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## A Proactive Approach for the Compliance Committee



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The compliance committee of the hospital's governing board should pursue a more pro-active approach in response to increased anti-fraud challenges arising in a post-reform environment. These new challenges reflect more restrictive federal laws; significant new court rulings; broader OIG permissive exclusion authority; and the anti-kickback and Stark issues arising from hospital-physician integration initiatives, including ACO arrangements. Individually and collectively, these challenges present new enforcement theories and liability exposure with which the committee must be familiar. As such, they serve to prompt the committee to be more assertive in evaluating and monitoring the organization's anti-fraud risk profile.

This is not about duplicating the efforts of the general counsel or compliance officer, or involving the committee in activities typically the province of management. Indeed, these emerging compliance challenges are well-known to legal and compliance officers. Rather, it is about placing the committee in a position from which it

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can more effectively exercise its "Caremark"-based<sup>1</sup> compliance oversight duties. Informing the board and standing committees on critical developments is, of course, an important obligation of executive management. This is in part because committee conduct will be guided in part by the particular circumstances; e.g., a more aggressive anti-fraud climate for hospitals and health systems. Thus, this really is all about reducing the potential for the "Why didn't you tell us about this?" moment from the committee.

The organization's anti-fraud profile will benefit when the compliance committee has a better "pulse" of the current enforcement environment, and can more capably evaluate compliance risk in a coordinated manner.

### I. Focused Compliance Education

The fundamental educational message to be shared with the committee is that there has been a noticeable "uptick" in anti-fraud enforcement activity at the federal level that likely will affect the oversight perspective of committee members. "Need to know" developments for committee members include the following:

#### A. New Federal Statutes

The health reform legislation enacted in 2010 (the Patient Protection and Affordable Care Act or PPACA) includes significant anti-fraud enforcement and program integrity initiatives. Unlike other parts of PPACA, these provisions faced little or no opposition, and their significance is just beginning to be felt in practice. These include the following:

- Failure to return a federal health care program overpayment within 60 days of identifying the overpayment or the date the corresponding cost report is due, whichever is later, becomes a "reverse false claim." The combination of affirmative repayment obligation and tight—indeed arguably unrealistic—repayment timeframe must be understood through

<sup>1</sup> A series of leading Delaware cases, beginning with *In re Caremark* (698 A.2d 959 (Del. Ch. 1996)), articulate a specific compliance plan oversight fiduciary duty of the governing board. This duty can be described as an attempt in good faith to ensure both (a) the existence of a corporate information and reporting system (i.e., a compliance plan) that the board concludes is adequate, and (b) that this system/plan is sufficient to ensure that appropriate information regarding organizational compliance with applicable laws will come to the board's attention in a timely manner and in the ordinary course.

out the organization, in order to ensure that every effort is made to comply.

- The False Claims Act has been amended in a number of additional ways that make it easier for whistleblowers to bring false claims actions on behalf of the government.
- The intent standard for purposes of the anti-kickback law has been amended to provide that a person need not have actual knowledge of the anti-kickback law or specific intent to commit a violation for the government to prove a kickback violation.
- While it was hoped that the Self-Referral Disclosure Protocol (SRDP) implemented pursuant to PPACA would create an avenue for obtaining expeditious relief from “technical” Stark law violations (e.g., expired contracts or other violations that do not involve potential anti-kickback exposure), to date, this has not proved to be the case. Therefore, addressing potential Stark law issues remains a significant challenge for the compliance committee.
- The so-called “Sunshine Act” provisions do not directly implicate most hospitals, but the reports of payments made by drug and device manufacturers to physicians and teaching hospitals may have a ripple effect beyond teaching hospitals, since the reports could lead to scrutiny of physicians’ treatment decisions within any hospital (e.g., potential influence of such payments on choice of treatment modality within the hospital).
- PPACA includes initiatives that require closer scrutiny of Medicare and Medicaid enrollment and re-enrollment applications than in the past, with particular scrutiny on so-called “high risk” areas such as DME. Processing of enrollment and re-enrollment applications used to be an administrative function that likely operated without much compliance committee involvement or knowledge. However, increasingly, enrollment applications can be a source of scrutiny and significant disruption of Medicare and/or Medicaid payments. Therefore, this area, just like traditional risk areas such as physician relationships, should be subject to rigorous oversight.
- Finally, PPACA includes increased funding for fraud fighting initiatives. On a related note, the OIG has established a compliance training initiative as an outgrowth of the HHS/DOJ Health Care Fraud Prevention and Enforcement Action Team’s (HEAT) efforts. The educational materials prepared by the OIG (found at <http://oig.hhs.gov/compliance/provider-compliance-training/index.asp>) are a good source of compliance training information for the compliance committee and indeed most of a health care organization’s constituencies.

