organizations should be mindful of those characteristics that truly make them “Catholic” in light of increasing scrutiny, decreasing presence and oversight of religious sponsors, and the constant evolution of technology.

Trend 2—Compliance With State/Federal Laws

Catholic hospitals are also faced with unique issues when trying to comply with state and federal laws that conflict with the ERDs and other sources of Catholic teaching. These issues are critical, as hospitals are often one of the largest employers in a community. Catholic facilities may need to consider alternative arrangements to provide employees with benefits that are consistent with Catholic principles.

Beginning in the 1990s, many states mandated that health insurance benefit plans cover certain contraceptives or fertility treatments.¹¹ Such mandates were felt to be contradictory to Church teaching, putting Catholic facilities between a rock and a hard place to achieve compliance without compromising their religious belief system in circumstances when the state statute does not otherwise permit religious exemption.¹² In addition, some anticipate that the expansive definition of



“preventive care” under federal healthcare reform may result in more mandated coverage requirements for insurers without exceptions for religious employers.¹³ As employers, Catholic hospitals have to look at alternatives for providing required plan components required by state law without compromising their ethical and religious obligations.

More recently, this employee benefit equation has gotten more complex for Catholic healthcare employers in relation to compliance with the increasing state civil union laws, some of which require employers to provide comparable employee benefits to domestic partners.¹⁴ Catholic hospitals struggle with funding benefits in compliance with law and without endorsing the recognition of such unions, which are not consistent with Church teaching. Catholic hospitals have considered alternatives to comply with the law, such as providing benefits for “employee plus one” (where the “one” can be any individual related or unrelated to the employee) rather than explicitly providing for and thereby endorsing domestic partners. Such mechanisms may require close communication and input of the local bishop.

Another state law complexity for Catholic hospitals is the provision of emergency contraception through their hospital emergency departments and pharmacies. Some states mandate provision of emergency contraception services for all victims of sexual assault.¹⁵ Unlike the funding issues arising from provision of certain health benefits, the provision of emergency contraceptives is viewed as abortifacient if the victim is pregnant and a direct provision of care issue, in violation of ERDs. Catholic hospital operators need to be knowledgeable of the requirements of both state law and clinical guidelines as technology and laws in this area continue to evolve.

Catholic hospitals, as employers, need to take steps to plan for increasing state and federal mandates while ensuring compliance with Catholic teaching and ERDs. With respect to benefit plans, such steps would include, in each state where the Catholic entity operates, determining whether there are particular obligations and options with regard to provision of contraceptives, fertility treatments, and domestic partner benefits, as well as direct patient care issues. If religious exemption is not available or could not be met, thorough evaluation of options is key.

Trend 3—Transactions and Business Affiliations

Yet another trend has resulted from the fundamental changes in payment and care delivery models for hospitals, health systems, and other health providers anticipated as part of federal healthcare reform legislation. Such changes are necessarily prompting Catholic healthcare providers to examine their strategies for continuing to achieve their core clinical mission. This coincides with the reality faced by many Catholic healthcare institutions that their sponsoring congregations of women or men religious are aging and unable to continue to meaningfully be present or oversee sponsorship of the organization. Based on their conviction to follow mission, many Catholic hospitals are located in urban, rural, or other markets that have been abandoned or left untouched by other healthcare providers, resulting in financial

distress and the need to entertain proposals for partnership or consider ceasing operations. This collision of ideals has prompted many entities to actively consider mergers, acquisitions, member substitutions, joint ventures, or clinical affiliations with other hospitals, health systems, and academic medical centers. The logical partners in these transactions may not be Catholic and some may be for profit.

In an effort to preserve Catholic healthcare or maintain Catholic health presence, Catholic healthcare providers are exploring a range of transactions. Coming out of these transaction trends are developments unique to Catholic healthcare providers—the first is Catholic providers’ expansion of creative models to address viability of care in the community; the second is the non-Catholic buyer’s willingness to maintain Catholic identity through a contractual obligation; and last is non-Catholic providers affiliating with Catholic providers.

