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INSIDE:

All Children's Health Qui Tam Case Is Latest Attack on Hospital Growth Practices 4

Enforcement Topics for Nursing Homes 7

Non-Delegable Duties & Hospital Liability for Independent Contractor Physicians: A Split Worth Resolving? 8

OIG Work Plan Fiscal Year 2013 - What's New and What's Still on the Radar? 11

The Interplay Between A Provider's Repayment and Self-Disclosure Obligations, and The Consequences of a RAC Audit 11

Health Care and Medicare Fraud in Florida: exploring a broader legal arsenal and recent examples 12

"Sorry Works!" Offers Chance to Break Med-Mal Gridlock in Florida 14

Is Your Hospital Client Compliant With the Changes Under § 501(r)?

By Brian K. Wright, Esquire, Tampa, FL*

On March 23, 2010 the Patient Protection and Affordable Care Act ("PPACA") was enacted. Section 9007(a) of the PPACA amended § 501 of the Internal Revenue Code ("IRC") adding § 501(r),¹ the impact of which has added new, onerous and unclear compliance requirements (the "Requirements") for § 501(c)(3) charitable hospitals to maintain their tax-exempt status. Compliance with the Requirements began for tax years after March 23, 2010, with the exception of the Community Health Needs Assessment.² The Internal Revenue Service ("IRS") is still working toward enacting rules and regulations that fully implement the Requirements,³ which is evidenced by its June 22, 2012 notice of proposed rulemaking (the "June Notice"). This article will review the Requirements of § 501(r), the proposed regulations, and the criticism that has surfaced in regard to the onerous requirements and lack of clear guidance from the IRS to date.

Background for Hospitals as "Charitable Organizations."

Nonprofit hospitals have always been included within the group of exempt charitable organizations.⁴ The IRS first recognized not-for-profit hospitals as tax-exempt "charitable" organizations within the meaning of § 501(c)(3) in 1956 in Rev. Rul. 56-185⁵. Three years later the IRS issued Rev. Rul. 69-545, which set forth the Community Benefit Standard, specifically the interpretation of the term "charitable" for purposes of § 501(c)(3). A hospital will be considered to have furthered charitable purposes if it generally satisfies the following requirements:

- 1) Maintains an emergency room open to all persons requiring emergency care, regardless of the ability to pay;

- 2) Provides hospital care for all persons in the community otherwise able to pay the cost of medical services either directly or through third party reimbursement;
- 3) Maintains a board of directors drawn from the community;
- 4) Uses surplus receipts over disbursements to improve the quality of patient care, expand hospital facilities, and advance medical training, education, and research programs; and
- 5) Maintains an open medical staff.⁶

Today, the IRS continues to follow the Community Benefit Standard.⁷

PPACA and the Additional Requirements of § 501(r).

The addition of paragraph (r) to § 501 adds requirements above and beyond the requirements of the traditional Community Benefit Standard. § 501(r)(1) of the IRC states that a hospital organization will not be treated as tax-exempt under (c)(3) unless the hospital organization meets the requirements described in § 501(r)(3) – (r)(6).⁸ The Requirements of § 501(r) are as follows:

- § 501(r)(3) – Requires a hospital organization to conduct a community health needs assessment ("CHNA");
- § 501(r)(4) – Requires a hospital to establish a written financial assistance policy ("FAP") and a written policy relating to emergency medical care;
- § 501(r)(5) – Requires a hospital organization to limit the amount charged for emergency or other medically necessary care; and
- § 501(r)(6) – Requires a hospital to make

continued, next page

HOSPITAL CLIENT

from previous page

reasonable efforts to determine whether an individual is FAP eligible before engaging in extraordinary collection actions.⁹

If a hospital organization operates more than one hospital, then each hospital facility in the organization will be required to meet the Requirements set forth above.¹⁰

CHNA:

The provisions of § 501(r)(3) requires a hospital organization to conduct a CHNA at least once every three years and to adopt and implement a strategy to meet the community health needs that are identified as a result of the CHNA.¹¹ A CHNA shall meet the requirements of § 501(r)(3)(B) if it: 1) takes into account input from individuals representing the broad interest of the community served by the hospital facility, which includes those individuals with expertise in public health, and 2) it is made widely available to the public.¹²

In July 2011, the Treasury Department and the IRS issued Notice 2011-52, which set forth the anticipated regulations to demonstrate compliance with the CHNA requirements. The IRS in short will require a written CHNA report which sets forth the following information:¹³

1. A description of the community served by the hospital;
2. A description of the process and methods used to conduct the assessment¹⁴;
3. How the hospital organization took into

account the input of the persons who represent the broad interests of the community;¹⁵

4. A prioritized description of all community health needs identified through the CHNA;
5. A description of existing health care facilities available to meet the needs of the community.

The sources of data for the CHNA, “may be based on current information collected by a public health agency or non-profit organizations and may be conducted together with one or more organizations, including related organizations.”¹⁶ The regulation also requires the hospital facility to make its CHNA publicly available, which means posting the CHNA on the hospital website or providing a clear link to it.¹⁷ The IRS is anticipated to provide additional guidance on CHNAs, but hospital organizations may rely on the guidance in Notice 2011-52 for now and up to six (6) months following any additional guidance provided by the agency.

From a procedural standpoint, the IRS will require a hospital organization to file its implementation strategy for its CHNA with Form 990 on its annual return.¹⁸ It should be noted that the failure of a hospital organization to meet the CHNA requirements under the PPACA will subject it to an excise tax of \$50,000.00 for each hospital within the system that fails to meet the criteria of the CHNA. The IRS will also require the hospital organization to attach its implementation strategy for each CHNA to Form 990 on its annual return. The proposed

regulations set forth in Notice 2011-52 are the only guidance to date for completion of the CHNA, which may be problematic, as hospital organizations must comply in tax years starting after March 23, 2012. Additional guidance is expected, but as of November 2012, additional guidance from the IRS in regard to CHNAs had not been issued.

Financial Program Requirements:

Section 501(r)(4) requires a hospital organization to develop a written financial assistance policy (“FAP”) and a written policy in regard to emergency medical care.¹⁹ The FAP must include: 1) the eligibility criteria for financial assistance and whether free discount care is included; 2) the basis for determining patient charges; 3) the method for applying for financial assistance; 4) if the hospital does not have a separate billing and collection policy, the actions it may take if a bill is not paid; and 5) measures for widely publicizing the policy to the community that the hospital serves.²⁰ The FAP also has to provide care and treatment for patients with emergency medical conditions, regardless of their ability to pay.²¹

The proposed regulations set forth in the June Notice are consistent with the PPACA, as there are no specific criteria set forth which direct when an individual qualifies for financial assistance under a hospital organization’s FAP. However, the IRS has requested comments on whether the FAP should be closely tied to the needs of a hospital’s community based on its CHNA. At this time, the FAP must only specify the financial assistance available, including any discounts or free care available, and the criteria for assistance under the FAP.²²

Section 501(r)(5)(A) requires a hospital organization to place a limitation on its charges. Specifically, the hospital organization must limit the amounts charged for emergency or other medically necessary care provided to individuals under the FAP to no more than the amounts generally billed (“AGB”) to individuals who have insurance covering such care.²³ Section 501(r)(5)(B) prohibits the use of “gross charges,” i.e. “the chargemaster rate,” under the FAP, which will impact the amount a hospital facility may ultimately charge FAP eligible patients.²⁴

As part of the FAP, the hospital facility must set forth which method the hospital uses to determine its AGB, either the

continued on page 19

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All Children's Health *Qui Tam* Case Is Latest Attack on Hospital Growth Practices

By Timothy M. Moore, Esq., Miami, FL*

The All Children's Health *qui tam* case is the latest symptom of the increasing and feverish zeal by *qui tam* claimants for alleging wrongdoing under the False Claims Act in connection with government healthcare.¹

In August 2012, the United States District Court for the Middle District of Florida unsealed a whistleblower lawsuit by an All Children's Health former employee, Barbara Schubert. Ms. Schubert, the *qui tam* relator, brought her suit under the federal False Claims Act as well as the Florida False Claims Act, authorizing private individuals to sue in the name of the federal and Florida governments for violations thereof.² The complaint alleges that All Children's Health compensated doctors it hired at above the market rate to induce those doctors to refer patients and services to All Children's Hospital, which in turn would bill Medicare for the treatment rendered. This case is proceeding without the United States, which noticed the court on July 26, 2012, that it would not be intervening at that time.³

This case does more than signal the continually rising tide of cases critical of how hospitals compensate physicians. It shines light on the difficulty healthcare providers face creating fair employment relationships with doctors while also making profitable business decisions.⁴

I. The Stark Law, Anti-Kickback Statute, and False Claims Act: The Plaintiff's Ensemble for Sounding the Cause of Action in This Medicaid *Qui Tam* Case

The plaintiff, in pleading her case, invokes four separate laws: the Stark law, the Anti-Kickback Statute, the federal False Claims Act, and the Florida False Claims Act.

A. The Federal Stark and Anti-Kickback Statutes Regulate Physician-Entity Relationships and Referrals but Create No Private Right of Action

The federal Stark law restricts the relationships between physicians and healthcare providers. A physician cannot refer a patient to an entity with which the physician has a financial relationship, as defined in the Stark law.⁵ In turn, a healthcare entity cannot present,

or cause to be presented, a claim for healthcare services it rendered due to a referral prohibited by the Stark law.⁶ The Stark statute and regulations define "financial relationship" as (1) an ownership or investment interest or (2) a compensation arrangement with the entity.⁷

Unlike the Stark law, which focuses on the relationship between the referring physician and the healthcare entity receiving the referral, the federal Anti-Kickback Statute targets the referral transaction. Generally, it prohibits the payment or solicitation of "remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in exchange for referring someone to a person for providing, or arranging for the providing, of services or items paid by a federal healthcare program.⁸

However, "[i]n recognition of the fact that legitimate relationships may exist between hospitals and physicians who practice in or refer patients to hospitals, exceptions . . . were included in both the Anti-Kickback Statute and the Stark Statute."⁹ The Stark and Anti-Kickback Statutes, and the federal regulations implementing those statutes, prescribe the necessary requirements to submit a claim to the government when those statutes would ordinarily bar that claim.¹⁰

B. The Federal and Florida False Claims Acts Provide the Private Right of Action Based on Falsely Certifying Compliance With the Stark and Anti-Kickback Statutes

Although neither the Stark nor the Anti-Kickback Statutes provide for a private cause of action, they can form the foundation for a claim under the federal False Claims Act, which does create a private right of action, and thus is a means by which the relator has been able to bring her *qui tam* case against All Children's Health. The federal False Claims Act, which dates back to the Civil War, prohibits (1) knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment or approval; or (2) knowingly making, using, or causing to be made or used, a false record or statement material

to a false or fraudulent claim.¹¹

Yet, the mere violation of the Stark or Anti-Kickback Statutes does not create liability under the federal False Claims Act.¹² Instead, it is the false certification of compliance with the "Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program" that furnishes the basis for a False Claims Act suit.¹³ For example, the False Claims Act makes illegal a healthcare provider (1) falsely certifying compliance with the Stark and Anti-Kickback Statutes when submitting a claim directly to the federal government or (2) causing a state to submit false claims to the federal government for services provided due to prohibited referrals.¹⁴

Similarly, the Florida False Claims Act provides a private cause of action for those who have evidence of someone (1) knowingly presenting, or causing to be presented, to a state agency a false or fraudulent claim for payment or approval; or (2) knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.¹⁵ Also, like the federal False Claims Act, the Florida counterpart is violated through a false certification of compliance with the Stark and Anti-Kickback Statutes, not through merely violating those statutes. Accordingly, conduct similar to that which is actionable under the federal False Claims Act, if it involved presenting or making false claims or statements to a state agency, is likely to provide a basis for a suit under the Florida False Claims Act.

