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Staying Well Within the Law

A newsletter on the current legal issues facing today's health care industry

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Sunlight, Transparency and Required Disclosures

By William H. Maruca



"Sunlight is the best disinfectant," wrote Supreme Court Justice Louis Brandeis in 1913, addressing corruption and the banking industry. President Obama is

particularly fond of citing this adage, and his administration is putting it into practice in a proposed regulation implementing the transparency provisions of the Affordable Care Act (ACA). This legislation seeks to shine the light of day on financial relationships among providers and manufacturers that may indicate potential conflicts of interest. Both legitimate and questionable arrangements will be exposed to greater scrutiny under these rules, so physicians should be prepared for potentially unwelcome publicity.

Unlike many of the more technical elements of the ACA, the transparency rules are grabbing mainstream media attention, both locally and nationally. A January 20, 2012, *Post-Gazette* editorial titled "Hidden Charge: Lobbying Has No Place in the Doctor's Office" commended the rules. The *New York Times* cited its own research in a January 16, 2012, piece titled "U.S. to Force Drug Firms to Report Money Paid to Doctors," claiming "The Times has found that doctors who take money from drug makers often practice medicine differently from those who do not and that they are more willing to prescribe drugs in risky and unapproved ways, such as prescribing powerful antipsychotic medicines for children."

The ACA requires applicable manufacturers of drugs, devices, biologicals or medical supplies covered by Medicare and other government programs to report annually to the Secretary of Health and Human Services certain payments or transfers of value provided to physicians or teaching hospitals. In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. Electronic reporting to CMS must begin by March 31, 2013, and continue on the 90th day of each calendar year thereafter.

On December 19, 2011, the Centers for Medicare and Medicaid Services (CMS) released proposed regulations implementing the ACA's transparency

requirements. The proposed regulation was developed after an extensive open-door forum with industry representatives was held on March 24, 2011. Although CMS has been responsible for the interpretation of the Stark physician self-referral law since its inception, the agency felt a need to better understand the relationships between drug and device manufacturers and prescribing physicians before crafting the regulatory framework governing these relationships.

Many of you may recall reading front-page articles detailing orthopedic device company payments to physicians. Disclosure of such payments was required by agreements between the Department of Justice and five manufacturers: Biomet, Inc., DePuy Orthopaedics, Inc., Smith & Nephew, Inc., Zimmer, Inc. and Howmedica Osteonics Corp./Stryker Orthopedics. These companies, who represented nearly 95 percent of the market in knee and hip implants, had been accused of overpaying orthopedic surgeons for consulting services and providing travel and other inducements in exchange for the surgeons recommending the use of their products. Four of the five companies agreed to engage independent monitors and paid significant financial penalties. All five companies agreed to disclose the name of each consultant and what they have been paid on their company web sites. Many media outlets mined the data looking for physicians in their area and published lists of recipients and dollar amounts, sometimes not distinguishing

In This Issue:

Sunlight, Transparency and Required Disclosures	1
Will the Threat of Personal Liability Stifle Corporate Activity?	3
Hospitals That Participate in TRICARE No Longer Considered Federal Subcontractors Simply by Participation in TRICARE Network	6
3 Ways to Improve Hospital Compliance	7
Navigating the Minefield of Arrangements Between DMEPOS Suppliers and Physicians	8

between consulting fees and sizeable royalties paid to physician patent holders. Expect more of the same when the ACA rules take effect.

The proposed rules require that “applicable manufacturers” report payments or “transfers of value” in excess of \$10 each or \$100 per year in the aggregate. Transfer of value includes all payments or other transfers of value given to a covered recipient, regardless of whether the recipient specifically requested the payment or other transfer of value. The term does not include a transfer made indirectly to a covered recipient through a third party if the manufacturer is unaware of the identity of the covered recipient. The report must describe the form of each payment or transfer as either cash or cash equivalent; in-kind items or services; or stock, stock option or other ownership interest, dividend, profit or other return on investment. The payment or transfer must be classified as one of the following:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food and beverage (Query: will this bring an end to pizza for the office staff and other drug company freebies?)
- Travel and lodging
- Education
- Research (direct or indirect)
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest

- Compensation for serving as a faculty or as a speaker for a medical education program
- Grant
- Other

In addition, payments or transfers of value made to an individual or entity (such as the physician’s professional corporation or employer) at the request of or designated on behalf of a covered recipient must be reported under the name of the covered recipient.

An “applicable manufacturer” is a manufacturer of at least one prescription drug, device, biological or medical supply that is covered by Medicare, Medicaid, state Children’s Health Insurance Plan (CHIP) or other state program that is operating in the United States. The term also includes entities that outsource the physical manufacturing process but hold the applicable FDA approval, licensure or clearance.

The rule also requires GPOs to report payments and transfers. GPOs are defined as entities that purchase, arrange for or negotiate the purchase of a covered drug, device, biological or medical supply for a group of individuals or entities, and not solely for use by the entity itself, and would include physician-owned distributors (PODs).

Payments made to teaching hospitals must be reported under the name of the physician designated as the principal investigator. If this rule does not change in the final version, physicians acting in this capacity can anticipate inquiries about the substantial amounts that will be reported as if they received them personally. I predict this will be one area of the proposed rule that will draw significant criticism during the comment period.