Recent examples of creative transaction models include the formation of Steward Health, a non-exempt, private equity-backed company, which acquired six-hospital Caritas Christi Health System,¹⁶ and Ascension Health’s announced formation of a for-profit venture with private equity fund, Oak Hill Capital Partners, to acquire distressed Catholic hospitals that do not want to exchange their Catholic identity in order to obtain capital resources.¹⁷ Such innovative options provide alternatives for Catholic organizations that might otherwise choose to dispense with or close facilities.

In addition, in instances where the Catholic provider is unwilling to completely forego its longstanding Catholic tradition when seeking a transaction, some non-Catholic providers have demonstrated a willingness to continue to operate organizations consistent with those traditions.¹⁸ One recently announced structure is St. Joseph’s Hospital and Emory Healthcare’s formation of a joint operating company where Emory will own a majority interest but the hospitals will retain Catholic identity and St. Joseph (or its owner, Catholic Health East) will retain certain supermajority powers for issues relative to mission and values.¹⁹ Others involve secular for-profit health systems like Vanguard Health Systems, which has demonstrated a willingness to continue to operate hospitals with a Catholic identity.²⁰

Finally, when a non-Catholic provider is affiliating with the Catholic provider, it is prudent, along with undertaking financial, legal, and operational due diligence, to undertake a Catholic identity audit and due diligence on the sponsors, including details regarding their succession plan. It is important to identify the impact to the non-Catholic organization—such as restrictions on procedures, amendments to physician employment contracts, leases for ERD compliance, and funding of pastoral care programs, etc.—sufficient to enable a board of directors to construct an infrastructure that would achieve Catholic identity following closing. There is controversy associated with such transactions as there may be community concern regarding changes around the conversion of a non-Catholic provider to Catholic, and the change in scope of services offered (even if actual changes are minimal).

Catholic healthcare institutions should work with their counsel and financial advisors to develop and implement strategic plans that articulate strategic and charitable goals in pursuing transactions, and carefully analyze the paths available for meeting these goals. Non-Catholic healthcare organizations that have elected to participate in ensuring Catholic identity need to seek advice and counsel to remain compliant with their obligations.

Conclusion

Complicated issues arise at the intersection of Church and civil laws, particularly when Church law is subject to varying interpretation and the matters are further complicated by application to real-life and emerging issues. Layer on health reform, changes at the state and federal level, and the demographics of sponsoring women and men religious, Catholic healthcare organizations are uniquely challenged in an otherwise challenging environment.

Increasing vigilance by local bishops, watchdog groups, attorneys general, and other third parties require Catholic hospitals to continue to remain mindful of obligations to preserve and maintain Catholic identity in demonstrable compliance. The best way to avoid issues is to monitor compliance with “Catholicity” along with the other areas a healthcare organization routinely monitors. In addition, non-Catholic providers who become affiliated with a Catholic provider must understand the meaning of Catholic identity and its influence and impact on operations.

In sum, Catholic and non-Catholic healthcare providers have found ways to adapt to address the needs of the changing healthcare landscape, and to hold to longstanding traditions in the Catholic Church. Like the organizations themselves, counsel and advisers to Catholic hospitals and healthcare facilities need to stay abreast of changes and the impact of such changes on Catholic healthcare organizations.