## B. The New Anti-Fraud Cases

As noted above, fighting health care fraud is a high and well-funded priority for government enforcement authorities. On a daily basis, settlements of anti-kickback law, Stark law, and/or False Claims Acts cases by hospital and other health care providers are publicized through press releases and OIG website postings. Most cases settle and do not result in substantive opinions. Moreover, some of the recent, highly publicized cases involve unique facts and circumstances that may allow individual hospitals and health systems to draw legitimate distinctions from their own practices (i.e., make it easy to say “this is not us.”)

**However, these cases have generated statements by courts that have implications for a much broader range of factual scenarios, and indicate that the courts and prosecu-**

**tors do not understand or are not sympathetic toward the pitfalls faced by providers in complying with the technical requirements of the Stark law in real world situations.** The following are just a few of the ramifications of recent cases.

### 1. Strict Construction of Stark Law

In Stark law cases, the health care provider, not the government, bears the burden of proving that an exception from the Stark law referral prohibition applies. While one court has advocated for a flexible interpretation of the Stark law another, more recent case reflects a much stricter, technical view. In particular, in the *Solinger*<sup>2</sup> case, the court stated:

... throughout their successive rulemakings HCFA and CMS have focused on achieving a goal, namely prevention of health care fraud, more than on ensuring rigid adherence to any particular regulatory provision. (543 F. Supp. 2d 687)

In the *Kosenske*<sup>3</sup> case, by contrast, the court held the parties to a stricter standard of showing that the services at issue were explicitly included in a contract, in order to meet the personal services exception. This reflects a possible trend toward a stricter construction, and neither the courts nor CMS have provided much comfort that a flexible, common-sense approach will prevail. Even so-called “technical” violations, such as an expired contract, where the only defect is a lack of a signed extension, must be analyzed carefully and appropriate corrective action taken.<sup>4</sup> Consequently, contract management functions that once would not have been a focus for upper management are now an important element in ensuring that contracts with physicians meet a Stark law exception and are regularly reviewed to ensure that they do not fall out of compliance through failure to ensure that, over time, the written agreement remains consistent with the actual relationship.

### 2. Fair Market Value

The OIG has historically noted the difference between the concept of fair market value for ordinary business purposes and for health care purposes. As a result, arrangements that might make sense from a business perspective can be interpreted as health care fraud by prosecutors. The following statement dates back to 1992:

When considering the question of fair market value, we would note that the traditional or common methods of economic valuation do not comport with the prescriptions of the anti-kickback statute . . . . Merely because another buyer may be willing to pay a particular price

<sup>2</sup> *United States ex rel. Villafane v Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008) (*Solinger*). The *Solinger* case involved compensation to faculty physicians and application of the Stark law academic medical center exception.

<sup>3</sup> *Kosenske v. Carlisle HMA Inc.*, 554 F.3d 88 (3d Cir. 2009) (*Kosenske*). The *Kosenske* case involved an exclusive agreement between a hospital and an anesthesiology group, and the status of the agreement under the Stark law personal services exception as the scope of the underlying relationship changed somewhat over time.

<sup>4</sup> The specifics involved in analyzing Stark law and other violations and determining specific corrective actions, such as repayment or self-disclosure, are beyond the scope of this article.

is not sufficient to render the price paid to be fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase.<sup>5</sup>

Independent third party valuations traditionally have been used to address the dilemma of how to determine fair market value without including any additional amount a buyer might be willing to pay to a referral source. However, the approaches taken in recent cases have made it **increasingly difficult to prove** that an arrangement has not impermissibly “taken into account” the business generated between the parties in setting the compensation or purchase price.