II. The Alleged Facts in the All Children's Health Case: Allegations of Volume-Based and Unjustifiably High Compensation as Inducement for Referrals

The plaintiff has sued several related defendants in this case: All Children's Health System, Inc. ("ACHS"), Pediatric Physician Services, Inc. ("PPS"), and All Children's Hospital, Inc. ("ACHI"). ACHS is "a Florida corporation that owns and operates All Children's Hospital ("ACH"), a specialty children's hospital predominantly serving the west central Florida community."¹⁶ ACHS uses several other corporations to run ACH. For

continued, next page

QUI TAM CASE

from previous page

example, ACHS uses ACHI, a wholly owned subsidiary, for the management and daily operations of ACH.¹⁷ Among other things, ACHI “is responsible for... making claims and receiving payment for services rendered pursuant to government healthcare coverage.”¹⁸ PPS, another ACHS subsidiary company, manages physician staffing for ACH and “is responsible for implementing the strategy of physician recruitment and practice acquisition, and for providing administrative oversight of employee-physicians.”¹⁹

The plaintiff worked for PPS from 1998 through 2011 as its Director of Operations.²⁰ In that role, the plaintiff reported directly to an executive at ACHS who allegedly negotiated the compensation arrangements the plaintiff claims were unlawful.²¹ According to the plaintiff, that executive concluded that ACHS could best shore up its allegedly dwindling market share by “employ[ing] as many physicians as possible to guarantee their loyalty, and therefore their referrals, to ACH.”²²

In the complaint, the plaintiff identifies two financial arrangements that ACHS allegedly used to recruit doctors and, so the plaintiff argues, induce the doctors to refer cases to ACH:

(1) Volume-based compensation of doctors hired: The plaintiff alleges that the defendants “offered a volume-based incentive bonus to four neurosurgeons if the practice group as a whole could maintain the volume of procedures that six neurosurgeons had completed the year prior, so long as the procedures were conducted at ACH.”²³ The plaintiff also identifies one employment agreement whereby a surgeon’s base salary and bonus were predicated upon him performing a minimum number of surgeries during one year, with the agreement that the surgeon and the defendants may revisit his yearly salary and bonus based upon the number of surgeries he performed.²⁴

(2) Compensating hired doctors above market value: The plaintiff, as PPS’s Director of Operations, developed a compensation and bonus incentive plan for new doctors.²⁵ The plaintiff alleges several examples of compensation beyond what she determined was the 75th percentile of the fair market value for the doctors’ services:

(A) PPS added new emergency room physicians with a base salary of at least approximately \$70,000 over the compensation rate at the 75th percentile, two of whom had no post-fellowship experience;²⁶

(B) PPS bought a pediatric hematology/oncology practice at its highest estimated value, as determined by an outside valuation company, and agreed to pay its owner a salary that was \$90,000 above the highest salary reported in the considered compensation surveys;²⁷

(C) PPS hired a pediatric surgeon with a base salary “nearly \$200,000 more than the median fair market value salary for a pediatric general surgeon of his experience, and \$80,000 more than the 90th percentile”;²⁸ and

(D) PPS used “side letters” guaranteeing physicians additional compensation or benefits that were not part of PPS’s main employment agreement with the physicians, such as tail coverage, indemnification in defending in a non-compete suit, and employment for spouses.²⁹

Ultimately, the plaintiff claims that the volume-based and over market-value compensation arrangements violated the Stark and Anti-Kickback laws because the defendants offered the compensation intending to induce the recipient doctors to refer cases to ACH.³⁰ Furthermore, the plaintiff alleges that those violations of the Stark and Anti-Kickback Statutes made false Stark and Anti-Kickback Statute compliance certifications, which accompanied each claim ACHS submitted to the federal and Florida governments for services referred by those physicians.³¹

III. Early Lessons From the All Children’s Health Qui Tam Case: Knowledgeable Counsel May Help the Qui Tam Bull Avoid Seeing the Red Flag of Paying Over Fair Market Value for Physician Services

The All Children’s Health case is in its early stages. Consequently, much remains to be seen. For example, will the financial arrangements be defensible under the “bona-fide employment relationship” exceptions to the Stark and Anti-Kickback Statutes?³² The plaintiff in this case explicitly raises this possibility, but implicitly argues that the exception does not apply.³³ Whether the exception applies may depend upon, among other things, the defense evidence that the

compensation agreements were in fact “consistent with the fair market value of the services” and were “commercially reasonable.”³⁴

Even still, the immediate teaching point the All Children’s Health case offers is that paying hospital staff above market rate may be a glaring signal for a *qui tam* claimant. A *qui tam* plaintiff does not need to rely upon an explicit agreement between the healthcare provider and the doctor for referrals in violation of the Stark or Anti-Kickback Statutes. Instead, the *qui tam* plaintiff, such as the one in the All Children’s Health case, will argue that compensation outside of the prevailing market rate has no other purpose than to induce referrals, and thus inferentially proves Stark and Anti-Kickback Statute violations. In fact, *qui tam* plaintiffs’ successes with this theory are recent and recurring, as evidenced by the multi-million dollar settlements in *qui tam* cases such as those involving St. Joseph Medical Center and HCA Inc.³⁵ The resulting question: How does a healthcare provider balance the tension between the legitimate business decision to pay top dollar for top talent and making sure that compensation arrangements do not violate the Stark and Anti-Kickback Statutes?

The answer to that question is for the healthcare provider to have knowledgeable counsel who can work towards preventing, or minimizing, the impact of *qui tam* litigation. Specifically, knowledgeable counsel can, reduce future compliance costs by evaluating whether past or current transactions may be subject to a claim that they violated the Stark or Anti-Kickback Statutes. If either is the case, then knowledgeable counsel will be able to identify the best solution for solving potential legal issues before the *qui tam* plaintiff files suit.

Thus, counsel can help diminish future risk by structuring future transactions to comply with the Stark and Anti-Kickback Statutes. Additionally, counsel may devise strategies for defending appropriate business decisions that a *qui tam* claimant may question by lawsuit. For example, counsel may suggest that a healthcare provider obtain independent valuations of practices before purchasing them, reasoning that having evidence supporting the soundness of the healthcare provider’s business decision when that decision is made is better than having to rely on an after the fact justification.

continued, next page

QUI TAM CASE

from previous page

Endnotes

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1 *United States of America and State of Florida ex rel. Barbara Schubert v. All Children's Health System, Inc. et al.*, Case No. 8:11-CV-1687 (hereinafter "Schubert").

2 31 U.S.C. § 3730(b); § 68.083(2), Fla. Stat.

3 *Schubert*, Notice of the United States That It is Not Intervening at This Time, July 26, 2012 (Docket Entry # 3).

4 When this article went to press, discovery had not commenced and the defendants had not filed an answer. Furthermore, the plaintiff's motion for leave to file their proposed Third Amended Complaint was pending before the court. Accordingly, this article presents only the allegations in the plaintiff's Second Amended Complaint and proposed Third Amended Complaint.

5 42 U.S.C. § 1395nn(a)(1).

6 *Id.*

7 § 1395nn(a)(2)

8 42 U.S.C. § 1320a-7b(b)(2).

9 *United States ex rel. Wilson v. Crestwood Healthcare, L.P.*, Case No. CV-11-S-3361-NW, 2012 WL 1886351, at *5 (N.D. Ala. May 18, 2012).

10 *See, e.g.*, 42 U.S.C. §§ 1320a-7b(b)(3) (containing exceptions to the Anti-Kickback Statute), 1395nn(b)-(e) (listing statutory exceptions to the Stark Statute); 42 C.F.R. §§ 411.350-.357 (providing regulatory exceptions to the Stark Statute), § 1001.952 (creating exceptions to Anti-Kickback Statute).

11 31 U.S.C. § 3729(a)(1)(A)-(B); *United States v. Halifax Hosp. Med. Ctr.*, Case No. 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, at *4 (M.D. Fla. Mar. 19, 2012).

12 *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, Case No. 2:11-cv-89-FtM-29DNF, 2012 WL 523623, at *4 (M.D. Fla. Feb. 16 2012) (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)).

13 *Halifax Hosp.*, 2012 WL 921147, at *3; *Mastej*, 2012 WL 523623, at *4.

14 *Halifax Hosp.*, 2012 WL 921147, at *4.

15 §§ 68.081-.089, Fla. Stat. One federal court observed that Florida's False Claims Act "mirrors the federal statute nearly verbatim. *Eve Barys and Dwayne Ostrom ex rel. United States v. Vitas Healthcare Corp.*, Case No. 04-21431-CIV, 2007 WL 2310862, at *1 n.1 (S.D. Fla. July 25, 2007).

16 *Schubert*, Second Am. Compl. 9 (Docket Entry # 2).

17 *Id.* 11.

18 *Id.*

19 *Id.* 10.

20 *Id.* 8; *Schubert*, Third Am. Compl. 11 (Docket Entry # 21).

21 *Id.*

22 *Id.* 30-31; Second Am. Compl. 20-31.

23 Third Am. Compl. 62-69.

24 *Id.* 51-55.

25 Second Am. Compl. 33.

26 Third Am. Compl. 37-41.

27 *Id.* 42-47.

28 *Id.* 48-50.

29 Second Am. Compl. 38.

30 *Id.* 45-62; Third Am. Compl. 6, 80-116.

31 *Id.* 6, 80-116; Second Am. Compl. 45-62.

32 42 U.S.C. §§ 1395nn(e)(2) (containing the bona-fide employment exception to the Stark Statute), 1320a-7(b)(3)(B) (containing the bona-fide employment exception to the Anti-Kickback Statute).

33 Second Am. Compl. 2, 23.

34 42 U.S.C. § 1395nn(e)(2)(B), (C).

35 Press Release, Dep't of Justice, St. Joseph Medical Center in Maryland to Pay U.S. \$22 Million to Resolve False Claims Act Allegations (Nov. 9, 2010); Press Release, Dep't of Justice, Hospital Chain HCA Inc. Pays \$16.5 Million to Settle False Claims Act Allegations Regarding Chattanooga, Tenn., Hospital (Sept. 19, 2012).

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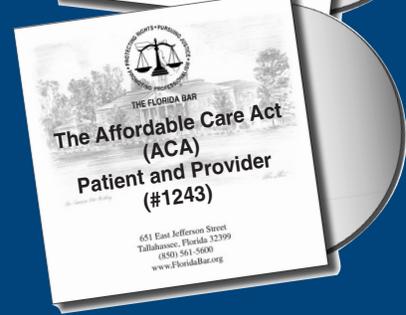
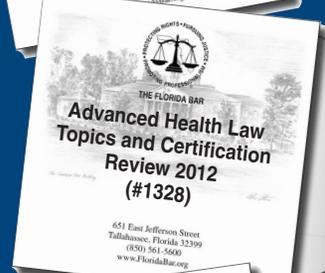
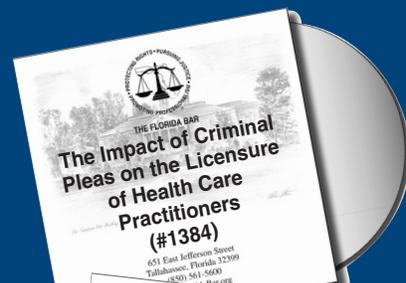
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Enforcement Topics for Nursing Homes

By Autumn B. Matthews, Esquire, Bartow, FL*

The 2013 Office of Inspector General (OIG) Work Plan, has been released. It lists three new enforcement areas for nursing homes. This article will discuss each of the three new enforcement areas and will outline some preparation tips for nursing homes.

1. State Verification of Deficiency Correction

OIG will determine whether State survey agencies verify correction plans for deficiencies identified during nursing home recertification surveys. During a prior OIG review, it was found that one State survey agency did not conduct the verification in accordance with federal requirements.

Preparation Tip

Although this new enforcement area has a greater impact on state agencies, a nursing home undergoing a correction plan for a deficiency can expect more follow-up from state surveyors. This could mean more onsite reviews, audits, or other evidence of correction. For the nursing home, the key here is documentation. For example, if a state review found that a nursing home failed to have an emergency evacuation plan, then the nursing home, pursuant to the correction plan, needs to document everything that is done in order to create and implement such an evacuation plan. This can include drafting a written policy, educating and training staff, maintaining logs of practice drills, *etc.* Having this type of documentation can achieve two ends; first, it helps the nursing home document correction and second, it helps the state agencies comply with federal law.

2. Use of Atypical Antipsychotic Drugs

OIG will assess nursing homes' administration of atypical antipsychotic drugs, including the percentage of residents receiving these drugs and the types of drugs most commonly received. OIG will also describe the characteristics associated with nursing homes that frequently administer atypical antipsychotic drugs.

