HOOPER LUNDY & BOOKMAN, INC.

HEALTH LAW PERSPECTIVES

Newsletter
Volume 5, No. 5

June 2003

OIG Issues Special Advisory Bulletin On "Contractual Joint Ventures"

The Health and Human Services Office of Inspector General has issued a *Special Advisory Bulletin*" criticizing a wide range of contractual arrangements for the provision of health care services. The OIG refers to these arrangements as "contractual joint ventures".

While the OIG attempts to tie its new Bulletin to its 1989 Special Fraud Alert dealing with true joint ventures, it is clear that the new Bulletin is addressing a much broader variety of arrangements, including ones which would not constitute joint ventures under any standard definition. According to the Bulletin, a "joint venture" is "any common enterprise with mutual economic benefit," and the OIG makes it clear that its concerns are not limited to those "joint ventures" that meet "technical qualifications under applicable state or common law".

The OIG is responding to common arrangements under which health care providers in a position to refer business to an outside vendor have instead chosen to "internalize" that business. Such arrangements often involve management and other support services being provided by a party that is also in the line of business providing those types of services directly.

The arrangements that the OIG believes are problematic typically exhibit the following common elements. First, a health care provider in one line of business (hereinafter referred to as the "Owner") expands into a related line of business which is dependent on referrals from, or other business generated by, the Owner's existing business. Second, the Owner neither operates the new business itself, nor commits substantial financial, capital or human resources to the venture. Instead, it contracts out substantially all operations of the new business to an existing provider (hereinafter referred to as the "Manager/Supplier"). Third, the Manager/Supplier is a provider of the same items or services as the Owner's new line of business. Fourth, the Owner and Manager/Supplier share the economic benefit of the Owner's new business, with the Manager/Supplier taking its share in the form of payment under various contracts with the Owner and the Owner benefiting by retaining the residual profit from the business. Finally, the OIG observed that these arrangements involve payments to the Manager/Supplier which vary with the volume or value of business generated for the new business by the Owner.

OIG has identified a number of what it calls "suspect contractual joint ventures", calling into question a wide range of arrangements. It is far from clear that the positions taken by the OIG in this Bulletin would be upheld by courts. For example, in the 1995 *Hanlester Laboratory v. Shalala* litiga-

In this issue:

Hooper Lundy & Bookman, Inc.
HEALTH CARE LAWYERS

tion, the OIG had challenged an arrangement under which a national laboratory company provided "turn-key" management services to a number of licensed laboratories which the government had characterized as "sham" businesses. Representing Hanlester, HLB successfully convinced the Ninth Circuit to reject the government's argument by concluding that remuneration flowed from the managed business to the manager, and not the other way around.

Despite questions about the OIG's analysis, however, it will be prudent for providers to evaluate their existing arrangements within the scope of the Bulletin under these new guidelines, particularly where those arrangements include some or all of the characteristics of "suspect" ventures identified by the OIG.

For more information, pleas contact Brad Tully at (310) 551-8160, David Henninger at (310) 551-8177 in Los Angeles or Pam Riley at (415) 875-8507 in San Francisco.

FCA Should Only Apply to Condition of Payment Noncompliance, Court Rules

Health care providers are routinely subjected to claims brought under the federal False Claims Act (FCA) which are triggered by the provider's having failed to comply with one or more health care regulatory requirements. However, most federal payment programs have inspection and correction mechanisms that are intended to serve as the principal safeguards for regulatory compliance. Allowing the government to short circuit such established remedial systems by proceeding directly under the FCA improperly converts mere regulatory noncompliance into false claims, bypasses the benefits of agency expertise and judgment, opens up inappropriate opportunities for whistleblowers, and, in short, unleashes an enforcement bull in the regulatory china shop.

The Fifth Circuit's recent decision in the *Southland Management* case strongly supports the view that the FCA should only be triggered by regulatory noncompliance where the requirement that was not complied with was a condition of payment *(United States v. Southland Management Corporation,* 2003 WL 1711940, C.A. 5, Miss, 2003 (April 1, 2003)).

Specifically, *Southland* presented the situation of certifications that public housing property had been maintained by its owner in a decent, safe and sanitary condition. These certifications had to be made in connection with the owner's submission of claims to the United States for subsidy payments. Under the owner's contract with the United States, the government had the right to terminate the owner's right to continue to receive subsidy payments if the property was not maintained in a satisfactory condition.

In a ruling consistent with an amicus (friend of the court) brief on the case submitted by HLB Attorney Brad Tully, the court held that "[i]t is only those claims for money or property to which a defendant is not entitled that are 'false' for purposes of the False Claims Act." Applying that standard, the court reasoned that the owner could not have been required to maintain the property in a decent safe and sanitary condition as a condition of payment, since, under the contract, the government was to take affirmative steps to cut off the owner's rights to continued payment if the property was not maintained in satisfactory condition. Even then, the sanction would only have been a prospective one.