In the *Kosenske* case, the court refused to give any weight to the fact that the parties had indeed negotiated their arrangement, stating:

as a legal matter, a negotiated agreement between interested parties does not ‘by definition’ reflect fair market value. To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation (554 F.3d 97).

Two additional recent cases, *Tuomey*<sup>6</sup> and *Bradford*,<sup>7</sup> illustrate that using third party valuations and compensation consultants is **not enough** to shield an arrangement from scrutiny, and that valuations in the heat of negotiations may not hold up later. In *Tuomey*, a jury found the hospital guilty of Stark law violations relating to physician compensation arrangements and awarded over \$44 million. In the *Bradford* case, a third party valuation of a sublease of equipment from physicians that included a noncompete explicitly took into consideration revenues the hospital was expected to receive from referrals by those physicians. Accordingly, the court found that “the aggregate compensation received by the doctors takes into account the volume or value of anticipated referrals generated by the doctors.” (752 F. Supp. 2d 633) **At the least, this illustrates that an uninformed business valuation can create, rather than minimize, risk.**

### 3. One Purpose Rule

The “one purpose rule”—i.e., the concept that an arrangement violates the anti-kickback law if “one purpose” is to induce referrals—unquestionably has been the position of the regulators as well as the majority of courts for many years. Providers have struggled with the practical realities of trying to distinguish between a purpose to “induce” referrals versus hoping for referrals. However, it generally has been well-accepted that intent does not matter for *safe harbored* arrangements.

<sup>5</sup> Dec. 22, 1992 letter from D. McCarty Thornton, associate general counsel, OIG, to T.J. Sullivan at IRS. <http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm>

<sup>6</sup> *United States ex rel. Drakeford v. Tuomey*, 2010 U.S. Dist. LEXIS 143457, (D.S.C. July 13, 2010) (*Tuomey*). The *Tuomey* case, which is on appeal to the Fourth Circuit, involves hospital arrangements with certain physicians alleged to be in excess of fair market value for the services performed by the physicians. The amounts paid to the physicians for services were in excess of the corresponding collections.

<sup>7</sup> *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa. 2010) (*Bradford*).

The Seventh Circuit’s ruling in the *Borrasi* case<sup>8</sup> has raised the possibility that courts might look behind the safe harbor and look at underlying intent. While we think the better interpretation of the court’s opinion is that a sham arrangement (in that case, a sham employment arrangement) is not entitled to safe harbor protection, **the government’s argument can also be read to suggest that even a bona fide employment arrangement could violate the anti-kickback law if “one purpose” were to induce referrals.**

## C. Permissive Exclusion Authority

The committee also should be aware of the exposure of corporate officers and key employees to exclusion from the Medicare and Medicaid programs, pursuant to statutory-based HHS OIG guidelines released in October, 2010.<sup>9</sup> This authority provides two different bases for exclusion.

At one level, the exclusion guidance provides that in circumstances where the facts indicate that an owner, officer, or managing employee of a sanctioned entity knew or should have known of the prohibited conduct that led to the entity sanction, OIG will act with a presumption in favor of excluding the individual from Medicare/Medicaid. This presumption may be overcome if OIG determines that significant factors weight against exclusion. The exclusion guidance does not define these factors, however.

At another level, officers and managing employees may in certain circumstances be held to a higher, strict liability-style, standard of conduct than that applied to owners. The exclusion guidance provides that officers and managing employees may also be subject to exclusion in the absence of evidence that they knew or should have known of the corporate misconduct. In this way, the exclusion guidance authorizes a strict liability basis for excluding officers and managing employees solely on the basis of their position with the organization.

A precondition for exclusion under both approaches is that the organization itself has been convicted of a criminal offense requiring mandatory Medicare/Medicaid program.

OIG’s use of the permissive exclusion authority is consistent with the broader government efforts to hold individuals responsible for corporate misconduct. The strict liability provisions of the guidance present the compliance committee with particular challenges on how to effect compliance plan changes that will address the potential exclusion risk of valued executives.