The use of antipsychotic drugs in nursing homes has been a hot topic for regulators recently because elderly nursing home patients have an increased risk of death associated with using these drugs. A recent OIG report found that 99% of records pertaining to atypical antipsychotic drugs failed to meet one

or more federal requirements for resident assessments and/or care plans.¹ The report also found that nearly half the drugs were not given for medically accepted indications as defined by Medicare.²

Preparation Tip

If not already doing so, nursing homes should ensure they are complying with the following Medicare regulations:

- 1) Nursing home staff must assess each resident's functional capacity upon admission to the facility and periodically thereafter.³
- 2) Staff must then specify in a written care plan based on these assessments, the services that each resident needs.⁴
- 3) Nursing homes must ensure that residents who have not previously taken antipsychotic drugs are not given them unless it is necessary to treat a specific condition as diagnosed and documented in the residents' clinical records. Furthermore, when antipsychotic drugs *are* given, residents must receive gradual dose reductions and behavioral interventions in an effort to discontinue the drugs' use, unless clinically contraindicated.⁵

3. Oversight of the Minimum Data Set Submitted by Long Term Care Facilities

OIG will determine whether and the extent to which the Centers for Medicare and Medicaid Services ("CMS") and the states oversee the accuracy and completeness of Minimum Data Set ("MDS") data submitted by nursing facilities.

Preparation Tip

Certified nursing facilities are required

to complete the MDS for all residents at specified intervals and submit data electronically to the State. States then submit data to CMS, which uses it for a number of programs, including payment, quality monitoring, and consumer information.

When conducting the Resident Interview section of the MDS, it is best to do so in a place free from distractions and noise; a closed office is usually best. The interviewer should ask all questions in a clear and simple manner and be able to recognize when a resident does not understand a question.

Since OIG is going to be looking at accuracy and completeness, it is important to be thorough. An inaccurate MDS assessment can result in incorrect Quality Measure information. Therefore, it is important for clinical staff members responsible for completing the MDS to be well-trained.

Endnotes

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1 Daniel R. Levinson, Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs, Dept. of Health and Human Services, Office of Inspector General, July 2012, OEI-07-08-00151 http://media.mck-nights.com/documents/37/care_plans_9247.pdf

2 *Id.* at n.3 (Noting that medically accepted indications for atypical antipsychotic drugs generally include mental health conditions, such as bipolar disorder, schizophrenia, depression, and psychotic features.)

3 42 CFR § 483.20(b).

4 42 CFR § 483.20(k).

5 42 CFR § 483.25(l)(2).

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Non-Delegable Duties & Hospital Liability for Independent Contractor Physicians: A Split Worth Resolving?

By David W. Hughes, Esq., Tampa, FL*

INTRODUCTION

Florida's Second and Fourth District Courts of Appeal have been split for some time on the issue of vicarious liability for hospitals under the "doctrine of nondelegable duty"¹ for the negligence of nonemployee independent contractor physicians. In *Wax v. Tenet Health Systems Hospitals, Inc.*,² the Fourth District Court of Appeal reasoned that a hospital could be found vicariously liable for the acts and omissions of a non-hospital employee anesthesiologist under the doctrine of nondelegable duty. Thereafter, in *Tarpon Springs Hospital Foundation, Inc. v. Reth*,³ the Second District disagreed and certified a question of great public importance to the Florida Supreme Court—an overture the Court later denied.

This unresolved split of authority increases hospital exposure. Along with the classic theories of actual agency, apparent or ostensible agency, and joint venture, some courts are now imposing vicarious liability on hospitals for non-employee physician negligence.⁴ The aim of this article is to trace how the unresolved split of authority on nondelegable duty has been interpreted, applied, refined, and limited in a variety of medical malpractice contexts.

FLORIDA HOSPITAL AGENCY LAW IN GENERAL

In Florida, the general rule is that hospitals are not liable for the negligent acts or omissions of non-employee physicians with hospital privileges.⁵ Hospitals take advantage of this immunity by utilizing independent contractor physicians and/or their employer practice groups for high-risk hospital-based specialties such as radiology, pathology, anesthesiology, clinical laboratories, and emergency room services.⁶ In general, these contracts provide that the independent contractor physician is to receive no salary from the hospital and that the hospital has no right to control the physician's independent professional judgment while rendering physician services. Hospitals, in turn, contract with patients via admission and consent forms that typically inform patients of the physician's independent contractor status.⁷

While the general rule often suffices to shield hospitals from vicarious liability for non-employee physician negligence, there has been an observable national movement for some time towards increased hospital liability for independent-contractor malpractice.⁸ This movement is exemplified in Florida by claims that include allegations of nondelegable duties.

THE DOCTRINE OF NON-DELEGABLE DUTY

The doctrine of non-delegable duty is a species of vicarious liability that permits plaintiffs to bypass the general rule immunizing hospitals from independent contractor physician torts.⁹ Because nondelegable duties can arise out of statute, regulation, or express contract,¹⁰ the doctrine implicates intertwined duties founded in contract, tort, and agency law. Accordingly, the doctrine has been criticized for being "confusing and somewhat misleading."¹¹

In the United States, the doctrine appears to have first made its way into the medical malpractice field in *Darling v. Charleston Community Hospital*,¹² where the Illinois Supreme Court found that a hospital owed a direct and nondelegable duty to provide for a patient's care, safety, and management. In Florida, the doctrine was first applied to a suit for medical negligence in *Irving v. Doctors Hospital of Lake Worth, Inc.*,¹³ where a hospital was held liable for the negligent diagnosis and treatment of an independent contractor emergency room physician. The *Irving* court fashioned the following general rule: "[Hospitals] may not escape [their] contractual liability by delegating performance under a contract to an independent contractor."¹⁴

In sum, an entity subject to a nondelegable duty (the delegator hospital) will be held liable to third parties (patients) for a delegate's (physician) negligence regardless of any fault on behalf of the hospital.¹⁵ As addressed below, the doctrine has become increasingly popular in hospital medical malpractice suits as a result of the unresolved state of the law.

FLORIDA'S SPLIT ON THE ASSUMPTION OF STATUTORY AND REGULA-

TORY NONDELEGABLE DUTIES

Wax v. Tenet Health System Hospitals, Inc.

Wax was a medical malpractice suit brought by the personal representative of Gary Wax, a 37-year-old man admitted to the West Boca Medical Center for elective outpatient hernia surgery.¹⁶ Twenty minutes into the surgery, an emergency code blue was declared and after repeated attempts at resuscitation failed, Mr. Wax died on the operating table.¹⁷ The personal representative of Mr. Wax's estate brought a medical malpractice action against the hospital, the anesthesiologist, and the anesthesiologist's practice group, under Florida's Wrongful Death Act.¹⁸ The relevant issue on appeal was whether sections 395.002(13)(b)¹⁹ and 395.1055(1)(a)-(d),²⁰ Florida Statutes, and their corresponding provisions in Rule 59A-3.2085(4), Florida Administrative Code,²¹ imposed on hospitals an "expressed legal duty to furnish anesthesia services to its surgical patients 'consistent with established standards.'"²²

After extensively analyzing and interpreting the Fifth District's decision in *Pope v. Winter Park Healthcare Group, Ltd.*²³ and Mr. Wax's hospital admission and consent form, the Fourth District concluded that "the statute and regulation impose this duty for non-negligent anesthesia services on all surgical hospitals..."²⁴ In arriving at this conclusion, the court observed that the relationship between hospital and patient was "important enough.. that it should be deemed non-delegable without the patient's express consent."²⁵ In so doing, the *Wax* court found both "a statutory and a contractual basis for the hospital's duty of providing non-negligent, competent surgical anesthesia services to its patient."²⁶

Tarpon Springs Hospital Foundation, Inc. v. Reth

Four years after *Wax*, in *Tarpon Springs Hospital Foundation, Inc. v. Reth*, the Second District disagreed with the Fourth District in a case involving very similar facts and circumstances. *Reth* involved a medical malpractice action filed by the personal representative of a

continued, next page

NON-DELEGABLE DUTIES

from previous page

patient's estate against an anesthesiologist, nurse anesthetists, an anesthesia practice, and a hospital.²⁷ In its suit, plaintiff asserted that negligent anesthesia services provided during surgery resulted in Mr. Reth's death.²⁸ Regarding its cause of action against the hospital, Reth's personal representative alleged that the hospital was "liable for the conduct of [the] nurse anesthetists... under a theory of a nondelegable duty" by asserting that "sections 395.002(13)(b), 395.1055(1)(a), (d), Florida Statutes (2005), and Florida Administrative Code Rule 59A-3.2085(4) created an express legal duty for the Hospital to furnish nonnegligent anesthesia services to its surgical patients."²⁹

The hospital argued that while the statutes and rules required hospitals to "competently and adequately staff an anesthesia department," the "duty to practice anesthesiology in a non-negligent manner is owed by the patient's physician and nurse anesthetists, not the hospital, and that the statutes and rule do not create a non-delegable duty that requires the hospital to practice anesthesiology."³⁰ The Second District agreed, stating "the statutes and rule cited above required hospitals to have anesthesia departments and to have appropriate numbers of qualified personnel available to provide anesthesia services to the hospital's patients; however, the statutes and rule do not create a non-delegable duty on hospitals to practice anesthesiology."³¹

The Second District reasoned that the Wax court erroneously interpreted section 395.1055(1)(d) to apply anesthesiology standards of practice to hospitals, noting that "Chapter 395 regulates hospitals and addresses standards governing hospitals, not standards applicable to the practice of medicine that is regulated by other chapters of the Florida Statutes."³² The Reth court emphasized that the Wax court failed to "draw a distinction, as we do, between the duty to ensure that those services are available and provided by competent personnel versus the duty to provide anesthesia services non-negligently to a patient in a given instance."³³ Accordingly, the Second District certified conflict with Wax to "the extent that [Wax] determined a hospital has a non-delegable duty to provide non-negligent anesthesia services" based on the Florida Statutes and regulations.³⁴

POST WAX/RETH JURISPRUDENCE

Since Reth, the Fourth District has

issued two opinions which refined the broad implications set forth in Wax: *Kristensen-Kepler v. Cooney*³⁵ and *Newbold-Ferguson v. AMISUB (North Ridge Hospital), Inc.*³⁶ Central to both holdings was the idea that the nondelegable duty analysis is governed by patient control over physician selection, and whether a procedure is elective or emergent.

In *Kristensen-Kepler*, a patient's estate brought an action against an ambulatory surgical center because the patient's death resulted from a negligently performed elective, outpatient procedure meant to treat the patient's chronic back pain.³⁷ The complaint contained allegations of negligence in the pre-surgical consultation and assessment process, and in the administration and management of anesthesia during the procedure.³⁸ Plaintiff alleged that the surgical center "had a statutorily-created, non-delegable duty to provide anesthesiology services," and was therefore directly liable for the negligence of the independent contractor anesthesiologist.³⁹ The surgical center moved for summary judgment, which the circuit court granted.⁴⁰

On appeal, the Fourth District affirmed the circuit court's decision, reasoning that the surgical center "owed plaintiff no duty of care with regard to the physician selected by the patient."⁴¹ The court reasoned that while Wax held that the Florida Statutes and Florida Administrative Code "impose a 'duty for non-negligent anesthesia services on all hospitals,'" Wax "did not hold, however, that a hospital likewise has a non-delegable duty to supervise the physician a patient has chosen to perform an elective procedure."⁴³

In *Newbold-Ferguson*, the personal representative of a patient's estate brought a wrongful death action arising out of the alleged "negligent acts and omissions [of the emergency room physician] as a result of a nondelegable duty to supervise... so that competent and careful medical personnel are provided..."⁴⁴ During a deposition, the plaintiff's expert witness testified that the emergency room physician deviated from the standard of care by delaying his response to the patient's emergency code.⁴⁵ However, the trial court ultimately ruled that plaintiff could not refer to the negligence of the emergency room physician, a decision that barred plaintiff from establishing a nondelegable duty claim.⁴⁶

On appeal, the Fourth District reversed, invoking *Irving* and Wax and reasoning that hospitals that "provide[]

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NON-DELEGABLE DUTIES

from previous page

emergency room services [have] a non-delegable duty to provide competent emergency treatment based upon an implied contract.”⁴⁷ The court reasoned that “an emergency room [patient] generally has little, if any, *control* over who will be the treating physician.”⁴⁸

CONCLUSION

While the doctrine of nondelegable duty is alive and well in Florida’s Fourth District Court of Appeal medical malpractice jurisprudence, the Second District has been more cautious, refusing to apply the doctrine to a hospital’s provision of anesthesiology services. The Fourth District’s emphasis on a lack of patient choice and control over physician selection as a trigger for application of the doctrine is instructive, but hospitals, surgery centers, and other institutions utilizing the services of non-employee independent contractor physicians must be ever mindful of potential exposure to liability created by this unresolved split of authority. Until the Florida Supreme Court addresses this issue, trial courts in the First, Third, and Fifth Districts are free to choose between either of the Second or Fourth Districts’ theories, which creates considerable uncertainty for future litigants.