**The authors gratefully acknowledge the input and assistance of Fr. William Grogan, canon lawyer and ethicist, Ethics Advisor to Cardinal Francis George of the Archdiocese of Chicago and System Director for Clinical and Organizational Ethics, Provena Health.*

- 1 Catholic Health Association, *Fast Facts - Care Provided at Catholic Hospitals*, http://www.chausa.org/Pages/Newsroom/Fast_Facts/ (last visited Mar. 15, 2011).
- 2 United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services, Fifth Edition*, November 17, 2009 (ERDs).
- 3 Canon law views the assets held by a sponsored ministry to be “ecclesiastical” or Church goods, which require the oversight of the Catholic sponsor.
- 4 Rev. Francis Morrissey, OMI, JCD, *Catholic Identity in a Challenging Environment*, 80 *Health Progress* (Nov.–Dec. 1999) at 39-40.
- 5 *Provena Covenant Medical Center v. Dept. of Revenue*, No. 107328. (Ill. Mar. 18, 2010) (finding that a Catholic hospital sponsored by three groups of women religious, despite providing charity care and other community benefits, did not qualify for a religious exemption basis for property tax exemption). *See also*, *Catholic Charities of Sacramento Inc. v. Superior Court*, *infra*, n. 13.
- 6 *See* ERDs, *supra* n.3.
- 7 Anne Hendershott, *Catholic Hospitals vs. The Bishops*, *The Wall Street Journal*, Dec. 31 2010, at A9.
- 8 Of note, the religious sponsors of St. Charles Medical Center in Bend, OR, relinquished religious control of the facility and entrusted maintenance of Catholic identity to a “concerned group of Christians” some years prior to this incident. Ed Langlois, *Bishop: Oregon hospital no longer Catholic*, *National Catholic Reporter*, Feb. 16, 2010, <http://ncronline.org/news/accountability/bishop-oregon-hospital-no-longer-catholic> (last visited Mar. 15, 2011).
- 9 Robert Stein, *Religious hospitals’ restrictions sparking conflicts, scrutiny*, *Washington Post*, Jan. 20, 2011, at A01.
- 10 To the extent that an organization derives its federal tax exemption through participation in the United States Conference of Catholic Bishops’ Group Ruling with the Internal Revenue Service (i.e., through approval and listing in the Official Catholic Directory as an entity that is part of the Catholic Church), the loss of Catholic identity would also mean the loss of tax exemption. This implicates not only day-to-day operations, but also impacts tax-exempt financing mechanisms, including bonds.
- 11 The Beckett Fund for Religious Liberty, *Implications of Mandatory Insurance Coverage of Contraceptives for Catholic Colleges and Universities*, (Oct. 2009) at 3, www.catholichighered.org/ResearchPublications/StudiesinCatholicHigherEducation/ImplicationsofMandatoryInsuranceCoverage/tabid/665/Default.aspx (last visited Mar. 15, 2011). *See also*, Guttmacher Institute, *State Policies in Brief, Insurance Coverage of Contraceptives*, (Mar. 1, 2011).
- 12 Twenty-eight states require insurers that cover prescription drugs to cover all prescription drugs and devices, eighteen states exempt certain employers from complying with the mandate of including contraceptive coverage in their plans. Often the exemption issue focuses on whether an employer seeking exemption qualifies as a “religious employer.” *See, e.g., Catholic Charities of Sacramento Inc. v. Superior Court*, 32 Cal.4th 527, 85 P.2d 67 (2004) .
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- 14 Currently eleven states and the District of Columbia permit same-sex marriages, civil unions, or spousal-equivalent domestic partnerships. A number of these states also require employers to provide comparable benefits to opposite sex spouses under state law. Todd Solomon, *Civil Unions Legalized in Illinois; Implications for Employee Benefit Plans*, *McDermott Newsletter*, www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/2957f288-6d0c-4702-b7f1-95d339ea6c70.cfm (last visited Mar. 15, 2011).
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- 17 Joe Carlson, *Offering salvation: Ascension, equity firm forge deal they say could save Catholic hospitals*, *Modern Healthcare*, p. 6, Feb. 21, 2011.
- 18 *See, e.g.,* Terry Weinburg, M.S., *Catholic Presence, A Post-Merger Assessment*, 91 *Health Progress* (Mar.–Apr. 2010) at 49.
- 19 Carrie Teegardin, *St. Joseph’s Avoids Sale with Emory Partnership*, *Atlanta Journal-Constitution* (Mar. 11, 2011), www.ajc.com/news/emory-partnership-gives-st-868621.html (last visited March 11, 2011).
- 20 Bruce Japsen *Vanguard Health to Buy Holy Cross Hospital*, *Chicago Tribune* (Dec. 15, 2010), <http://chicagobreakingbusiness.com/2010/12/vanguard-health-to-buy-holy-cross-hospital.html> (last visited March 11, 2011). Vanguard Health Systems acquired St. Vincent Medical Center in Worcester, MA, in 2005, and agreed to maintain that facility’s Catholic identity. *History of St. Vincent Hospital*, available at www.stvincenthospital.com/About/history.aspx (last visited March 15, 2011). *See also*, *Modern Healthcare, Late News* at 4 and *Regional News* at 22 (Mar. 28, 2011) (describing agreements by Yale New Haven Hospital and LHP Hospital Group, in separate potential acquisitions, to continue to operate the acquired facilities as Catholic).