Some payments or transfers are exempt from reporting, including product samples and other in-kind items intended for patient use, educational materials that directly benefit patients or are intended for patient use, loans of devices for up to 90 days for evaluation, discounts, warranties, items provided to a physician as a patient and expert witness fees in litigation.

The rules also require manufacturers and GPOs to report physician ownership or investment interests, including the amount invested. Publicly traded securities and stock benefits in retirement plans covering employees are exempt, and stock options must only be reported when they are exercised. CMS is looking into whether to require reporting of ownership interests held by physicians’ immediate family members as well.

The final component of transparency is public access to the information gathered under the CMS rule. CMS proposes to post all data online in a searchable and downloadable format.

Now may be a timely opportunity for physicians to review their relationships with drug and device companies and evaluate them for compliance with health care counsel before the regulations are finalized and reporting begins on March 31, 2013. Newspapers, broadcast media, web sites and other watchdogs will be combing the data for suggestions of impropriety. Make sure you have nothing to fear from a little sunlight.

For more information about this topic, please contact [William H. Maruca](mailto:wmaruca@foxrothschild.com) at 412.394.5575 or wmaruca@foxrothschild.com.

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Will the Threat of Personal Liability Stifle Corporate Activity?

By David Restaino



Both the federal Food and Drug Administration (FDA) and Office of the Inspector General (OIG) have authority to seek personal consequences against corporate officers deemed responsible for federal health care violations. For example, the FDA has the power to exclude officers from federal health care programs and seek debarment of corporate officers. The power to punish individuals, however, goes beyond sanctions. Recent developments demonstrate that individual criminal liability is a distinct possibility. More importantly, these developments have expanded the ranks of corporate owners, officers and managers who face criminal liability—and have also expanded the nature of that liability itself. Individuals who have no actual knowledge of wrongdoing can still face criminal consequences merely as a result of their position within a company. This expansion of prosecutorial authority promises to have an immediate impact on corporate compliance programs. Whether it encourages managers to become more actively involved—or to avoid involvement altogether—remains to be seen.

The Evolving Standard of Individual Criminal Liability

The FDA has the authority to investigate criminal conduct arising under a number of statutes, including the federal Food,

Drug and Cosmetic Act (FDCA) and laws regulating mail fraud and counterfeit goods or services. Essentially, the FDA can investigate misbranding of products as well as the promotion, manufacture and sale of unapproved products. The OIG has similar jurisdiction to investigate FDA-regulated activities.¹

The FDCA has, for decades, prohibited the introduction of a misbranded drug into interstate commerce; it also imposes criminal consequences upon violators.² Criminal prosecutions can be, and have been, brought against corporate officials over the years, with prosecutions becoming more prevalent in recent years. This is best exemplified by the decision in *United States v. Park*, in which a corporation's chief executive officer was found criminally liable for inadequate warehouse sanitation.³ In reaching that conclusion, the court emphasized two points: First, a corporation can only act through the individuals who act on its behalf; and second, the liability of people serving in managerial positions does not depend on their knowledge of the criminal acts but, rather, can be predicated on the individual's power to prevent the prohibited acts.⁴ Stated differently, the court concluded that those who have a duty to implement measures to avoid violations, or who have some responsible relationship to the offending situation, could be criminally liable—and that such persons bore the burden of proving that they were powerless to prevent or correct a violation.⁵

Since the *Park* decision, this “responsible corporate officer” concept of strict liability—the fact that a violation can result in a conviction even without proving actual knowledge—has been continually expanded. It now threatens each and every owner, officer and manager in the health care and pharmaceutical industries.

Recent Developments Expand Prosecutorial Powers

After receiving criticism about lax criminal enforcement in a report authored by the Government Accountability Office,⁶ the FDA announced in 2010 that it would revitalize its approach to corporate officers by both increasing the use of misdemeanor prosecutions and enhancing its debarment and disqualification actions.⁷

The Patient Protection and Affordable Care Act (PPACA)⁸ also expanded prosecutorial authority by revising the Anti-Kickback Law (42 U.S.C. §§ 1320a-7b) to strengthen the government's powers. Today, claims submitted in violation of the Anti-Kickback Law are automatically deemed violations of the False Claims Act (31 U.S.C. §§ 3729 to 3733), and prosecutors no longer need to prove that a defendant had actual knowledge of the Anti-Kickback Law or a specific intent to violate the statute.⁹

The liability scheme of the False Claims Act itself was also recently clarified so

¹ United States Government Accountability Office: “Food and Drug Administration – Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations” Report No. GAO-10-221; January 2010, at page 6.

² See 21 U.S.C. § 301 et seq. The prohibited acts are located in 21 U.S.C. § 331 and the violations in 21 U.S.C. § 333.

³ *United States v. Park*. 421 U.S. 658, 95 S.Ct. 1903, 44 L.Ed.2d 489 (1975).

⁴ *Id.*, 421 U.S. at 668, 670-71 (citations omitted).

⁵ *Id.*, 421 U.S. at 672-674 (citations omitted).