Endnotes

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1 The spellings “nondelegable” and “non-delegable” are used interchangeably by courts and treatise writers alike; there is no established spelling.

2 955 So. 2d 1, 9 (Fla. 4th DCA 2006) (“We conclude that because the statute and regulation impose this duty for non-negligent anesthesia services on all surgical hospitals, it is important enough that as between the hospital and its patient it should be deemed non-delegable without the patient’s express consent.”)

3 40 So. 3d 823, 824 (Fla. 2d DCA 2010) (“Thus, we reverse the denial of the Hospital’s motion for directed verdict and remand for the trial court to enter judgment in the Hospital’s favor. In doing so, we certify conflict with *Wax v. Tenet Health System Hospitals, Inc.*, 955 So. 2d 1 (Fla. 4th DCA 2006), to the extent that it determined a hospital has a nondelegable statutory duty to provide nonnegligent anesthesia services to patients.”)

4 To establish an actual agency relationship, the following three elements must be established: (1) acknowledgement by the principal that the agent will act for him or her, (2) the agent’s acceptance of the undertaking, and (3) control by the principal over the actions of the agent. See

Goldschmidt v. Holman, 571 So. 2d 422, 424 n.5 (Fla. 1990) (citing Restatement (Second) of Agency § 1 (1957)). An apparent agency exists only if all three of the following elements are present: (a) a representation by the purported principal; (b) a reliance on that representation by a third party; and (c) a change in position by the third party in reliance on the representation. *Roessler v. Novak*, 858 So. 2d 1158, 1161 (Fla. 2d DCA 2003). The elements of a joint venture are: (1) a community of interest in performance of a common purpose; (2) joint control or right of control; (3) joint proprietary interest; (4) a right to share in the profits; and (5) a duty to share in any losses. See *Kislak v. Kreedian*, 95 So. 2d 510 (Fla. 1957).

5 See, e.g., *Public Health Trust of Dade County v. Valcin*, 507 So. 2d 596, 601 (Fla. 1987).

6 See, e.g., H. Ward Classen, *Hospital Liability for Independent Contractors: Where Do We Go From Here?*, 40 Ark. L. Rev. 469, 471 n.7 (1987); Arthur F. Southwick, *Hospital Liability: Two Theories Have Been Merged*, 4 J. Legal Med. 1 (1983).

7 By contrast, when a hospital employee, e.g. a registered nurse, nurse’s assistant, or respiratory therapist, is negligent, the doctrine of *respondeat superior* is triggered and the hospital will be held vicariously liable for its agent-employee’s torts committed within the course and scope of employment. See, e.g., *Roessler*, 858 So. 2d at 1161.

8 See, e.g., Martin C. Williams & Hamilton E. Russell, III, *Hospital Liability for Torts of Independent Contractor Physicians*, 47 S.C. L. Rev. 431, 434-36 (1996); Ryan Montefusco, *Hospital Liability for the Right Reasons: A Non-Delegable Duty to Provide Support Services*, 42 Seton Hall L. Rev. 1337, 1340-41 (2012).

9 See, e.g., Restatement (Second) of Agency § 2 (1957); see also Restatement (Second) of Torts § 429 (1965).

10 *Pope v. Winter Park Healthcare Group, Ltd.*, 939 So. 2d 185, 188 (Fla. 5th DCA 2006) (“In Florida case law, nondelegable duties are often said to arise out of the common law, statutes or regulations, or contract.”) While nondelegable duties “can be undertaken pursuant . . . to express contract,” they do not arise out of implied contracts. *Id.* at 187.

11 *Id.*

12 211 N.E.2d 253 (Ill. 1965), *cert. denied*, 383 U.S. 946 (1966). *Darling* was an action brought on behalf of a minor, Dorrence Darling, by his father to recover damages for allegedly negligent medical and hospital treatment necessitating leg amputation of the right leg below the knee.

13 415 So. 2d 55, 56-60 (Fla. 4th DCA 1982). In arriving at its conclusion, the *Irving* court borrowed heavily from construction law and the 1976 New York wrongful death case *Mduba v. Benedictine Hospital*, 52 A.D.2d 450 (N.Y. App. Div. 1976).

14 *Irving*, 415 So. 2d at 59.

15 See, e.g., *Wax*, 955 So. 2d at 9.

16 *Id.* at 3.

17 *Id.*

18 §§ 768.16-768.26, Fla. Stat. (2011). The allegations in *Wax* included the following: (1) the negligent performance of a pre-surgical consultation and assessment, (2) the negligent administration and management of anesthesia, and (3) negligent attempts at failed resuscitation.

Wax, 955 So. 2d at 3.

19 Section 395.002(13)(b), Florida Statutes defines a “hospital” as an establishment that regularly makes “treatment facilities for surgery.”

20 Section 395.1055(1)(a), Florida Statutes, requires the Agency for Health Care Administration (AHCA) to adopt rules that include “reasonable and fair minimum standards for ensuring that . . . [s]ufficient numbers and qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care and safety.”

21 Rule 59A-3.2085(4), Florida Administrative Code, provides that “Each Class I and Class II hospital, and each Class III hospital providing surgical or obstetrical services, shall have an anesthesia department, service or similarly titled unit directed by a physician member of the organized professional staff.”

22 *Wax*, 955 So. 2d at 9 (citing § 395.1055(1)(d), Fla. Stat.).

23 939 So. 2d at 191. In *Pope*, the Fifth District held that the delegation of a *contractual* duty to an independent contractor does not eliminate the duty of the delegating party. *Id.* See also Section 318 Restatement (Second) of Contracts, which provides:

Delegation of Performance of Duty

(1) An obligor can properly delegate the performance of his duty to another unless the delegation is contrary to public policy or the terms of his promise.

(2) Unless otherwise agreed, a promise requires performance by a particular person only to the extent that the obligee has a substantial interest in having that person perform or control the acts promised.

(3) Unless the obligee agrees otherwise, neither delegation of performance nor a contract to assume the duty made with the obligor by the person delegated discharges any duty or liability of the delegating obligor.

24 *Wax*, 955 So. 2d at 9.

25 *Id.*

26 *Id.* at 11.

27 *Reth*, 40 So. 3d at 825.

28 *Id.* at 824-25.

29 *Id.* at 825. The *Reth* court noted that plaintiff’s nondelegable duty claim relied “primarily” on the Fourth District’s holding in *Wax*. *Id.* at 826.

30 *Id.* at 825.

31 *Id.* at 826-27 (emphasis added).

32 *Id.* at 828.

33 *Id.*

34 *Id.*

35 39 So. 3d 518 (2010).

36 85 So. 3d 502 (2012).

37 *Kristensen-Kepler*, 39 So. 2d at 519-20.

38 *Id.* at 520.

39 *Id.* at 519 (citing *Wax*, 955 So. 2d at 11).

40 *Id.*

41 *Id.* (emphasis added).

42 *Id.* at 520 (citing *Wax*, 955 So. 2d at 8-9).

43 *Id.*

44 *Newbold-Ferguson*, 85 So. 3d at 503.

45 *Id.*

46 *Id.* at 503-04.

47 *Id.* at 505.

48 *Id.* (emphasis added).

OIG Work Plan Fiscal Year 2013 - What's New and What's Still on the Radar?

By Myla Reizen, Esquire, Miami, FL*

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently released a *Work Plan for Fiscal year 2013 (Work Plan)*. This Work Plan outlines the OIG's current focus areas and states the primary objectives of each project. A work plan is released on an annual basis by the OIG.

In evaluating the proposals for the Work Plan, the OIG considers a number of factors:

- mandatory requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget (OMB);
- top management and performance challenges facing HHS;
- work to be performed in collaboration with partner organizations;

- management's actions to implement our recommendations from previous reviews; and
- timeliness.

The Work Plan is divided into seven parts and has two appendices. For reference, the seven parts and appendices are as follows:

- Part I: Medicare Part A and Part B
- Part II: Medicare Part C and Part D
- Part III: Medicaid Reviews
- Part IV: Legal and Investigative Activities Related to Medicare and Medicaid
- Part V: Public Health Reviews
- Part VI: Human Services Reviews
- Part VII: Other HHS-Related Reviews
- Appendix A: Affordable Care Act Reviews
- Appendix B: Recovery Act Reviews

This article is going to concentrate on the first part of the Work Plan concerning

Medicare Part A and Part B.

Under Medicare Part A and Part B, the OIG identifies areas for various types of providers and suppliers, such as hospitals, nursing homes, hospices, home health agencies, and medical equipment and supplies. There is a section on "Other providers and suppliers" as well. This part also includes sections on prescription drugs, Part A and Part B Contractors and Other Part A and Part B Management and Systems Issues. Under each Section, the OIG has identified certain areas for review. Certain areas are identified as "new", while other areas were contained in the OIG's prior work plan.

This Work Plan serves as a useful tool for organizations or entities to review and analyze when preparing and/or updating a compliance program. It is also helpful to attorneys who advise the various types of organizations or entities referenced in the Work Plan. As previously noted, this article is meant to summarize certain

continued on page 16

The Interplay Between A Provider's Repayment and Self-Disclosure Obligations, and The Consequences of a RAC Audit

By Fabienne E. Fahnestock, Esquire, Fort Lauderdale, FL*

RAC Audits

Between fraud and overpayments made to providers for services rendered, the Centers for Medicare and Medicaid Services ("CMS") was losing billions of dollars. In an effort to identify and recoup some of its losses, CMS implemented a pilot program known as the Medicare Recovery Audit Contractor ("RAC"). The RAC was initially established in 2003 as part of the Medicare Modernization Act of 2003. A three-year pilot program was launched in a few states. RAC audits reviewed claims for: hospital inpatient and outpatient, skilled nursing facility, physician, ambulance and laboratory, and durable medical equipment for the preceding three years. Unlike some other provider audits, RAC audits are not one time or intermittent reviews - they are a systematic and concurrent operating process designed to ensure compliance

with Medicare coverage criteria.

As a result of the RAC audits, over the three year time frame from 2005 - 2007, CMS and RAC auditors recouped nearly \$1 billion from providers in Florida, New York and California. The RAC program gained permanency as part of the Tax Relief and Health Care Act of 2006, and the CMS rolled the program out in all 50 states.

Provider's Reaction to RAC Audits

In response to the permanent institution of the RAC program, many institutional providers took proactive measures and implemented internal policies to ensure compliance with CMS' regulations and policies. These policies are critical in identifying patterns of overpayments as a proactive measure to avoid findings that overpayments have been made during a RAC audit, as well as complying with a provider's self-disclosure and repayment

obligations under Patient Protection and Affordable Care Act ("PPACA").

RAC audits identify a broad spectrum of improper claims spanning from technical errors to more significant issues that may be related to a pattern of abuse. The interplay between the RAC audit and a provider's self-disclosure and repayment obligation come into play with the more significant issues - for instance, where a pattern of errors affect a myriad of claims.

The Interplay Between RAC Audits and Self-Disclosure/Repayment Obligations Under PPACA

The process of identifying instances where overpayments have been made and need to be refunded is complicated and time consuming, especially where the error appears to be part of a larger pattern. Often times, the universe of

continued on page 15

Health Care and Medicare Fraud in Florida: exploring a broader legal arsenal and recent examples

By Shari Gerson, Esquire and Shayna A. Freyman, Esquire, Fort Lauderdale, FL*

Most of us who work or practice in the health care industry are familiar with the federal statutes dealing with health care and Medicare fraud and other unlawful practices, such as the Stark Act, the federal False Claims Act (“FCA”), and the Anti-Kickback Statute.¹ What some may not know is that there are many more tools available in the arsenal for deterring the unlawful practices addressed in the federal statutes. These tools include the state law analogues to the federal statutes, Florida statutes regulating payors and providers, Florida criminal statutes, and state agency investigations. The import of these alternative legal tools is, among other things, that they apply to reimbursements by private payors, whereas the federal statutes apply exclusively to payments made by the government under federal programs, such as Medicare. And it is not only the private and government payors that have a stake in this fight. The increased efforts and tools designed to deter fraudulent and other unlawful practices are critical to the availability of affordable health care services for the public and efficient payment to providers.