The Rights of Patients to Visitors of Their Choice: CMS Expands the Meaning of “Immediate Family” and Through Regulation Requires Hospitals to Do the Same

Erin Shaughnessy Zuiker, Esquire, MPH
Smith Moore Leatherwood LLP
Raleigh, NC

“There are few moments in our lives that call for greater compassion and companionship than when a loved one is admitted to the hospital.”

Presidential Memorandum, *Hospital Visitation—Respecting the Rights of Hospital Patients to Receive Visitors and to Designate Surrogate Decision Makers for Medical Emergencies* (April 15, 2010).

The Case of *Langbehn v. Public Health Trust of Miami-Dade County*

Lisa Marie Pond and Janice Langbehn had been partners for eighteen years and adoptive parents to four children. The two women and their children were residents of the state of Washington. In February 2007, the family was in Miami, FL, to depart for a cruise vacation. Pond, an otherwise-healthy thirty-nine year-old, became critically ill aboard the cruise ship and was immediately rushed to the Ryder Trauma Center at Jackson Memorial Hospital. Despite efforts to save her, Pond suffered a brain aneurysm and died less than twenty-four hours after her arrival at the Ryder Trauma Center.

This was not a case of medical malpractice, but rather a case alleging negligence on the part of the providers at the Ryder Trauma Center with respect to a duty owed to the patient’s loved ones who were denied access to Pond during critical hours of her care.¹ The case gained national attention in 2008 and 2009² and had a direct impact on President Barack Obama’s issuance of the April 15, 2010, Presidential Memorandum.

Langbehn filed suit against the Public Health Trust of Miami-Dade County, d/b/a Jackson Memorial Hospital, as well as three of the providers involved in Pond’s care, two physicians and one social worker. Langbehn alleged that she informed the admitting staff of the couple’s relationship, requested both access to Pond and information about her care and medical status, but was denied both during the critical hours of Pond’s hospitalization. Specifically, Langbehn alleged that the admitting clerk refused to give Langbehn any information and refused her and the couple’s children the opportunity to be at the patient’s bedside throughout the ordeal. The medical record shows that approximately an hour after her arrival, Langbehn had a friend fax an executed power of attorney to the Ryder Trauma Center staff. The power of attorney authorized Langbehn to make medical decisions on behalf of her partner in the case of incapacity.³ Despite the documentation

of this authority, the allegations were that the staff continued to deny access and information to the patient’s family.

By the time Pond’s sister arrived at the Ryder Trauma Center, approximately eight hours after Pond first arrived, the staff finally agreed to provide all of Pond’s family, including Langbehn, her children, and her sister, with medical information and access to her. At that time, the family learned that Pond had been transferred to the intensive care unit and were provided the room number. However, so many hours had passed and Pond was unconscious when her life partner and her children were able to be with her. She died the following morning.