⁶ United States Government Accountability Office: “Food and Drug Administration – Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal and Misconduct Investigations” Report No. GAO-10-221; January 2010, pages 13-18 and 25.

⁷ March 4, 2010, letter from Dr. Margaret Hamburg, Commissioner of Food and Drugs, to Senator Charles Grassley.

⁸ Public Law No. 111-148, 124 Stat. 119 (March 23, 2010).

⁹ Public Law No. 111-148, 124 Stat. at 759, adding 42 U.S.C. § 1320a-7b(g) and (h).

that now, among other things, it is a violation to knowingly present or cause to be presented a false or fraudulent claim for payment or approval, knowingly make or use a false record or statement material to a payment of a false or fraudulent claim, or conspire to defraud the government by getting a false or fraudulent claim paid or allowed.¹⁰ Notably, liability under the False Claims Act can also include a penalty of \$5,000 to \$10,000 per claim, as adjusted by inflation, plus treble damages.¹¹

In 2010, the False Claims Act's concept of a *qui tam* action, in which a relator (i.e., a whistleblower) can bring a fraud action on behalf of the government,¹² was changed to narrow a prohibition against certain actions. Specifically, relators can now sue based upon a broader class of publicly disclosed information and a broader class of original source information.¹³

The Government's Administrative Powers Have Been Expanded

The government also has other methods of making things difficult for corporate owners, officers and managers. Medicare payments can be suspended if a pending investigation has shown credible allegations of fraud.¹⁴ Also, the PPACA provides for the enhanced exclusion of individuals who own, control or manage an entity that is suspended or excluded.¹⁵ Government debarment, or exclusion from participation in federal health care programs, comes in several forms.

Debarment can be permissive (i.e., discretionary) or mandatory. With respect to the former, OIG guidance confirms the discretionary nature of the OIG's power to debar owners and those who have a controlling interest when they knew, or should have known, of the offending conduct; but it goes much further. The OIG has also indicated it will more actively pursue corporate officers and managing employees of entities who were excluded or convicted of certain crimes solely based upon those persons' position within the entity. The main point, which cannot be emphasized enough, is that the owner liability standard is higher than that set for officers and managers, putting the latter persons at much greater risk.¹⁶

In all situations, there is a presumption favoring exclusion—making debarment a considerable weapon—but the OIG has also stated it did not intend to exclude all persons falling within the OIG guidance. To that end, the OIG has developed non-binding factors concerning the use of its power, including:

- The nature of the offense itself; for example, whether it caused harm;
- The degree of managerial control or authority possessed by the person in question and whether the person was in the "chain of command;"
- Whether any mitigating steps were taken by the person in question; and
- If a timely disclosure was made by the individual in question.¹⁶

Similar factors are contained within the FDA's *Regulatory Procedures Manual*.¹⁷

With respect to mandatory exclusion, Section 1128 of the Social Security Act states the Department of Health and Human Services shall exclude four classes of people: those convicted of program-related crimes, those with a conviction relating to patient abuse, those convicted of a felony relating to health care fraud and those convicted of a felony relating to a controlled substance.¹⁸

Debarment is also allowable under federal procurement regulations, which provide that a contractor may be suspended based upon adequate evidence of fraud in, among other things, obtaining a contract. This includes a violation of the False Claims Act.¹⁹

Since 1996, the OIG has used its exclusion authority in more than 30 cases, but until recently, had not used it against executives of large and complex corporations. The OIG stated it would not seek to exclude all officers and managers of a company convicted of health care fraud, but it will nevertheless seek exclusion if the officer or employee knew or should have known of the criminal misconduct. For example, the OIG obtained a federal felony conviction against a corporation for failing to inform the FDA about production problems and excluded the owner for a period of 20 years.²⁰

¹⁰ 31 U.S.C. § 3729(a)(1).

¹¹ 31 U.S.C. § 3729(a)(1)(G). The adjustments have increased the potential penalty range up to \$5,500 to \$11,000 per claim. 28 C.F.R. § 85.3(a)(9).

¹² 31 U.S.C. § 3730(b).

¹³ Public Law No. 111-148, 124 Stat. at 901-02, amending 31 U.S.C. § 3730(e)(4).

¹⁴ 76 Fed. Reg. 5862, 5928, 5961-62, 5966 (February 2, 2011), amending 42 C.F.R. Parts 405 and 455.

¹⁵ Public Law No. 111-148, 124 Stat. at 776.

¹⁶ Health and Human Services OIG: "Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act." October 20, 2010. See also 42 U.S.C. § 1320a-7(b)(15).

¹⁷ FDA Regulatory Procedures Manual at § 6-5-3.

¹⁸ 42 U.S.C. § 1320a-7(a).

¹⁹ 48 C.F.R. § 9.407-2.

²⁰ April 5, 2011, testimony of Gerald T. Roy before the United States House of Representatives Committee on Oversight and Government Reform, Subcommittee on Health Care, Etc., at page 11.