The Federal Statutes and their Florida Counterparts

The Stark Act prohibits, with certain statutory exceptions, a physician who has a financial ownership interest in or a compensation arrangement with an entity, from referring patients to that entity for the provision of designated health services if payment for those services may be made by Medicare or Medicaid. 42 U.S.C. §1395nn. The Middle District of Florida recently stated that, “[t]he goal of the Stark Amendment to the Medicare Act, is ‘to curb overutilization of services by physicians who could profit by referring patients to facilities in which they have a financial interest.’” *U.S. v. Halifax Hosp. Medical Center*, 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, at *2, (M.D. Fla. Mar. 19, 2012).

Under the False Claims Act (“FCA”), private persons may file a civil action against (and recover damages on behalf of the United States from) any person who (1) knowingly presents, or causes to

be presented, a false or fraudulent claim for payment or approval or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1) (A)-(B); *U.S. v. Halifax Hosp. Medical Center*, 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, at *3, (M.D. Fla. Mar. 19, 2012).

Private citizens in *qui tam* actions, or the federal government, often utilize the Stark Act in conjunction with the FCA to “blow the whistle” on fraudulent or otherwise improper referral or billing practices. For example, the plaintiff in such a case may allege the defendants have an improper financial relationship with physicians who are making referrals to a subject entity, and, because of those financial relationships, the referrals violate the Stark Act. Consequently, the bills submitted as a result of those referrals violate the FCA. Allegations such as these have survived defendants’ motions to dismiss, even where defendants allege that the Stark Act only applies to Medicare claims, and the claims at issue are through the Medicaid program (which are paid by the states). The Middle District has recently rejected that argument, noting that the Medicaid statute also prohibits a state from receiving federal funding for medical services resulting from improper referrals, as defined by the Stark Act. 42 U.S.C. §1396b(s). Under the FCA, a defendant may be liable for submitting its own false claim or for causing another to submit a false claim. Therefore the plaintiff’s theory that the defendants caused the state of Florida to submit false claims to the federal government for services furnished on the basis of improper referrals survived a Rule 12(b)(6) challenge. *U.S. v. Halifax Hosp. Medical Center*, 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, at *4, (M.D. Fla. Mar. 19, 2012). It is worth noting that when pleading the alleged fraud and unlawful practices under these Acts, the plaintiff must plead with more particularity in compliance with Rule 9(b)’s heightened standard. Recent examples of how to do so effectively can be found in *U.S. ex rel. Santa Ana*

v. Winter Park Urology Associates, P.A., 6:10-CV-806-ORL-28, 2012 WL 386680 (M.D. Fla. Feb. 7, 2012) and Order Denying Motion to Dismiss Complaint, *United Healthcare Insurance Company v. Louis Scott Ulin, M.D.*, 0:11-CV-62743 (S.D. Fla. May 29, 2012).²

The federal Anti-Kickback Statute prohibits the knowing and willful solicitation, receipt, offer, or payment of “any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind” in return for or to induce the referral, arrangement, or recommendation of any service for which payment will be made in whole or in part under a federal health care program. 42 U.S.C. §1320a-7b(b)). This statute is also used in conjunction with actions brought pursuant to the FCA, because, for example, as with the Stark Act, falsely certifying compliance with the Anti-Kickback Statute in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. See *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir.2004) (citing *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir.1997)).

Although it is clear that the federal statutes summarized above provide a basis to prosecute unlawful and fraudulent referral and billing practices in the Medicare and even Medicaid context, they are limiting in that they do not apply to claims for services paid by private payors. Florida’s analogues to the federal statutes fill this gap.

Florida’s “Mini Stark” is similar to and shares the goal of the federal Stark Act: “to provide guidance to health care providers regarding prohibited patient referrals between health care providers and entities providing health care services and to protect the people of Florida from unnecessary and costly health care expenditures.” Fla. Stat. §456.053(2). However, the Florida “Mini Stark” does have its differences. For example, the Federal Stark Act contains an exemption for referral of clinical laboratory services

continued, next page

FRAUD IN FLORIDA

from previous page

for end-stage renal disease patients, whereas the Florida “Mini Stark” does not contain that exemption and prohibits such a referral. *Fresenius Med. Care Holdings, Inc. v. Francois*, 832 F. Supp. 2d 1364, 1367 (N.D. Fla. 2011). The Florida “Mini Stark” also serves as a basis for providers to seek a declaratory statement from the Agency of Health Care Administration (“AHCA”) to determine whether they are in compliance with the provisions of the Referral Statute. The Florida “Mini Stark” specifically states that AHCA should encourage the use of declaratory statements regarding the applicability of the statute to hospitals’ and providers’ actions. Fla. Stat. §456.053(5)(b)(4); *Adventist Health System/Sunbelt, Inc. v. Agency For Health Care*, 955 So. 2d 1173, 1177 (Fla. 1st DCA 2007).

Florida also has a version of the federal Anti-Kickback statute. Like the federal version, Florida’s Anti-Kickback Statute, prohibits “kickbacks” or, “remuneration or payment, by or on behalf of a provider of health care services or items, to any person as an incentive or inducement to refer patients for past or future services or items, when the payment is not tax deductible as an ordinary and necessary expense.” Fla. Stat. §456.054. The difference is that under the Florida version, the prohibitions are not limited to where payments are made in whole or in part by federal programs. The Florida Anti-Kickback Statute makes kickbacks

unlawful by its own terms and also classifies violations under the statute as patient brokering criminally punishable as set forth in Section 817.505. Specifically, Section 817.505 criminalizes patient brokering by prohibiting any person from offering to pay any commission, bonus, rebate, kickback, or bribe, or engage in any split-fee arrangement to induce referral of patients from health care providers or facilities. Furthermore, the Florida Anti-Kickback Statute provides strong medicine for its violation, in that “[a]ny person, including an officer, partner, agent, attorney, or other representative of a firm, joint venture, partnership, business trust, syndicate, corporation, or other business entity, who violates any provision of this section commits a felony of the third degree, punishable as provided in s. 775.082 [up to five years imprisonment], s. 775.083 [a fine up to \$5,000.00] or s. 775.084 [imprisonment up to 10 years for habitual offenders].” Fla. Stat. §817.505(4).

Other Florida Statutes

The Florida statutes are replete with tools for combating health care fraud over and above what the federal statutes and their state law counterparts provide. For example, Florida’s legislature has recently passed, and the Governor has approved, a bill amending Section 456.0653, *Florida Statutes*. Fla. HB 653 (2012). House Bill 653, signed into law on April 6, 2012, changed the title of section 456.0635 from “Medicaid fraud” to “Health care fraud,” broadened the duty of a licensed health care practitioner to

report allegations of health care fraud, and rendered the surrender of a license due to an allegation of health care fraud or the anticipation of an allegation of health care fraud a permanent revocation of the license. This amendment gives licensed health care professionals an increased incentive to act lawfully in their referral and billing practices.

The Florida statutes aimed at regulating and penalizing health care professionals and other fraud perpetrators also specifically regulate the conduct of private payors—insurers and Health Maintenance Organizations (“HMOs”). Pursuant to Section 626.989(2), if the department or its Division of Insurance Fraud has reason to believe that a person has engaged in, or is engaging in a fraudulent insurance act or an act or practice that violates certain specified statutes, it may administer oaths and affirmations, request the attendance of witnesses or proffering of matter, and collect evidence, including procedures by representatives if the matter is out of state. Fla. Stat. §626.989(3) and (4). To assist the Department in these efforts, the statute also provides that any insurer or employee or agent thereof, having knowledge or who believes that a fraudulent insurance act or any other act or practice which, upon conviction, constitutes a felony or a misdemeanor under the code, is being or has been committed, “shall send to the Division of Insurance Fraud a report or information pertinent to such knowledge or belief

continued, next page

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FRAUD IN FLORIDA

from previous page

and such additional information relative thereto as the department may require.” Fla. Stat. §626.989(6). Additionally, Section 626.9891 requires insurers to establish and maintain investigation units within the company that monitor for and investigate possible fraudulent claims by insureds or persons making claims on behalf of insureds. Lastly, Section 641.3915 applies the requirements imposed upon private insurers by Sections 626.989 and 626.9891 to Health Maintenance Organizations.

Another example of a Florida statute addressing insurance and health care fraud is Section 627.736(12), which provides insurers with a civil cause of action against any person convicted of or who pleads guilty or nolo contendere to insurance fraud under Section 817.234, patient brokering under Section 817.505, or kickbacks under Section 456.054, associated with a claim for personal injury protection benefits. Sections 817.505 and 456.054 were discussed above in connection with their related statutes. Section 817.234 provides that a person commits insurance fraud if that person, with the intent to injure,

deceive, or defraud any insurer, submits a claim for payment containing any false, incomplete, or misleading material information. The statute also provides for significant sanctions, such as loss of professional licensure for up to five years, prohibition from receiving reimbursement for personal injury protection benefits for 10 years, as well as other serious financial sanctions or incarceration.

These statutes have teeth and are utilized statewide to uncover fraudulent schemes and bring their organizers to justice. For example, a recent investigation by the Florida Department of Financial Services Division of Insurance Fraud uncovered a PIP fraud ring in Manatee County whereby two men were engaging in an elaborate patient brokering scheme involving a “straw” health care facility, a chiropractor, and a body shop engaging in illegal billing and referral practices.³ The two men involved in the scheme were charged with eight counts of patient brokering and may face up to five years in prison.⁴

Conclusion

While the epidemic of health care fraud is nothing new, especially to South Floridians, it is clear that the government is increasing its efforts to crack down. President Obama’s administration is

being more aggressive, as are states and local agencies. More schemes are being uncovered, resulting in more arrests. Many of the tools described above assist the government as well as private payors in recouping and preventing the loss of billions of dollars on fraudulent claims. Preserving health care dollars, both in the public and private sectors, is essential to our delivery of efficient and affordable health care. It benefits all of the health care players to take an active role in this effort.

Endnotes

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1 The Stark Act is codified at 42 U.S.C. §1395nn. The Anti-Kickback Statute is codified at 42 U.S.C. §1320a-7b(b)). The FCA is codified at 31 U.S.C. §3729.

2 The Plaintiff, United Healthcare Insurance Company, was represented in this action by Shari Gerson, Esq., co-author of this article.

3 Claims Journal, <http://www.claimsjournal.com/news/southeast/2012/11/06/216831.htm> (November 6, 2012).

4 Claims Journal, <http://www.claimsjournal.com/news/southeast/2012/11/06/216831.htm> (November 6, 2012).

“Sorry Works!” Offers Chance to Break Medical Gridlock in Florida

By Doug Wojcieszak, Bruce Blitman, Esq., James W. Saxton, Esq. and Maggie M. Finkelstein, Esq.*

For too long, the Florida medical, legal, and insurance communities have fought an expensive and pitched battle over medical malpractice issues. Nobody will ever really win the political brawl; patients, families, and doctors all lose. Fortunately, the national disclosure and apology movement known as “Sorry Works!” provides the opportunity to break this gridlock by reducing:

- the number of lawsuits and litigation expenses for the medical and insurance communities
- providing fair and swift justice for patients and families
- increasing patient safety (which further reduces litigation exposure and associated costs)

The philosophical basis for Sorry Works!, or enhanced post-adverse event communication, has been known to

arbitrators and medical/legal researchers for well over a decade. In a nutshell, anger – not greed – is what often pushes patients and families to file medical malpractice lawsuits. Patients and families become angry when healthcare professionals display poor communication and customer service skills post-adverse event. Doctors have been asked or taught traditionally to cut off communication with patients and families when “something goes wrong” – even in instances where an adverse event was *not* caused by error – leaving patients and families feeling abandoned by the providers and institutions they entrusted with their care.

Healthcare providers usually counter that any attempts to offer sympathy, empathy, excellent service, or even an apology will probably be used against them in court. This is true when not done in the right way. When done the right way, it can help improve the circumstances.

Seasoned plaintiffs’ attorneys often say that a caring, empathetic provider makes for a poor target in the courtroom, whereas the physician who cut off communication with his/per patient at the time of greatest need is extremely vulnerable, even in cases where the medicine itself is defensible. This is because it is an aggravating circumstance, or a “plus” factor that impacts severity.

Sorry Works! is *not* arbitration. At the heart of Sorry Works! is a three-step process: 1) empathy & good customer service; 2) credible and quick investigation; and 3) information, and where appropriate, resolution.