On the basis of these allegations, Langbehn filed suit against Jackson Memorial Hospital. Despite her efforts to seek a remedy in the courts, in October 2009 Langbehn’s case was dismissed by the U.S. District Court for the Southern District of Florida, on the grounds that there was no duty owed by Jackson Memorial Hospital’s physicians or other healthcare providers as to Langbehn and her children to substantiate a negligence action.

Presidential Memorandum and Promulgation of Expanded Conditions of Participation

Although the case was dismissed from federal court, Langbehn’s high-profile battle has led, in part, to the new Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) that participate in the Medicare and Medicaid programs with respect to patient’s rights and visitation. On April 15, 2010, President Barack Obama issued a memorandum to U.S. Department of Health and Human Services Secretary Kathleen Sebelius instructing the Secretary to implement new rules to ensure that hospital patients have the right to designate the visitors of their choice, whether or not they fall into a traditional legal designation of “immediate family member.”⁴

On November 19, 2010, the Centers for Medicare & Medicaid Services (CMS) released its final rule promulgating the regulations that now require hospitals and CAHs to have “written policies and procedures regarding the visitation rights of patients.”⁵ These new regulations took effect on January 18, 2011. CMS did not add or create a new CoP for hospitals; instead, it simply added to the existing Patient’s Rights CoP found at 42 CFR § 482.13. The new regulations for hospitals regarding patient visitation rights are set forth at 42 CFR § 482.13(h)(1-4). CAHs did not previously have a CoP that specifically addressed patient rights, therefore, CMS created a new CoP for CAHs found at 42 CFR § 485.635(f)(1-4).

The language of the regulation is simple and mandates that in addition to having written policies and procedures in place, hospitals and CAHs must:

1. Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section;
2. Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to a spouse, domestic partner (including same-sex

domestic partners), another family member, or a friend, and his or her right to withdraw consent at any time;

3. Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability; and
4. Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.⁶

The regulations specifically address that a patient may designate a “support person” to act on the patient’s behalf as to visitor preferences, in the event that the patient is incapacitated or otherwise unable to articulate their preferences. The concept of a support person is to be distinguished from a legal representative or patient representative who may have the authority to make medical and/or other legal decisions on the patient’s behalf. CMS notes that a support person is distinguishable from the patient representative, whose authority may be governed by state law and regulation and is made known by the presentation of an advanced directive or healthcare power of attorney. Therefore, CMS removed the term “representative” from the rule and instead uses the term “support person” throughout.

CMS also makes clear that the patient’s designation of a support person need not be any more formal than a verbal indication by the patient. Despite the informality, the hospital or CAH staff may be advised to make a notation of such preference in the patient’s medical record for later reference. CMS counsels that formal documentation to establish the support person’s status should only be required in the event that: (1) the patient is incapacitated, and (2) two or more individuals claim to be the patient’s support person.⁷

The proposed language included the term “immediate family” at 42 CFR § 482.13(h)(4). In the final rule, CMS acknowledges that based on the comments received, “families of choice” may not necessarily conform to traditional definitions or legal designations of the term “immediate family,” which may be defined by marriage, bloodlines, or adoption. CMS notes that the term itself is “difficult to define, measure and enforce.”⁸ Therefore, CMS removed the term “immediate family” from the regulations. The new language, which reads “[e]nsure that all visitors enjoy full and equal visitation privileges consistent with patient preferences” is intended to be “patient-centered” and allow visitation by the patient’s loved ones, regardless of any legal relationship the person may have to the patient.⁹

In order to ease the burden on hospitals, CMS does not set forth any specific guidance with respect to what must be contained in the facility’s policy beyond what is noted above. CMS also makes clear that it does not believe that hospitals and CAHs must include each clinical reason that may justify a limitation to the patient’s rights with respect to visitors. The language is instead broad and allows hospitals and CAHs the ability to determine what may or may not be a clinically appropriate reason to limit visitation. CMS does note, however, that hospitals and CAHs have a duty to clearly communicate the reasons for any restrictions and explain how they are aimed at patient safety. Examples provided include when the patient is undergoing care interventions, when infection control issues may be implicated, and when visitation may interfere with other patient care.¹⁰ It is important to

note that the burden is on hospitals and CAHs to demonstrate that a restriction to a patient’s visitation rights is clinically necessary.