Recent History of Corporate Officer Liability

The recent history of prosecutions tells a deeply troubling story for corporate officials. The government's use of the responsible corporate officer doctrine in the post-*Park* era has been gaining steam in recent years. In 2007, for example, three executives pled guilty to misbranding a drug and received sentences involving probation, community service and disgorgement of millions of dollars.²¹ In 2010, four corporate officers pled guilty to misdemeanors concerning the alleged unapproved use of a medical device, among other violations.²²

A slew of government press releases in 2011 indicate that the trend is not only continuing but increasing. Consider the criminal liability imposed upon the following corporate officials for health care fraud:

- The former president of a physical therapy company was sentenced to 24 months in prison for defrauding Medicare by submitting claims for services not provided and for paying kickbacks to obtain the billing information utilized in the scheme.²³
- The owner of a mental health company was sentenced to 35 years in prison for a fraud and kickback scheme that resulted in Medicare bills exceeding \$200 million.²⁴
- The owner of a durable medical equipment company was sentenced to 66 months in prison for fraud, kickbacks and the obstruction of justice.²⁵

In order to enhance the government's criminal enforcement, many of these cases are the result of coordinated efforts between government agencies. The Department of Health and Human Services reported that the government collected more than \$4 billion in fiscal year 2010 as a result of the health care fraud prevention and enforcement efforts. In that fiscal year, 284 defendants were indicted, 217 guilty pleas were negotiated and 146 defendants were sentenced to prison time (averaging 40 months of incarceration).²⁶

Based on the enhanced power to pursue responsible corporate officials and the sums involved in the fraudulent schemes, the government's criminal enforcement efforts can be expected to rise.

Impact on Corporate Compliance

Recent developments have certainly expanded government power to exclude individuals and to charge them with a crime and, by extension, prosecutorial discretion. It is not clear, however, how this discretion will be exercised and how many people will face these draconian sanctions. But it is clear that the potential adverse exposure to executives, officers and managerial employees has vastly increased. It is also clear these persons can be charged with a criminal offense, even when actual knowledge of a violation does not exist.

To complicate an assessment of the new liability scheme even further, corporations with an adequate compliance program have additional defenses to government enforcement and,

thus, so do the individuals involved in such a compliance program. The government has recognized the perverse incentives in assessing personal liability and has attempted to deflect those incentives by a full examination of all factors surrounding corporate compliance programs.

Simply put, the risk of criminal liability will prove too great to suggest that a hands-off approach to compliance is the "right" approach. Thus, lack of knowledge and lack of an ability to correct adverse situations should not be viewed as a defense to criminal charges. In fact, they are not.

The government's increasing use of criminal liability—and individual exclusion—should, if anything, be considered yet another reason to stay involved and heavily focused on compliance. Implementation, continual monitoring and "pressure-testing" of stringent compliance programs should be at the top of the corporate priority list. Wholesome compliance programs remain the only tried and true responsible approach to avoiding personal criminal liability.

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²¹ *U.S. v. Purdue Frederick, Inc.*, E.Supp.2d (W.D.Va. 2007).

²² *U.S. v. Synthes, Inc.*, United States Department of Justice, Press Release dated October 4, 2010.

²³ *U.S. v. Chalarca*, United States Department of Justice, Press Release dated September 19, 2011.

²⁴ *U.S. v. Valera*, United States Department of Justice, Press Release dated September 19, 2011.

²⁵ *U.S. v. Saul*, United States Federal Bureau of Investigation, Press Release dated September 14, 2011.

²⁶ Available at <http://www.hhs.gov/news/press/2011pres/01/20110124a.html>.

Hospitals That Participate in TRICARE No Longer Considered Federal Subcontractors Simply by Participation in TRICARE Network

By **Kenneth A. Rosenberg** and **Todd A. Palo**



Although the holiday season may be over, hospitals and other healthcare providers received a belated but generous gift from the federal government on Dec. 31, 2011, when President Obama signed The National Defense Authorization Act (NDAA)¹ into law. The enactment of the NDAA is significant to all hospitals because Section

715 of the law provides that a federal subcontractor relationship will not be created merely because of one's participation in a TRICARE² provider network. Specifically, Section 715 of the NDAA provides:

For the purpose of determining whether network providers under such provider network agreements are subcontractors for purposes of the Federal Acquisition Regulation or any other law, a TRICARE managed care support contract that includes the requirement to establish, manage, or maintain a network of providers may not be considered to be a contract for the performance of health care services or supplies on the basis of such requirement.

This provision ostensibly overturns the U.S. Department of Labor's Office of Federal Contract Compliance Programs' (OFCCP)³ recent attempts to assert jurisdiction over hospitals that have

entered into TRICARE network provider support contracts⁴ even if they have not contracted directly with the federal government or have attempted to avoid OFCCP jurisdiction through explicit contract language. Importantly, the NDAA seemingly makes clear that a hospital that enters into a support contract is not a federal subcontractor for purposes of the Federal Acquisition Regulations or "any other law." The importance of the phrase "or any other law" cannot be overstated because the OFCCP has taken the position that hospitals are "federal subcontractors" due to their participation in TRICARE and thus are subject to the myriad of EEO and affirmative action statutes and regulations that it enforces. Based on this alleged jurisdiction, the OFCCP has notified hundreds of hospitals that they must submit a written affirmative action plan and supporting documents or risk being audited and fined.