Southland points out the somewhat unintuitive fact that the "materiality" of a false statement is not sufficient in itself to cause a false claim to result. This is because cases defining materiality, which has arisen primary in the not completely analogous area of false statements law, have defined materiality rather loosely to mean, in essence, "of interest to the government." Thus, a false statement might be material in that the statement may relate to a matter that would be of interest and of importance to the government, and may even relate to a matter that could have influenced the government to take action detrimental to the claimant (for example, by initiating a criminal prosecution or terminating a contract). However, under Southland, even a material false statement is not actionable under the False Claims Act unless the falsity was such that it negated the claimant's right to be paid. Thus, the court resisted the tempting, but ultimately fallacious, argument that because the certification was required to be made, it therefore had to be material and a condition of payment as a matter of law.

For more information, please contact Brad Tully at (310) 551-8160 or wtully@health-law.com.

Federal Court Rules on Kickbacks as False Claims

The question of whether kickbacks result in false claims was recently squarely addressed by *United*

States ex rel. Bidani v. Lewis, 2003 WL 925998 (N.D. Ill., March 5, 2003).

This case involved claims that Abbot Laboratories and Baxter Healthcare Corporation gave the defendant American Medical Supply Corporation (AMS) discounts and rebates from the list prices that AMS was charged for dialysis related supplies. AMS did not report receiving these discounts in its claims to Medicare.

The *qui tam* relator claimed that the discounts were illegal kickbacks. The relator then further argued under an implied certification theory that the defendant's claims were false. The court cited *Mikes v. Straus,* 84 F. Supp. 2d 427, 434 (S.D.N.Y. 1999) for the proposition that the implied certification test is as follows "a claim made in contravention of statutory or regulatory requirements may be deemed 'false' under the FCA in cases where the defendant's certification of compliance with the statutes and regulations in question is a condition of receiving funds from the Government."

However, since this test focuses on whether the certification, and not the compliance, was a condition of payment, it is hard to see how this could be a standard for "implied" certification. The court translated the *Mikes* standard to mean that "[t]o succeed, Bidani must show that the alleged AKS [antikickback] violation was material to the government's treatment of defendants' Medicare claims."

The court applied the "outcome materiality" standard, which it stated meant that, to be actionable under the FCA, the kickback would have to have affected the government's ultimate decision to remit funds. The court found it difficult to apply this test:

> But even knowing that the more stringent outcome materiality test applies, we are still left with the task of flushing out what evidence would suffice to satisfy the element. Since there was no disclosure, how the government would have treated defendants' individual claims is a hypothetical question. So we turn instead to the inquiries of whether compliance with the AKS was so important to the Medicare reimbursement process or so central to Medicare reimbursement agreements that compliance with the AKS was a condition of reimbursement so that failure to disclose non-compliance resulted in wrongful payments.

There was apparently no evidence presented as to what the government in fact would have done had it known there was a kickback. The court therefore proceeded to resolve what it had posed as a factual question of materiality as a question of law:

> The government has entered a statement of interest in this case, arguing that since the AKS is a critical provision of the Medicare statute, compliance with it is material to the government's treatment of claims for reimbursement. We agree. The AKS criminalizes receiving remuneration intended to affect decisions to purchase supplies for which payment may be made under Medicare. 42 U.S.C. § 1320a-7b(b)(1). Those convicted under the AKS they [sic] are barred from participating in the federal health care program. 42 U.S.C. § 1320a-7(a)(1). Compliance with the AKS is thus central to the reimbursement plan of Medicare. To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place. Reimbursing a claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact. This situation exemplifies the "inducing wrongful payment" test for determining materiality contemplated in Luckey, supra.

Apparently the court concluded that the fact that the law provides that a person criminally convicted under the antikickback statute will be prospectively barred from receiving any Medicare payments also means that a person who has not been so convicted, and who in fact has not been subjected to any Medicare sanction, is barred from billing the particular services induced by the kickbacks to the Medicare program. Whether or not this might be the right conclusion, the court's logic is a bit stretched. In addition, this decision appears to be inconsistent with the decision in the Southland case discussed above.

For more information, please contact Brad Tully at (310) 551-8160 or wtully@health-law.com.

Calendar

June 11 HLB Attorneys Jodi Berlin and Elspeth Delaney speak on HIPAA to the San Fernando Valley Continuity of Care Association.

Hooper Lundy & Bookman, Inc.

HEALTH CARE LAWYERS

1875 Century Park East, Suite 1600
Los Angeles, California 90067-2799

PRESORTED
FIRST-CLASS MAIL
U.S. POSTAGE
PAID
NASHVILLE, TN
PERMIT 989