## II. Related Committee Initiatives

Defending health care fraud allegations involves proving a negative, i.e., providing that the parties did not have bad intent. Moreover, despite best efforts to avoid considering physician referrals when structuring arrangements with physicians, it is very difficult to ensure that such considerations do not creep into the conversations, even incidentally. Providers must be vigilant to ensure that arrangements do not become tainted by

<sup>8</sup> *United States v. Borrasi*, 639 F.3d 774 (7th Cir. Ill. 2011)

<sup>9</sup> “Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act” (Oct. 20, 2010), available at [http://oig.hhs.gov/fraud/exclusions/files/permissive\\_excl\\_under\\_1128b15\\_10192010.pdf](http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf).

improper statements that later can be used to show improper intent. Therefore, it is important for the Compliance Committee to be aware of these important new developments, and recognize them for what they represent: **a significant increase in government anti-fraud focus.**

There is **no expectation** that the committee itself has any obligation to master the details of these new anti-fraud initiatives. Rather, it is **entitled to rely** upon—and indeed should expect—educational briefings from executive management (e.g., the general counsel and the compliance officer) that share the basic themes of these new developments. *However, the educational briefings must be sufficient such that the committee “gets it”—i.e., is aware that these developments reflect a substantial increase in government anti-fraud activity, and is able to reflect that awareness in the exercise of its oversight activity.* Armed with such knowledge, the committee is in position to undertake a series of pro-active compliance plan initiatives intended to reduce organizational risk from these new anti-fraud challenges. These initiatives could take the following form:

1. **Uniform Process:** The committee should seek assurances that the organization has a consistent and organized process by which transactions and relationships with anti-fraud risk are reviewed for legal feasibility. Elements of such a process would logically include, among others:

- initial identification of those types of transactions and relationships;
- involvement of general counsel to evaluate the extent of anti-fraud risk;
- determination of scope of legal and other expert advice necessary to support the transaction; and
- a process by which the business and mission considerations for the transaction are formulated and reviewed; i.e., what committee(s) have jurisdiction to review such transactions—and the extent of intra system coordination.

Here, the committee is not necessarily dictating an internal review process, nor insisting that the committee be part of such process. Rather, as part of its oversight duties it is asking the key question—are the organization’s internal review and legal feasibility processes sufficient to identify and address the increased anti-fraud risk? That’s a totally appropriate exercise of the committee’s responsibility and consistent with the organization’s overarching approach to enterprise risk management.

2. **Risk Evaluation:** It is particularly important that the committee play a leading role on behalf of the board in reaching a leadership-level agreement of the level of anti-fraud risk that is acceptable for the organization to assume. This with the understanding that it is virtually impossible to eliminate all anti-fraud risk when entering into transactions and arrangements with physicians and other referral sources. The initiative would include three components:

**First**, for the board (on the initiative of the committee) to reach an informed decision, consistent with its compliance oversight and duty of loyalty to mission obligations, on an acceptable organizational risk profile in anti-fraud-implicated transactions. This would necessarily require advice from counsel on the levels of risk inherent to the organization and to individuals from transactions with anti-fraud implications. The board must understand the scope of potential risks, ranging

from a corporate integrity agreement, civil penalties, criminal prosecution or even organizational/individual program exclusion. Any such decision should also reflect an awareness of the organizational and individual costs associated with enduring a governmental anti-fraud investigation (even one that ends up short of a formal enforcement action). It should also reflect a pragmatic understanding of the specific costs of anti-fraud litigation, should individual board members entertain romantic thoughts about “taking on” the government. Such an understanding is crucial to the ability of the committee, and the full board, to act as proper and informed stewards of the organizational mission and reputation.

**Second**, for that risk profile decision to be communicated throughout the organization so that proposed transactions with unacceptable levels of risk will either not be pursued (where the level of risk is obvious from inception of transaction planning) or approved (where the level of risk becomes more apparent through the transaction incubation process). It should also be communicated to outside counsel in order that requested legal advice will reflect the organization’s approved legal risk corridor; i.e., better enable outside counsel to identify circumstances/transactions/arrangements that likely fall within, or without, that corridor. The role of the committee will in part be to direct management to make sure that the communication is effective and that adherence to the risk profile determination is part of the executive performance evaluation process/compensation methodology.

**Third**, that an effective monitoring system is established to assure compliance with the risk profile standard. The extent to which there is wide internal adherence to such a profile (along with other compliance controls) will enhance the good faith nature or the organization’s commitment to compliance. Perhaps more importantly, it will reduce the risks associated with an inconsistent application of transaction evaluation standards throughout the organization and on a case-by-case basis with individual transactions. Again, assuring the implementation of coordinated risk evaluation controls are essential to the committee’s core oversight responsibility.