Where hospitals have challenged the OFCCP's assertion, they have often been subjected to OFCCP enforcement actions as in *OFCCP v. Florida Hospital of Orlando, 2009-OFC-00002* (Oct. 18, 2010). There, the OFCCP asserted that Florida Hospital was a covered subcontractor, in part, because it had contracted with Humana Military Healthcare Services (Humana) to be a network provider for TRICARE beneficiaries. Humana had contracted with the U.S. Department of Defense to provide medical services to TRICARE

beneficiaries. In ruling in favor of the OFCCP, the Department of Labor's Administrative Law Judge reasoned that Florida Hospital had assumed some of Humana's responsibility to provide healthcare services to TRICARE beneficiaries and thus was a federal subcontractor subject to OFCCP jurisdiction.

Accordingly, Section 715 of the NDAA appears to overturn the Florida Hospital decision because the OFCCP can no longer assert that Florida Hospital is a federal subcontractor simply due to its TRICARE participation. This is a welcomed gift indeed not only for Florida Hospital, but also for all similarly situated hospitals.

However, notwithstanding the passage of Section 715 of the NDAA, there are many other ways in which a healthcare provider can become a federal subcontractor and thus subject to the OFCCP's jurisdiction.

In fact, despite the plain language of the legislation, the OFCCP has not conceded that it no longer has jurisdiction over healthcare providers under TRICARE. Director of the OFCCP Patricia Shiu has publicly stated, "Section 715 of the NDAA seeks to exempt certain TRICARE providers from complying with civil rights laws that – for nearly a half a century – have prohibited employment discrimination and ensured affirmative action for vulnerable workers. Our commitment to enforcing those laws

¹ The National Defense Authorization Act for Fiscal Year 2012, Pub. Law No. 112-81 (December 31, 2011) is more than 1,200 pages in length and covers a multitude of legislative topics.

² TRICARE is the federal healthcare program serving active-duty military service members, members of the National Guard and Reserve, military retirees and their families. TRICARE is administered by TRICARE Management Activity, a program of the U.S. Department of Defense. TRICARE includes insurance and supplemental insurance, direct healthcare services, managed/coordinated care and special needs plans.

³ The OFCCP is the governmental agency responsible for enforcing the federal affirmative action and equal employment opportunity obligations mandated by: (i) Executive Order 11246, (ii) Section 503 of the Rehabilitation Act of 1973, and (iii) the Vietnam Era Veteran's Readjustment Assistance Act of 1974. See Exec. Order No. 11,246, 3 FFR.330 (1964-1965), reprinted in 42 U.S.C. § 2000e app. at 28-31 (1982); The Rehabilitation Act of 1973, Pub. L. No. 93-112, 87 Stat. 355 (codified as amended at 29 U.S.C. § 793 (1988)); Vietnam Era Veteran's Readjustment Assistance Act of 1974, 38 U.S.C. §§ 4211-4215 (2002), as amended.

⁴ Over the past year, the OFCCP has taken an expansive position regarding its authority over healthcare providers based on contracts for services under the TRICARE program and other relationships with the federal government. This aggressive stance was buttressed by Executive Order 11246. Pursuant to the Order and related statutes, an entity such as a hospital can be deemed a "federal contractor" or "subcontractor" not only for having a direct arrangement or contract with the United States government, but also where it enters into a subcontract with a United States government contractor.

is unwavering. This isn't over yet.”⁵ As such, while the NDAA is a positive development regarding TRICARE, issues still remain as Section 715 only refers to TRICARE contractors and does not address contracts that hospitals enter into with administrators of other healthcare programs, such as the Federal Employees Health Benefits Program or Medicare Parts C and D.

Thus, all hospitals should immediately take proactive steps to ensure they are in compliance with any applicable

affirmative action obligations in light of the OFCCP's unwavering desire to assert jurisdiction over the healthcare industry. Specifically, hospitals should determine whether their contracts with the federal government or federal contractors could result in them being deemed federal contractors or subcontractors and thus subject to OFCCP jurisdiction. Failing to do so could result in a hospital unnecessarily incurring monetary penalties and/or having to engage in costly and time-consuming litigation with the OFCCP.

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⁵ Jay-Anne B. Casuga, *Shiu Says OFCCP Will Assess Its Policies In Light of Subcontractor Provision in NDAA*, BNA Daily Labor Report, 245 DLR A-11, Dec. 21, 2011.

3 Ways to Improve Hospital Compliance

By *William H. Maruca*

1. Do Your Homework – Review the OIG Work Plan

Remember when you were in college and the professor would say, “Listen up. This will be on the final exam.” The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) gives you a similar preview each year with the publication of its work plan – the latest version is posted here.¹

This document sets forth the OIG's enforcement priorities for the coming year. Any vigilant compliance officer² should be familiar with what's on the enforcement agency's agenda and prepare accordingly.

Highlights from the Fiscal Year 2012 Work Plan for hospital compliance³ issues include a number of perennial hot spots: reporting for adverse events, reliability of hospital-reported quality measure data, admissions with conditions coded present

on admission, reconciliations of outlier payments, hospital claims with high or excessive payments, same-day readmissions, Medicare payments for beneficiaries with other insurance coverage, duplicate GME payments, payments for nonphysician outpatient services, Medicare brachytherapy reimbursement, Medicare inpatient and outpatient hospital claims for the replacement of medical devices, and observation services during outpatient visits.