Step 1: Empathy & Good Customer Service

We encourage medical providers and their institutions to initiate *immediately* after an adverse event. Empathize with the patient/family, say “sorry” about the event

continued, next page

“SORRY WORKS!”

from previous page

(say, “I’m sorry this happened” – do not admit fault). Provide good customer service including handling simple yet important issues such as food, lodging, phone calls, etc., and promise a quick and credible investigation. Step 1 is about maintaining a relationship with a patient/family when something has gone wrong, whether the standard of care has been breached or not. Instead of abandoning patients, embrace them and draw them closer just like any good customer service program.

Step 2: Investigation

Investigation should be done quickly and credibly, including the involvement of outside experts when necessary. Simply put, Step 2 is all about determining if an adverse event was caused by a breach of the standard of care – an error, mistake, systems error.

Step 3: Resolution

Resolution should occur in a meeting with the patient or family and with counsel if the patient/family so chooses. If the investigation determines that an error occurred, the providers and/or institution, working in concert with their insurer(s) and defense counsel, should offer an apology, explain what happened and how it will be prevented in the future, and begin to discuss the economic and non-economic needs of the injured party. If no mistake occurred, the providers and/or institution should again empathize,

share the results of the investigation, offer the records to the patient/family and their legal counsel, and answer all questions – but no settlement will be offered and any lawsuits will be contested all the way to jury verdict if necessary.

This three-step process should be used whether a case is small or big (wrongful death, crippling injury, “bad baby” case, etc.). for the three-step process to truly be successful, it must be housed in a disclosure program within the hospital, medical practice, and/or insurer(s). The program needs a well-defined policy, training for all involved parties, and a team of experts in charge to help medical providers through the three-step process.

Sorry Works! is not theory – it’s actually working. Take, for example, the University of Michigan (UM) Health System, the largest healthcare business in the State of Michigan. After operating a disclosure program for over seven years, UM has cut its lawsuits by over half, reduced reserves against future losses from \$72 million to less than \$20 million, and cut defense litigation costs by two-thirds or \$2 million annually. Other large hospital systems and risk retention groups, such as the Central Pennsylvania Physicians Risk Retention Group, across the country are starting to report similar positive results.

Sorry Works! can work even in Florida’s med-mal legal environment. Fearful providers, institutions, and insurers should remember that if they truly want to

limit litigation, they need to do all they can to preserve relationships with patients and families post-adverse events. The pro-active, customer service techniques of Sorry Works! can help. Sorry Works! reduces the anger felt by most patients and families and the need to pursue litigation, and in those cases that do not move forward to litigation, Sorry Works! provides a mountain of strong evidence for the defense by removing so-called plus factors, especially in cases where the medicine is defensible.

Sorry Works! was endorsed last summer by the Florida Patient Safety Corporation. Hopefully, it continues to trend throughout Florida’s medical, legal, and insurance communities. To learn more, visit www.sorryworks.net.

Endnotes

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RAC AUDIT

from page 11

claims to be reviewed is exceptionally large. However, determining whether a refund is necessary, and the amount to be refunded, can only be identified by reviewing the records of each case. Given the volume of records involved, it would be impractical and improbable to complete the review in compliance with the 60-day review period provided for under PPACA.

The 60-day deadline imposes the sense of urgency on providers to perform the self-audit. Even if the amount of the refund cannot be determined within that time period, providers are strongly encouraged to make disclosure, in writing, to the appropriate agencies, explaining the issues involved, the status of the review, and when the amount to be refunded will be calculated.¹ Another option available to a provider, however, is to perform a random, statistical sampling

as a more efficient and realistic method to review substantial volumes of records to calculate a refund by extrapolating the determined error rate.

Hypothetical

Suppose that a provider has identified a potential error regarding the claim for a particular, yet common procedure (i.e., a catheterization). Because it would be impossible to review each medical record associated with the procedure within the 60-day deadline, you use a random, statistical sampling method. Based upon the results of this method, you determine that overpayments were made for the claims reviewed for that procedure at an average of \$200 per claim. There are 1,000 claims that meet the criteria used for the random, statistical sampling, and therefore, extrapolating the data collected during the sampling, you repay the appropriate agency \$200,000.

Six months later, you are notified that you will be the subject of a RAC audit. The audit will include some, but

not all of the claims that were part of the random, statistical sampling voluntarily performed a few months ago. During the audit, a particular claim is identified to have been overpaid by \$15,000. This particular claim has all of the criteria used for the sampling, and you argue that this particular claim has been repaid. The auditors disagree because this particular claim was not one of the claims chosen as part of the sampling. Rather, this particular claim was in the pool of claims in which the calculated amount was extrapolated and applied. What do you do?

Options

The time and hassle of complying with the documentation requests that come with an audit may outweigh the potential dollar amount of Medicare payments that are in dispute.² This means that it may not be worth the headache associated with identifying those claims that have been disclosed and voluntarily repaid through a statistical sampling.

continued, next page

RAC AUDIT

from previous page

Option 1: Do nothing.

If the dollar amount at issue is substantial, what are your choices? What can you do if you believe that a RAC audit has identified a potential overpayment that was previously disclosed and repaid by you under PPACA?

Option 2: Appeal the RAC audit findings.

Prior to initiating the RAC appellate process, a provider can initiate a Discussion Period within 15 days of an overpayment demand letter. Notwithstanding the initiation of the Discussion Period, the time to file an appeal continues to run.

If the dispute is not resolved in the Discussion Period, RAC audits offer providers with five levels of appeal. Level One: Redetermination; Level Two: Reconsideration; Level Three: Administrative Law Judge; Level Four: Medicare Appeals Council; and Final Appeal: Judicial Review.

Although claims that have been appealed to the Final Appeal are rare, it is a possibility. The RAC appellate process can be time consuming and costly. More importantly, it should be noted that a provider's repayment obligations for the "overpaid claims" identified during the RAC audit are not tolled during the appellate process. This means that in addition to the costs associated in legal fees and the resources dedicated to the appeal of the RAC findings, which can span over several years, the provider must also repay the alleged overpayments identified during the audits, and continue to self-disclose and repay any overpayments identified by the provider pursuant to PPACA.

Option 3: Go back in time.

Before you begin the self-audit process, consult a qualified healthcare attorney to help you establish the appropriate protocols and measures that may be able to help you anticipate and prepare for circumstances, such as this one.

Seriously, RAC audits and PPACA are

both still relatively in their infancy, and there are many kinks that have not yet surfaced. As it has been said time and time again, offense is the best defense. While providers cannot be prepared for every nuance that can arise, they can try to be in the best position should one arise.

Conclusion

Deciding when and how to make disclosure is complicated and fraught with risk. There are no easy answers, and when deciding how to proceed when confronted with potential conflicts, such as those discussed above, the best advice is to consult an experienced healthcare attorney first.

Endnotes

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1 "Disclosing and Refunding Overpayments in Healthcare Cases", 24 No. 3 Health Law. 16

2 "Business is Booming for Medicare Recovery Audit Contractors," by Charles Fiegl; amednews.com, May 16, 2011.

OIG WORK PLAN

from page 11

areas from the Work Plan. Therefore, readers should review the Work Plan in its entirety to understand its complete content.

This document should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult an attorney concerning your own situation and any specific legal questions you may have.

Hospitals

The Work Plan identifies 25 areas for hospitals. With respect to these areas, the OIG has identified the following ten new areas.

- **Inpatient Billing for Medicare Beneficiaries**
OIG will describe how hospital billing for inpatient stays changed from FY 2008 to FY 2012. OIG will also describe how billing for inpatient stays in FY 2012 varied among different types of hospitals and how hospitals ensure compliance with Medicare requirements for inpatient billing.
- **Diagnosis Related Group Window**
OIG will analyze claims data to determine how much the Centers for Medicare and Medicare Services (CMS)

could save if it bundled outpatient services delivered up to 14 days prior to an inpatient hospital admission into the diagnosis related group (DRG) payment. Medicare currently bundles all outpatient services delivered three days prior to an inpatient hospital admission. Prior OIG work has also concluded that CMS could realize significant savings if the DRG window was expanded from three days to 14 days.

- **Hospital-Owned Physician Practices Using Provider-Based Status**
OIG will determine the impact of hospital-owned physician practices billing Medicare as provider-based physician practices and also determine the extent to which practices using the provider-based status met CMS billing requirements.
- **Compliance With Medicare's Transfer Policy**
OIG will review Medicare payments made to hospitals for beneficiary discharges that should have been coded as transfers. OIG will determine whether such claims were appropriately processed and paid. OIG will also review the effectiveness of the MAC's claims processing edits used to identify claims subject to the transfer policy.
- **Payments for Discharges to Swing Beds in Other Hospitals**
OIG will review Medicare payments

made to hospitals for beneficiary discharges that were coded as discharges to a swing bed in another hospital.

- **Payments for Canceled Surgical Procedures**
OIG will determine costs incurred by Medicare related to inpatient hospital claims for canceled surgical procedures.
- **Payments for Mechanical Ventilation**
OIG will review Medicare payments for mechanical ventilation to determine whether the DRG assignments and resultant payments were appropriate. OIG will review selected Medicare payments to determine whether patients received fewer than 96 hours of mechanical ventilation. Mechanical ventilation is the use of a ventilator or respirator to take over active breathing for a patient. For certain DRG payments to qualify for Medicare coverage, a patient must receive 96 or more hours of mechanical ventilation.
- **Quality Improvement Organizations' Work With Hospitals**
OIG will determine the extent to which Quality Improvement Organizations (QIO) worked with hospitals either to conduct quality improvement projects or to provide technical assistance. OIG will also assess the barriers QIOs

continued, next page

OIG WORK PLAN

from previous page

experience when engaging hospitals.

- **Acquisitions of Ambulatory Surgical Centers (ASC): Impact on Medicare Spending**

OIG will determine the extent to which hospitals acquire ASCs and convert them to hospital outpatient departments. OIG will also determine the effect of such acquisitions on Medicare payments and beneficiary cost sharing.

- **Payments for Swing-Bed Services**

OIG will compare reimbursement for swing-bed services at critical access hospitals (CAHs) to the same level of care obtained at traditional skilled nursing facilities (SNF) to determine whether Medicare could achieve cost savings through a more cost effective payment methodology.

- **Payments for Interrupted Stays**

OIG will determine the extent to which Medicare made improper payments for interrupted stays in long-term-care hospitals (LTCH) in 2011. OIG will also identify readmission patterns and determine the extent to which LTCHs readmit patients directly following the interrupted stay periods. Prior OIG work has identified vulnerabilities in Centers for Medicare & Medicaid Services' (CMS) ability to detect readmissions and appropriately pay for interrupted stays.

The OIG continues to focus on the following topics for hospitals:

- Same-Day Readmissions
- Acute-Care Inpatient Transfers to Inpatient Hospice Care
- Admissions With Conditions Coded Present on Admission
- Inpatient and Outpatient Payments to Acute Care Hospitals
- Inpatient Outlier Payments: Trends and Hospital Characteristics
- Reconciliations of Outlier Payments
- Duplicate Graduate Medical Education Payments
- Occupational-Mix Data Used To Calculate Inpatient Hospital Wage Indexes
- Inpatient and Outpatient Hospital Claims for the Replacement of Medical Devices
- Outpatient Dental Claims
- Outpatient Observation Services During Outpatient Visits
- Variations in Size, Services, and Distance From Other Hospitals

- Transmission of Patient Assessment Instruments
- Appropriateness of Admissions and Level of Therapy

Nursing Homes

With respect to the eight areas for nursing homes, OIG has identified three new areas.

- **State Agency Verification of Deficiency Corrections**

OIG will determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys. A prior OIG review found that one State survey agency did not always verify that nursing homes corrected deficiencies identified during surveys in accordance with Federal requirements.

- **Use of Atypical Antipsychotic Drugs**

OIG will assess nursing homes' administration of atypical antipsychotic drugs, including the percentage of residents receiving these drugs and the types of drugs most commonly received. OIG will also describe the characteristics associated with nursing homes that frequently administer atypical antipsychotic drugs.

- **Oversight of the Minimum Data Set Submitted by Long-Term-Care Facilities**

OIG will determine whether and the extent to which CMS and the States oversee the accuracy and completeness of Minimum Data Set (MDS) data submitted by nursing

facilities.