3. **“Intent” Instruction:** The significant focus on the “intent” component of the anti-kickback law in the PPACA and in recent decisions (e.g., *Borassi*) should be a specific area of compliance committee attention. As noted throughout this paper, the suggestion is not that committee members attain some expanded level of familiarity with the anti-fraud laws or the anti-kickback statute. That’s why they have lawyers to assist them. Rather, given the new anti-kickback developments, it is increasingly important that committee members appreciate at a fundamental level the concept of scienter/improper intent as contemplated by the anti-kickback law. The public policy reasons behind the improper intent prohibition (e.g., affecting the patient’s freedom of choice) can be counter-intuitive to committee members who engage in similar practices in their own, non-health care industries, where remuneration to influence business referrals are a legal and appropriate means of conducting business. If the committee members are to properly exercise oversight with respect to anti-kickback compliance, they will be aided by basic instruction on the murky topic of improper intent, and the

available statutory and regulatory exceptions and safe harbors.

4. *Clarification of Reliance*: As noted throughout this paper, the board/committee is entitled to—and should—rely on the advice and input of its executive management team (including the general counsel and compliance officer) in making decisions with respect to the anti-fraud exposure of the organization. Such reliance right is a bedrock component of the fiduciary duty of care. However, the reliance right is not unlimited, and assumes that board/committee members will be diligent when relying upon advisers and exercise the appropriate degree of “constructive skepticism” with respect to such advice. The committee can assist the board in this regard by focusing attention on such reliance-based issues as:

- specific expectations on the type and extent of the legal advice expected from the general counsel and, where necessary, from outside counsel, in order to support transactions in which anti-fraud risk has been identified;
- the types of transactions that require particularized legal advice, and those that are sufficiently generic that they can be supported on the basis of previously provided legal advice;
- the circumstances that warrant advice from outside counsel to supplement the advice provided by general counsel—and the qualifications of such outside counsel;
- the form of the advice to be provided by counsel (e.g., in writing with clarification of the risks associated with the transaction);
- the circumstances in which the board or relevant committee should be provided with a written copy of the legal advice and guidance on how to interpret the advice (and any caveats/assumptions/conditions on which it is based);
- the quality of third party valuations and similar data used to support the reasonableness of financial transaction terms; and
- whether the outside legal counsel conducted its analysis under potential limitations; e.g., a discounted fee arrangement that provided a material disincentive to invest significant time in its analysis and work product.

The committee can play an important role in improving the effectiveness with which the board (and its committees) evaluates legal advice on which it may ultimately seek to rely in making decisions with anti-fraud/compliance implications.

5. *Exclusion Defense*: The committee should be sensitive to the exposure, remote as it may be, of its officers and key managers to the HHS/OIG’s permissive exclusion authority, as described above. Despite the “strict liability” provisions of the most visible of the permissive exclusion “triggers,” the HHS/OIG guidelines recognize a very limited “impossibility” defense to exclusion efforts. Unfortunately, there is extremely limited guidance on the elements of such a defense, beyond the suggestion that a corporate officer who exercises “extraordinary care” and still is unable to prevent the underlying problematic behavior will not be held accountable therefor. In the absence of useful guidance, the committee can respond to this risk by supporting management efforts to assure that the organization’s compliance plan is “state of the art” in every respect—even where there had been no previously expressed concern with the effectiveness of the program. Special efforts could be made to enhance the ability of management to play a more direct role in enforcing a culture of compliance within the organization that may be appropriately interpreted as “extraordinary care” in the context of the impossibility defense.

### III. Conclusion

The compliance committee’s satisfaction of its *Caremark* oversight obligations depends in part on its awareness of the surrounding facts and circumstances. Significant new developments in anti-fraud enforcement represent the types of important circumstances that should be considered by the committee in the conduct of its affairs. The general counsel and the compliance officer are logical executives to educate the committee on these new developments, to advise on how they affect the way in which the committee conducts its oversight, and to recommend a series of proactive initiatives that are intended to be responsive to these new developments and the risks they pose to health care organizations.