CMS does remind providers of the requirement found at 42 CFR § 482.13(a), which mandates that hospitals inform patients of their rights, when possible, before administering care. This new requirement with respect to patient visitation rights is no different; therefore hospitals and CAHs must include the notice of visitation rights as described above, prior to the onset of care. Additionally, CMS reminds providers of the requirement to “notify patients of their advance directive rights and their right to access the hospital’s grievance system, and information on how to do so.”¹¹ There are several means by which a patient can report a hospital for noncompliance, including filing a complaint through the hospital’s grievance process, the state’s survey agency, or an accrediting body. If the patient is a Medicare beneficiary, the patient has the opportunity to file a complaint with the Quality Improvement Organization (QIO) of the state.¹² In addition to the patient, a visitor to the hospital who believes the hospital is not in compliance with the regulation may also file a complaint.

Conclusion

The *Langbehn* court admonished the hospital for its treatment of Langbehn and her children; however, it did not find that a duty was owed to them by the Ryder Trauma Center’s staff to establish a claim for negligence. As a result, the family had no remedy in the courts under Florida law. Although these new CoPs, by themselves, would not necessarily create a legal duty sufficient to establish a negligence claim, they do require hospitals and CAHs to establish written policies and to inform patients that their choice with respect to visitors will be honored and respected. As a result, hospitals and CAHs must develop new policies. Additionally they should take the opportunity to evaluate their existing policies with respect to patients’ rights and to revise them if necessary. Hospitals and CAHs also will need to educate and train their staff with respect to the new policy. This new CoP is not terribly onerous on its face, however, as with any CoP, noncompliance can be devastating for providers. In summary, while CMS has not created a new legal duty supporting third-party claims against a hospital per se, hospitals and CAHs should be aware that these new CoPs may bolster a negligence claim if the same allegations in *Langbehn* were to be made again.

1 *Langbehn v. Public Health Trust of Miami-Dade County*, 661 F. Supp. 2d 1326 (2009).

2 Tara Parker-Pope, Kept From a Dying Partner’s Bedside, N.Y. Times, May 18, 2009.

3 *Langbehn v. Public Health Trust of Miami-Dade County*, 661 F. Supp. 2d 1326, 1332 (2009).

4 Presidential Memorandum, *Hospital Visitation—Respecting the Rights of Hospital Patients to Receive Visitors and to Designate Surrogate Decision Makers for Medical Emergencies* (April 15, 2010).

5 75 Fed. Reg. 70831 (Nov. 19, 2010).

6 42 CFR § 482.13(h)(1-4).

7 See 75 Fed. Reg. 70831 (Nov. 19, 2010).

8 *Id.* at 70838.

9 *Id.*

10 *Id.* at 70839.

11 *Id.* at 70834.

12 *Id.* at 70835.

Don't Stand So Close to Me: CMS Revises the Supervision Requirements for Outpatient Services

Andrew J. Murray, Esquire

Heather K. Iverson, Esquire

*Bradley Arant Boult Cummings LLP
Nashville, TN*

In the 2011 Outpatient Prospective Payment System (OPPS) Final Rule, released on November 2, 2010, the Centers for Medicare & Medicaid Services (CMS) made several changes to the supervision rules for hospital outpatient services. The most significant is the change to the physical proximity component of "direct supervision" in the context of both therapeutic and diagnostic hospital outpatient services.