The OIG continues to focus on the following topics for nursing homes:

- Adverse Events in Post-Acute Care for Medicare Beneficiaries
- Medicare Requirements for Quality of Care in Skilled Nursing Facilities
- Oversight of Poorly Performing Facilities
- Hospitalizations of Nursing Home Residents
- Questionable Billing Patterns for Part B Services During Nursing Home Stays

Hospices

There are no new items for hospice. The items from last year were Marketing Practices and Financial Relationships with Nursing Facilities and General Inpatient Care.

Home Health

With the respect to the seven areas for home health, OIG has identified two new areas.

- **Home Health Face-to-Face Requirement**

OIG will determine the extent to which home health agencies (HHA) are complying with a statutory requirement that physicians (or certain practitioners working with physicians) who certify beneficiaries as eligible for Medicare home health services have face-to-face encounters with the beneficiaries. The encounters must occur within 120 days: either within the 90 days before beneficiaries start home health

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OIG WORK PLAN

from previous page

care or up to 30 days after care begins. OIG work conducted before the Affordable Care Act mandate went into effect found that only 30 percent of beneficiaries had at least one face-to-face visit with the physicians who ordered their home health care.

• **Employment of Home Health Aides With Criminal Convictions**

OIG will determine the extent to which HHAs are complying with State requirements that criminal background checks be conducted with respect to HHA applicants and employees. A previous OIG review found that 92 percent of nursing homes employed at least one individual with at least one criminal conviction; however, this review could not determine whether the nursing home employees were disqualified from working in nursing homes because OIG did not have access to detailed information on the nature of the employees' crimes. Nearly all States have laws prohibiting certain care-related entities from employing individuals with prohibited criminal convictions.

The OIG continues to focus on the following topics for home health agencies:

- States' Survey and Certification: Timeliness, Outcomes, Followup, and Medicare Oversight
- Missing or Incorrect Patient Outcome and Assessment Data
- Medicare Administrative Contractors' (MAC) Oversight of Claims
- Home Health Prospective Payment System Requirements
- Trends in Revenues and Expenses

Other Providers and Suppliers

With respect to areas for other providers and suppliers, OIG has identified *new* areas for:

- Program Integrity - Onsite Visits for Medicare Provider and Supplier Enrollment and Reenrollment
- Program Integrity - Improper Use of Commercial Mailboxes
- Program Integrity - Payments to Providers Subject to Debt Collection
- Anesthesia Services—Payments for Personally Performed Services
- Ophthalmological Services—Questionable Billing
- Rural Health Clinics—Compliance With Location Requirements
- Electrodiagnostic Testing—Question-

able Billing

- Claims Processing Errors—Medicare Payments for Part B Claims With G Modifiers

The OIG continues to focus on the following topics:

- Program Integrity - Medical Review of Part A and Part B Claims Submitted by Top Error-Prone Providers
- Program Integrity—High Cumulative Part B Payments
- Independent Therapists—High Utilization of Outpatient Physical Therapy Services
- Sleep Testing—Appropriateness of Medicare Payments for Polysomnography
- Sleep Disorder Clinics—High Utilization of Sleep Testing Procedures
- Physician-Owned Distributors— High Utilization of Orthopedic Implant Devices Used in Spinal Fusion Procedures
- Ambulances—Compliance With Medical Necessity and Level-of-Transport Requirements
- Ambulatory Surgical Centers—Payment System
- Ambulatory Surgical Centers and Hospital Outpatient Departments—Safety and Quality of Surgery and Procedures
- Partial Hospitalization Programs—Services in Hospital Outpatient Departments and Community Mental Health Centers
- Part B Imaging Services—Payments for Practice Expenses
- Diagnostic Radiology—Medical Necessity of High-Cost Tests
- Laboratory Tests—Billing Characteristics and Questionable Billing in 2010
- Laboratory Tests—Reasonableness of Medicare Payments Compared to Those by State Medicaid and Federal Employees Health Benefit Programs
- Laboratory Tests—Part B Payments for Glycated Hemoglobin A1C Tests
- Physicians and Other Suppliers—Non-compliance With Assignment Rules and Excessive Billing of Beneficiaries
- Physicians—Error Rate for Incident-To Services Performed by Nonphysicians
- Physicians—Place-of-Service Coding Errors
- Evaluation and Management Services—Potentially Inappropriate Payments in 2010
- Evaluation and Management Services—Use of Modifiers During the Global Surgery Period
- Chiropractors—Part B Payments for Noncovered Services
- Organ Procurement Organizations—

Compliance With Supporting Documentation and Reporting Requirements

- End Stage Renal Disease—Medicare's Oversight of Dialysis Facilities
- End Stage Renal Disease—Bundled Prospective Payment System for Renal Dialysis Services
- End Stage Renal Disease—Payments for ESRD Drugs Under the Bundled Rate System

Part A and Part B Contractors

There are a number of new items that were identified, as well as items from the prior work plan. For instance, for the *new* items:

• **Overview of CMS's Contracting Landscape**

This review will provide an overview of the contracting landscape at CMS. CMS relies extensively on contractors to help it carry out its basic mission, including administration, management, and oversight of its health programs. In fiscal year 2009, CMS awarded \$4 billion in contracts. This review will determine the number, types, and dollar amount of active CMS contracts and examine how CMS maintains all of its contract information.

• **CMS's Compliance With Contract Documentation Requirements**

OIG will determine the extent to which CMS complies with contract documentation requirements. CMS relies on contractors to perform many of its program functions. Prior work by the OIG has consistently identified vulnerabilities in CMS's oversight of its contractors, and reports by the Government Accountability Office have specifically identified contract file documentation as an area of concern.

• **Medicare Administrative Contractors (MACs)—CMS's Assessment and Monitoring of Performance**

OIG will determine the extent to which CMS conducted performance assessment and monitoring of MACs. We will also describe the extent to which MACs met, did not meet, or exceeded performance standards, and determine the extent to which CMS identified and MACs addressed performance deficiencies.

• **Medicare Administrative Contractors—Use and Management of System of Edits**

OIG will determine whether MACs fulfilled their contractual obligations specific to system edits in 2010 and 2011.

continued, next page

OIG WORK PLAN

from previous page

OIG will also describe how MACs's error rates varied across regions compared to differences in MACs's implementation, application, and evaluation of edits in 2010 and 2011.

• Claims Processing Contractors—Failure To Conduct Prepayment Reviews in Response to Edits

OIG will determine the number of Part B claims that were suspended for manual prepayment review on the basis of system edits but on which the reviews were not conducted. Because manual review is more timely and costly to the contractor, some suspended claims might not receive the review and, therefore, may be paid inappropriately.

• Zone Program Integrity Contractors—CMS's Oversight of Task Order Requirements

OIG will review CMS's oversight of fraud and abuse task order requirements for Zone Program Integrity Contractors (ZPICs). Prior OIG work on benefit integrity contractor evaluations found that evaluations contained little information about performance results related to the detection and deterrence of fraud and abuse. This review will build upon prior work by reviewing the methods used to evaluate ZPIC task orders and determining the extent to which these methods focus on fraud and abuse.

Other Part A and Part B Management and Systems Issues

In addition, OIG notes a number of new and previously listed items under the above referenced section. For instance, one new item is that the OIG will review CMS's overall strategy to maintain the integrity of Medicare.

With respect to Part A and B, as noted above, it is worth noting the OIG has identified certain areas in connection with prescription drugs, as well as medical equipment and supplies.

As noted above, this article is meant to highlight certain areas of the Work Plan to the reader. The entire Work Plan can be accessed on the OIG website. It is a very helpful document to attorneys, compliance officers as well as many other persons who work with various providers and suppliers.

Endnotes

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HOSPITAL CLIENT

from page 2

“look back” method or the prospective method.²⁵ The “look back” method is based on actual past claims paid to the hospital by either Medicare fee-for-service (not Medicare Advantage plans) or Medicare fee-for-service with all private health insurers paying claims filed by the hospital.²⁶ The claims used in determining the AGB, can be either one average AGB percentage for all emergency and other medically necessary care, or the hospital facility may calculate multiple AGB percentages for separate categories of care.²⁷ In the alternative, the prospective method requires a hospital organization to estimate what it would get paid by Medicare and a Medicare beneficiary for emergency care and other medically necessary care.²⁸ The individual methods for the AGB determination are mutually exclusive and the hospital organization must continue to use their chosen methodology until the IRS provides different guidance.²⁹

Another requirement of the hospital organization's FAP is set forth in Section 501(r)(6), which provides that a hospital organization only meets the requirements of paragraph (r) if the hospital does not engage in “extraordinary collection actions” (“ECAs”) before the hospital organization has made reasonable efforts to determine if the individual is eligible for financial assistance under the FAP.³⁰ The June Notice provides that a hospital organization will have engaged in ECAs if it takes action against an individual in regard to a bill for care covered under the FAP that requires legal or judicial process.³¹ ECAs that require legal or judicial process include, but are not limited to:

- Placing a lien of an individual's property;
- Foreclose on an individual's real property;
- Attach or seize an individual's bank account or other personal property;
- Commence a civil action against an individual;
- Cause an individual's arrest;
- Cause an individual to be subject to a writ of body attachment; and
- Garnish an individual's wages.³²

The proposed regulations also include reporting to credit agencies among those actions that constitute an ECA along with the sale of debt to a third-party.³³

The FAP also ensures that reasonable efforts are made to determine if a patient

or responsible party is eligible for financial assistance under the FAP. The proposed regulations provide that a hospital facility has made reasonable efforts if it:

- 1) Notifies the individual about the FAP;
- 2) Assists the individual with completion of the FAP if necessary;
- 3) Documents whether the individual is eligible under the FAP.³⁴

The relevant time periods during which these reasonable efforts must be undertaken are within the “notification period” and the “application period” (the “Time Periods”) The “notification period” begins on the date of treatment and ends 120 days following the day the first billing statement is issued to the patient or responsible party.³⁵ If an individual fails to submit a FAP application during this time, then the hospital facility may engage in ECAs.³⁶ However, the “application period” is longer and requires the hospital facility to process a FAP application up to 240 days after the first billing statement is provided to the individual.³⁷

The requirements of this subparagraph will significantly impact hospital organizations that currently assign or sell their accounts receivables, i.e. uncollected patient accounts; execute Letters of Protection; and file hospital liens in an effort to secure payment for medical services that were provided to uninsured individuals that may qualify for assistance under a hospital organization's FAP. In Florida, these proposed regulations may also impact whether it would even be proper to file a hospital lien against a patient that would qualify under the treating hospital's FAP. Unfortunately, the proposed regulations do not fully address these issues, but it is clear that some of the measures currently used by hospital organizations may constitute ECAs; therefore, compliance with the Time Periods under the proposed regulations will also impact the timing of any ECAs undertaken by a hospital organization.

Criticism.

Some critics say that the Requirements will increase the transparency of charitable organizations and require charitable hospitals to prove that they are in fact charitable organizations.³⁸ One commentator said that § 501(r), “...comes on the heels of the decade-long concern that charitable hospitals afforded tax-exempt status are not fulfilling their charitable missions” by providing charitable care.³⁹ Many hospital

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HOSPITAL CLIENT

from previous page

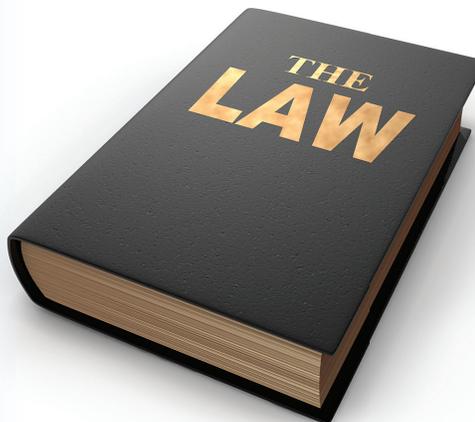
organizations would likely disagree with this assertion given the amount of free care provided to uninsured patients within their communities on an annual basis.