New issues in the OIG Work Plan for 2012 include in-patient rehabilitation facilities, critical access hospitals, accuracy of present-on-admission indicators submitted on Medicare claims and acute-care hospital inpatient transfers to inpatient hospice care.

If you have an effective compliance plan, you are already monitoring changes in applicable laws and regulations on an ongoing basis and reviewing your

institution's operations to identify vulnerabilities. The Work Plan can help you focus on where the OIG will be looking in the coming year so those areas can be addressed first and remedied if necessary. With the increased frequency of RAC audits and whistleblower suits, forewarned is forearmed.

2. Tighten up your HIPAA Compliance

Congress mandated that the DHHS audit covered entities and business associates to ensure that they are complying with the HIPAA Privacy and Security Rules and Breach Notification standards. The Department's Office of Civil Rights (OCR) has announced a pilot program of 150 audits of covered entities to assess privacy and security compliance.

If your hospital is not selected as one of the first 150 audit targets this year, you're not off the hook yet. It is anticipated that OCR will use the results of its pilot audit⁴ program to focus further audit

¹ <http://oig.hhs.gov/reports-and-publications/archives/workplan/2012/Work-Plan-2012.pdf>

² <http://www.corporatecomplianceinsights.com/category/jobs/>

³ <http://www.corporatecomplianceinsights.com/category/healthcare-compliance/>

⁴ <http://www.corporatecomplianceinsights.com/category/audit/>

activity on the areas of greatest noncompliance.

In either case, if you are audited, you can expect OCR to request complete documentation of your facility's privacy and security compliance efforts. Their team will conduct a site visit during which they will interview key personnel and observe processes and operations. After the site visit, OCR will draft a report including findings and proposed corrective actions. The covered entity will be permitted to discuss the draft and finalize its proposed responses.

Of particular interest are your relationships with business associates and subcontractors, and your procedures for responding to a breach of personal health information (PHI). A recent study reported that more than 46 percent of breaches were committed by business associates or other third parties, so make sure your business associate agreements are adequate to hold your BA's fully responsible for their mistakes.

Now is the best time to review your HIPAA compliance efforts, identify and rectify gaps, and bring your policies and procedures up to date. Don't wait until the inspector is at your door.

3. Fully Document FMV for All Transactions

As compliance professionals know, fair market value (FMV) is an essential element to satisfy a plethora of regulatory requirements and exceptions, including, but not limited to Stark, the Anti-Kickback Safe Harbors and tax exemption criteria. Accordingly, documentation of FMV is not the time to cut corners on appraisers or legal fees.

The term "fair market value" is defined in slightly different ways in each regulatory context, but the common elements require the amount to be within the range of prices that would be paid as the result of bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for each other, and who are not under any compulsion to enter into the transaction. In some situations there are additional requirements. For instance, the value of leases may not take into account the proximity of referral sources despite the well-known real estate mantra "location, location, location."

Although a written valuation from an independent valuation expert is generally not required by law, proceeding without one is risky indeed. Worse yet is a

valuation that includes impermissible factors such as anticipated referral volume or ancillary business to be generated under a transaction. Your valuation reports should always be obtained by your legal counsel to maximize their protection under the attorney client privilege and work product doctrine, but keep in mind that both such protections are not absolute.

FMV analysis and documentation is critical for all transactions with referring physicians including but not limited to employment and independent contractor agreements, medical directorships, leases, asset purchases, service agreements, joint ventures, investment opportunities and redemption of investments.

Don't stop with FMV – most Stark and Safe Harbor exceptions also require a showing of commercial reasonableness, i.e., a legitimate business purpose of the transaction apart from anticipated referrals.

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Navigating the Minefield of Arrangements Between DMEPOS Suppliers and Physicians

By *William H. Maruca*

Physician referrals are the lifeblood of suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). In recent years, common relationships between DMEPOS suppliers and physicians have come under regulatory attack, and ethical suppliers often face pressures to match arrangements offered by more aggressive competitors. Inconsistent guidance from enforcement agencies has led to conflicting rumors and advice within the industry. "But everyone else is doing it" is not a valid defense. There are still a variety of ways suppliers can work with

referring physicians that reduce both parties' exposure to liability.

The Legal Minefield

The most lethal landmines planted by Congress are the federal physician self-referral prohibition (Stark Law) and the federal Anti-Kickback Law. Additionally, the False Claims Act allows whistleblower plaintiffs ("relators") to bring suits on behalf of the government, and successful whistleblowers can receive between 15 percent and 30 percent of the monetary proceeds of the action or settlement recovered by the government.

The Stark Law prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and prohibits the entity from filing claims with Medicare (or billing another individual, entity or third-party payer) for those referred services. Designated health services are clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic

resonance imaging, computerized axial tomography scans and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

The Anti-Kickback Law provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursable under federal or state health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to five years. Violations of the Anti-Kickback Law may also result in the imposition of a civil money penalty or program exclusion under section 1128 of the Act. Section 6402(f) of the Patient Protection and Affordable Care Act (codified at 42 U.S.C. § 1320a-7b(g)) clarified that violations of the Anti-Kickback Law are automatic violations of the False Claims Act and modifies the intent required to establish a violation.