CMS defines three levels of supervision for outpatient services: general, direct, and personal. All hospital outpatient therapeutic services require direct supervision, whether furnished in the main hospital or in an off-campus provider-based department. The

level of supervision required for hospital outpatient diagnostic services is determined on a service-by-service basis, in accordance with the requirements set forth in the Medicare Physician Fee Schedule (MPFS). CMS has changed course several times regarding the requirements for direct supervision since the 2000 OPSS Rule. In its most recent interpretation, CMS required that a supervising physician or non-physician practitioner (NPP) must be physically located on the hospital campus or within the off-campus provider-based department (PBD) of the hospital while the procedure is being performed.

In the Fiscal Year 2011 Final OPSS Rule, CMS has updated the direct supervision requirement by deleting all references to physical boundaries, except as to diagnostic services furnished under arrangements in non-hospital locations. The supervising physician or NPP (in the case of therapeutic services) still must be "immediately available to furnish assistance and direction throughout the performance of the procedure," and must be able to step in and help "without interval of time." The supervising physician or NPP will not be considered "immediately available" while performing another procedure that cannot be interrupted or while "physically far away" from the service site. However, there is no longer a specific requirement that the supervising physician (or NPP) be physically on campus or within the PBD while the service is performed (see the chart on page 19). CMS

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Vice President and Associate
General Counsel, Division II
Community Health Systems
Franklin, TN
(615) 628-6563
marc_goldstone@chs.net



Albert 'Chip' D. Hutzler
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HealthCare Appraisers
Delray Beach, FL
(561) 330-3488
chutzler@hcfmv.com



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General Counsel, Division IV
Community Health Systems
Franklin, TN
(615) 628-6520
hal_mccard@chs.net



Andrew J. Murray
Vice Chair – Research and Website

Bradley Arant Boult Cummings LLP
Nashville, TN
(615) 252-2366
amurray@bab.com



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Washington, DC
(202) 625-3595
lisa.ohrin@kattenlaw.com



Claire M. Turcotte
Vice Chair – Educational Activities

Brickler & Eckler LLP
West Chester, OH
(513) 870-6573
cturcotte@bricker.com



also added a new category of “non-surgical and extended therapeutic services,” for which direct supervision will be required during only the initiation of a procedure (general supervision is required for the duration of the procedure).

The chart below summarizes the current status of the Medicare physician supervision requirements for hospital outpatient therapeutic and diagnostic services.



	Level of Supervision Required	Physician or Non-Physician Practitioner (NPP)	Direct Supervision Requirements in Hospital or On-Campus Provider-Based Department (PBD)	Direct Supervision Requirements in Off-Campus PBD	Direct Supervision Requirements in Non-Hospital Locations
Therapeutic Services	<p>Direct Supervision</p> <p><i>Exception— Non-Surgical and Extended Duration Therapeutic Services:</i></p> <p>Initiation Period—Direct supervision</p> <p>After patient is stable—General supervision</p>	<p>NPPs may supervise services they could perform themselves.</p> <p>However, NPPs may not supervise cardiac rehabilitation services, intensive cardiac rehabilitation services, and pulmonary rehabilitation services.</p>	<p><i>Old Rule:</i> Physician or NPP may supervise from anywhere on a hospital campus (within 250 yards of main buildings).</p> <p><i>New Rule:</i> Can be off campus, if immediately available.</p>	<p><i>Old Rule:</i> Physician or NPP must be physically present in PBD where service is furnished.</p> <p><i>New Rule:</i> Can be outside the PBD, if immediately available.</p>	N/A—Therapeutic services must be provided in hospital or PBD.
Diagnostic Services	Based upon MPFS	Physician supervision required. NPPs cannot supervise diagnostic services.	<p><i>Old Rule:</i> Physician may supervise from anywhere on a hospital campus (within 250 yards of main buildings).</p> <p><i>New Rule:</i> Can be off campus, if immediately available.</p>	<p><i>Old Rule:</i> Physician must be physically present in PBD where service is furnished.</p> <p><i>New Rule:</i> Can be outside the PBD, if immediately available.</p>	<i>Rule unchanged:</i> Supervising physician must be present in the office suite.

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