The American Hospital Association (“AHA”) has raised concerns about the Requirements of § 501(r) since it was enacted.⁴⁰ In its May 2012 statement to the Subcommittee on Oversight on Ways & Means of the U.S. House of Representatives – Hearing on Tax Exempt organizations, the AHA reiterated its concerns over Form 990 and Schedule H specifically reasserting its position that the revised Schedule H went beyond what the law required and, “created onerous and redundant reporting requirements.”⁴¹ Tax experts believe that a not-for-profit hospital’s completion of Schedule H could balloon to 200 pages.⁴² In January of 2012, the IRS re-issued the 2012 Schedule H with none of the suggested changes made by the AHA.⁴³ The AHA has advised the IRS that Part V of Schedule H does not comply with the Paper Reduction Act, as it is not the least burdensome way for the proper performance of the IRS implementing § 501(r).⁴⁴ The AHA also advised the IRS that revised Part V to Schedule H constitutes a material change and that the changes were not approved by the Office of Management and Budget, which is required before the form can be made mandatory.⁴⁵ It should also be noted that the Healthcare Financial Management Association (“HFMA”) has also advised the IRS that the June Notice contains, “Duplicative or conflicting procedure or requirements; burdensome processes and record keeping; and inconsistent standards and unintended consequences.”⁴⁶ Despite these issues, as we end 2012 hospital organizations will be required to complete Schedule H, Part V, including information in regard to CHNAs as part of their 2012 returns, as well as ensure compliance with the IRS proposed rules issued to date.

It is clear that hospitals have to become compliant with the Requirements of § 501(r) and the IRS proposed regulations despite the fact that professional hospital organizations remain critical of the law and regulations and that not all the guidance from the IRS has been issued. Hospitals will need to comply by conducting a CHNA, creating a FAP, and implementing the necessary measures for compliance with the PPACA and the proposed regulations set forth herein. Although there are many levels of compliance set forth in § 501(r) and the proposed regulations, the FAP and required billing practices thereunder are significant and will require substantial changes in the way hospitals conduct their billing practices. Counsel and tax advisors will need to be aware of the requirements under the PPACA and the current proposed regulations in order to determine whether their client’s efforts will demonstrate compliance. Counsel and tax advisors will also need to maintain a watchful eye on any newly issued IRS regulations relating to § 501(r) and the additional guidance on CHNAs⁴⁷. Although an excise tax will be imposed for failure to meet the CHNA requirements, the hospital’s loss of its tax exempt status would be the ultimate penalty for non-compliance with the requirements of Section § 501(r).

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HOSPITAL CLIENT

from previous page

Endnotes

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1 Cynthia S. Marietta, J.D., L.L.M., *PPACA's Additional Requirements Imposed on Tax-Exempt Hospitals Will Increase Transparency and Accountability on Fulfilling Charitable Missions*, July 2010, Health Law Perspectives. Ms. Marietta's article sets forth the new 501(r) requirements and argues that these requirements will force charitable hospitals to prove they are fulfilling their charitable missions.

2 Internal Revenue Service, *New Requirements for 501(c)(3) Hospitals Under the Affordable Care Act*, [http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/New-Requirements-for-501\(c\)\(3\)-Hospitals-Under-the-Affordable-Care-Act](http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/New-Requirements-for-501(c)(3)-Hospitals-Under-the-Affordable-Care-Act) (last updated November 11, 2012).

3 *Id.*

4 John R. Washlick, Esq., CPA, *Non-profit Healthcare Organizations: Federal Income Tax Issues*, 873-2nd, A-5 – A-18 (Tax Management – BNA, May 21, 2012).

5 *Id.* at A-3.

6 *Id.*

7 *Id.* at A-5.

8 77 Fed. Reg. 38148 at 38148; *See also* 26 U.S.C. §501(r).

9 *Id.* at 38148 - 38149; § 501(r)(3) – (r)(6).

10 26 U.S.C. § 501(r)(2)(B)(i) and (ii).

11 § 501(r)(3).

12 *Id.*

13 *See Notice and Request for Comments Regarding the Community Health Needs Assessment Requirements for Tax-exempt Hospitals*, IRS Notice 2011-52 (July 25, 2011). (Setting forth the anticipated IRS regulations in regard to CHNA).

14 *Id.*; The description shall include sources and dates of data and the analytical method used to identify the community health needs. Any collaborations should also be noted. *Id.*

15 *Id.*; The Notice states that the IRS expects that state and/or local public health agencies or departments should be consulted.

16 Leah Guidry and Matthew Vogelien, Speech, *Internal Revenue Code Section 501(r) – Overview and Compliance Strategies for Tax-Exempt Hospitals*, Huron Healthcare, Webinar March 2, 2011 (citing *Joint Committee on Taxation, Technical Explanation of the Revenue Provisions of the Reconciliation Act of 2010*, as amended in combination with the "Patient Protection and Affordable Care Act" (JCX-18-10), at 81, March 21, 2010.)

17 IRS Notice 2011-52. Treasury and IRS intends to adopt rules similar to Treas. Reg. § 301.6104(d)-2(b), which would allow for the written CHNA to be posted on the hospital organization's website.

18 Richard A. Speizman, V. Moore, and Alexandra O. Mitchell, *Section 501(r) – Some Guidance Is Now Available for Charitable Hospitals*, (What's New in Tax – Washington National Tax, KPMG, March 28, 2011). This tax newsletter sets forth the significant changes to Form 990 and Sched-

ule H, which is intended to capture information in regard to compliance with the new requirements of Section 501(r). Part V of Schedule H appears to have the most significant revisions. *Id.*

19 77 Fed. Reg. 38148 at 38148.

20 Washlick, *supra* n. 4, at A-6; *See also* 77 Fed. Reg. 38148 at 38148 – 38149. There are specific instructions for distribution methods of the FAP in the Federal Register, which are in short: 1) the measures the hospital will take to make paper copies of the FAP available, including the application; 2) the measures the hospital will take to inform and notify patients and visitors of the FAP; 3) the measures the hospital will take to inform and notify members of the community served by the hospital; and 4) the measures the hospital will take to make the FAP and associated forms available on the hospital's website. *Id.*

21 77 Fed. Reg. 38148 at 38149. Emergency Medical Condition as used in the proposed regulations has the same meaning as in the Emergency Medical Treatment and Labor Act ("EMTALA").

22 *Id.* at 38151.

23 *Id.*

24 *Id.* at 38155. The June Notice provides, "The proposed regulations make clear that including the gross charges on hospital bills as the starting point to which various contractual allowances, discounts, or deductions are applied is permissible, as long as the gross charges are not the actual amount a FAP-eligible individual is expected to pay." *Id.*

25 *Id.* at 38154 - 38155.

26 *Id.* at 38154. The June Notice sets forth information about the methodology behind the determination of the AGB for an individual hospital facility. The June Notice states that the Treasury Department and the IRS believe that by using claim rates paid by all private health insurers and Medicare that the amount derived will be more consistent with the statutory phrase, "amounts generally billed to those who have insurance." To determine AGB for a FAP eligible individual the hospital facility needs to multiply the Gross Charges by the AGB percentage (Gross Charges x AGB percentage). The AGB percentage is determined on at least an annual basis by the hospital facility. The AGB percentage is the sum of certain claims paid in full (includes copayments, co-insurance, or deductibles) divided by the sum of the gross charges (sum of certain claims paid in full / gross charges for those same claims). The AGB percentage must be applied by the 45th day after the end of the 12 month period the hospital used to calculate the AGB percentage. Further comment has been requested on whether the AGB should be based on the private health insurer with the lowest rate or the three lowest rates and how that rate should be determined. Further comment has also been requested on whether the hospital facility should be able to eliminate Medicare fee-for-service from the equation. *Id.*

27 *Id.* at 38155.

28 *Id.* Further comment has been requested on whether a hospital organization should be able to utilize anticipated reimbursement rates from private health insurers for the prospective method. *Id.*

29 *Id.* at 38154. (Requesting additional comment on whether a hospital facility should be able to change its method of calculating its AGB, and if so, how frequently).

30 § 501(r)(6).

31 77 Fed. Reg. 38148 at 38155 – 38156.

32 *Id.*

33 *Id.* at 38156. The proposed regulations do not prohibit the use of a debt collection agency, based on the fact that the hospital facility is expected to have more control over an agent collection agency. Further comment has been requested to determine if a hospital can maintain sufficient control over the collection actions of parties to which it refers or sells debt and whether either referring debt or selling a debt (or both) constitutes ECAs. *Id.*

34 *Id.*

35 *Id.* at 38157. Under the proposed regulations a hospital must distribute a plain summary of the FAP, offer a FAP application form before discharge, and include a plain language summary of the FAP with at least three billing statements and all written communication in regard to the bill during the notification period. The individual must also be made aware of the FAP during any oral communications regarding the amount of the bill during the "notification period." The hospital must also inform the individual prior to the expiration of the notification period and thirty days prior to the deadline in the notice of what ECAs the hospital will take if the individual does not submit a FAP. Please see this reference for additional information in regard to the notification requirements, guidance on what actions must be taken for incomplete FAPs, and documentation of determinations under the FAP. *Id.*

36 *Id.*

37 Marietta, *supra* n. 1, at 6.

38 *Id.* at 5.

39 *Id.*

40 Statement of the American Hospital Association before the Subcommittee on Oversight of the Committee on Ways & Means of the U.S. House of Representatives – Hearing on Tax Exempt Organizations (May 16, 2012).

41 *Id.* at 2.

42 *Id.*

43 *Id.*

44 *Id.*

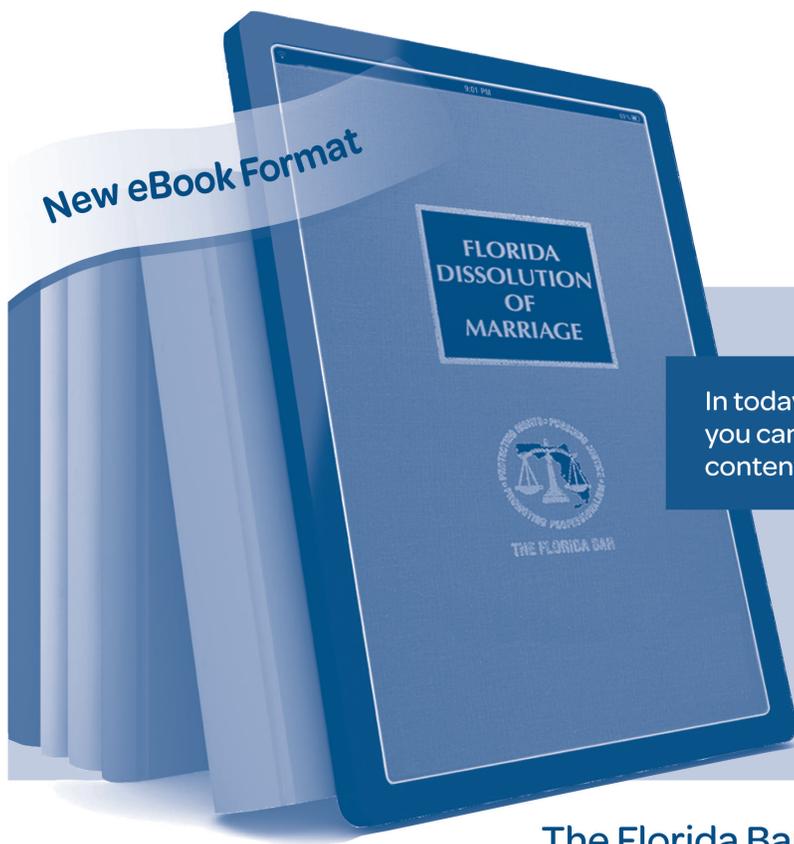
45 *Id.*

46 Joseph J. Fifer, FHFMA, CPA, "Comments in Response to Section 501(r) Proposed Regulations" (September 24, 2012). <http://www.hfma.org/template/blogposy.aspx?id=34400>. (Detailing each criticism of the HFMA in regard to the IRS proposed regulations issued in June 2012.)

47 Lidia Niecko-Najjum and Ivy Baer, J.D., "IRS Holds Public Hearing on Additional Requirements for Charitable Hospitals." (December 7, 2012). <https://www.aamc.org/advocacy/washhigh/highlights2012/322950/irsholdspublichearingonadditionalrequirementsforcharitablehospi.html>. The IRS held a public hearing on December 5, 2012 in regard to the Requirements; however, no additional guidance in regard to FAPs or CHNAs was provided. *Id.* Milton Cerny, "IRS Hearing on Charitable Hospital's Billing and Collection Practices (Reg – 130266-11)" (December 31, 2012). <http://www.mcguirewoods.com/Client-Resources/Alerts/2012/12/IRS-Held-Hearing-Regarding-Proposed-Regulations.aspx>. This author has reported that officials at the IRS are unlikely to provide further guidance on any sanctions for violations of 501(r) until after the proposed rules of Section 501(r) are finalized, which are on the Department of Treasury Priority Guidance Items for 2013. *Id.*



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