The Office of Inspector General (OIG) has issued compliance guidance documents focusing on various sectors of the health industry including DMEPOS suppliers.¹ This guidance describes a number of compliance problems that frequently arise in the DMEPOS field, including improper relationships with referring physicians.

Stock-and-Bill Arrangements/Compliance Closets

One of the most common arrangements between suppliers and physicians is for the supplier to lease storage space in a physician's office to store inventory of DMEPOS items and dispense those items from the physician's office. This is referred to as a "stock-and-bill" or "consignment closet" arrangement. The amount of rent that can legally be paid for a closet or

storeroom in a physician's office is typically modest. Nevertheless, physicians often find these arrangements to be desirable, both for the convenience factor, which affords their patients one-stop shopping, as well as the small financial reward. These arrangements have never been popular with regulators, and disparaging descriptions of them abound in the official literature. For instance, in the DMEPOS Supplier Compliance Guidance, the OIG lists among its risk factors:

Co-location of DMEPOS items and supplies with the referral source; in this situation, a physician allows a DMEPOS supplier to stock inventory (the storage space may or may not be rented by the DMEPOS supplier) in a physician's office. When such items and supplies are dispensed to the patient, Medicare is then billed. Although such arrangements are not prohibited per se, the OIG believes that such arrangements may potentially raise anti-kickback and self-referral issues, particularly when the DMEPOS supplier pays the physician an amount above fair market value to rent the space.²

In February 2000, the OIG issued a Special Fraud Alert on "Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer."³ This bulletin addressed a number of questionable rental arrangements for space in physician offices:

A number of suppliers that provide health care items or services rent space in the offices of physicians or other practitioners. Typically, most of the items or services provided in the rented space are for patients, referred or sent, either directly or indirectly, to the supplier by the physician-landlord.

In particular, we are aware of rental arrangements between physician-landlords and . . . suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) that set up "consignment closets" for their supplies in physicians' offices.

The OIG is concerned that in such arrangements, the rental payments may be disguised kickbacks to the physician-landlords to induce referrals. We have received numerous credible reports that in many cases, suppliers, whose businesses depend on physicians' referrals, offer and pay "rents" either voluntarily or in response to physicians' requests that are either unnecessary or in excess of the fair market value for the space to access the physicians' potential referrals.

Payments of "rent" for space that traditionally has been provided for free or for a nominal charge as an accommodation between the parties for the benefit of the physicians' patients, such as consignment closets for DMEPOS, may be disguised kickbacks. In general, payments for rent of consignment closets in physicians' offices are suspect.

Both the Stark Law exception and the Anti-Kickback Law safe harbor exception for space leases require the amount paid be consistent with fair market value. Despite the harsh language used by the OIG in this Bulletin, the OIG has cited no authority to suggest the fair market value of storage space is zero. All the same, suppliers and physicians should scrupulously document the evidence of fair market value for such payments. Such evidence should include the method of proration of the physician's rent as well as an independent appraisal of the rental value per square foot of comparable office space. The OIG Bulletin sets forth a formula for prorating space in physicians' offices, and I recommend to my clients that their leases track this formula as closely as possible.

The suppliers' payments to the physicians are only one element of a stock-and-bill arrangement. For the deal to work, the supplier needs to be able to bill Medicare for DMEPOS items dispensed out of the leased space. The Centers for Medicare

¹ <http://oig.hhs.gov/authorities/docs/frdme.pdf>.

² Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36368, 36374 (July 6, 1999).

³ <http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm>

and Medicaid Services (CMS) muddied the waters in 2009 by issuing, delaying, then ultimately retracting a new Medicare Program Integrity Manual provision that restricted the use of consignment closets or stock-and-bill arrangements in physician offices by suppliers. The transmittal prohibited stock-and-bill arrangements where an enrolled DMEPOS supplier maintains inventory at a practice location that is owned for the purpose of distribution by a physician, non-physician practitioner or other health care professional rather than the enrolled DMEPOS supplier. This transmittal would have forced the supplier to sell its products to the physician and require the physician to meet the strict new supplier standards in order to bill Medicare. Heavy lobbying by the DMEPOS industry educated CMS about the prevalence of this type of arrangement and the disruption that its ban would create, resulting in a decision to rescind the rule for now.⁴ At this time, there is no indication as to whether any new version of the transmittal will be issued.

In 2010, CMS finalized a proposed final rule setting forth standards for DMEPOS suppliers, which included a prohibition on “sharing practice locations” with other enrolled providers and included requirements for minimum space and hours of operation. Initially, many suppliers thought this rule may have been targeted at compliance closets, but informally CMS has indicated to a number of industry representatives that it is only to be applied to a DMEPOS supplier’s location as set forth on its enrollment application. This would mean a supplier that maintains a retail office where patients and regulators can visit during defined business hours would need to meet the standards at that location, but not at physician offices where inventory is maintained and dispensed. Reportedly, the target for this rule was DMEPOS manufacturers that do not maintain compliant physical locations and seek to enroll their physician office-based sites.

Physician Billing for DMEPOS

When can a physician practice bill for DMEPOS products? The Stark Law draws a distinction between most DME and POS items. Although prosthetics, orthotics and related supplies are designated health services under Stark, they are eligible for the “in-office ancillary services” exception allowing them to be supplied by physician practices under certain circumstances. There is a narrow exception for certain DME provided in a physician’s office, but it is limited to ambulatory aids such as canes, walkers and non-motorized wheelchairs. In the case of all DME and POS items, the Stark Law only applies if a physician makes a “referral” as defined in the law, and there is no referral where a physician personally performs or provides a service. So, can a physician bill Medicare directly for DMEPOS he or she dispenses? Not so fast—CMS says personal means personal.

There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in § 424.57(c).

DME suppliers are entities that provide services under the specific Part B benefit for the provision of medical equipment and supplies for use in the patient’s home. These entities must be enrolled with the appropriate Medicare contractor as a DME supplier and must meet all of the professional supplier standards and quality standards that we require through regulations and administrative or program instructions. The enrollment requirements and professional supplier standards are not waived in those situations in which a physician furnishes DME directly to the patient. The services to be personally performed by the physician would include, but not be limited to, the following, as appropriate:

- Personally fit the item for the beneficiary;
- Provide necessary information and instructions concerning use of the DME;
- Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME;
- Explain the purchase option for capped rental DME;
- Explain all warranties;
- (Usually) deliver the DME to the beneficiary at home; and
- Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.

A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that the physician personally performed these and other required DME supplier activities. All of these supplier requirements would need to be satisfied in order for a physician to be considered to be providing personally DME items and supplies.⁵

CMS has intentionally set the bar high for meeting the standards of a DME supplier, but it is not impossible. It requires the physician submit an application to be enrolled as a DME supplier and obtain a DME supplier number. It also requires that many activities ordinarily delegated to technologists or staff be personally performed by the physician him or herself and be documented as such. As CMS considers it “unlikely” that a physician could meet those standards, a physician would need to be particularly diligent and thorough in documenting the personal performance of each task.

Personal Service Arrangements

What other arrangements between suppliers and physicians are permissible? It is possible for a supplier to pay a physician or a physician practice for defined services

⁴ <http://www.cms.gov/transmittals/downloads/R300PI.pdf>

⁵ Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Fed. Reg.* 51012, 51019 (Sept. 5, 2007).

including medical directorships, certain patient education or fitting services, billing, consulting or other administrative services. Both the Stark Law exceptions and the Anti-Kickback Law safe harbors impose strict requirements on such arrangements, and “sham” service contracts are among the highest enforcement priorities.

The Stark Law requires all personal service arrangements to meet the following criteria, in order to satisfy the exception:

1. The arrangement is in writing and specifies the services covered by the arrangement.
2. The arrangement covers all of the services to be furnished by the physician to the entity.
3. The term of the arrangement must be for at least one year.
4. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
5. The compensation paid must be set in advance and be of a fair market value for the services provided and is not conditioned upon the volume or value of any referrals or other business generated between the parties.
6. The services do not involve the counseling or promotion of a business arrangement or other activity that violates any federal or state law.

The Anti-Kickback Law safe harbor includes similar requirements and also states that if the agreement is intended to provide for services on a periodic, sporadic or part-time basis, the agreement must specify the schedule of such interval, the precise length and the exact charge for such intervals over the term of the agreement.

Gifts, Meals, Etc.

What about sending your loyal physicians a holiday gift, buying them a fancy dinner or providing some other token of appreciation? Although there are certain thresholds under the Stark Law for hospitals providing incidental benefits to their medical staffs, there are no similar exceptions for DMEPOS suppliers. Similarly, there is no “de minimis” threshold under the Anti-Kickback Law safe harbor for such items. Suppliers should nonetheless proceed with caution when considering gifts to referring physicians.

Trade associations such as the Advanced Medical Technology Association (AdvaMed) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have adopted their own ethical codes governing interaction with health care professionals.⁶ AdvaMed’s code limits its members to providing meals only incidental to the *bona fide* presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event. With regard to gifts, the code states:

Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/iPod.

These industry codes, while not officially endorsed, create a minimum compliance

level that suppliers will be expected to honor or explain why their circumstances differ.

Get Guidance First

Ultimately, DMEPOS suppliers need to recognize they operate in a heightened risk environment. Reimbursements are shrinking for suppliers and referring physicians alike, which has driven some players to take ill-advised risks to preserve or grow their market share. Referring physicians may be approached with offers that are too good to be true, and an ethical supplier will help educate physicians about the risks they take by accepting such sweetheart deals. Both parties involved in an arrangement that violates the Stark Law or the Anti-Kickback Law face staggering potential penalties, and legal fees to challenge a defensible arrangement can quickly exceed any benefit the arrangement provided. Only with the input and guidance of experienced health care counsel can a supplier minimize its risk exposure while meeting today’s competitive pressures.

For more information about this topic, please contact [William H. Maruca](mailto:wmaruca@foxrothschild.com) at 412.394.5575 or wmaruca@foxrothschild.com.

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⁶ <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>;
http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf

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