*Honigman Miller Schwartz and Cohn's* *February 2001*

# HEALTH LAW FOCUS

***A Periodic Newsletter Published by The Health Care Department of Honigman Miller Schwartz and Cohn***

## GOVERNMENT CHALLENGES LEASE BETWEEN MICHIGAN HOSPITAL AND ORTHOPEDIC GROUP

*By: Carey Kalmowitz*

**Legal Background**. On September 26, 2000, the U.S. Attorney for the Eastern District of Michigan filed a civil complaint under the federal False Claims Act against McLaren Regional Medical Center (**"McLaren"**), Family Orthopedic Associates L.L.C., a Flint-based orthopedic group (**"FOA"**), and an affiliate of FOA, Family Orthopedic Realty L.L.C. (**"FOR"**). The Complaint alleges among other things, violations of the False Claims Act based on the parties' submission of Medicare and Medicaid claims for health care services that, according to the Government, were known to have been rendered in violation of the "Stark Law" and the "Antikickback Statute."

The alleged violations arose from McLaren's lease arrangement with FOR (whose shareholders comprise all but one of the physician shareholders of FOA), and the hospital's related medical director arrangement with FOA. From a Stark Law perspective, the government claims that the arrangements establish a "financial relationship" between the parties for which no Stark Law exception applies because the rental payments under the lease exceed fair market value. As a result, the referrals between the parties are prohibited. From an Antifraud Statute perspective, the government infers that, based on the alleged above fair market value remuneration to the FOA physicians for rent to FOR, coupled with referral practices of these physicians, the payments were made to induce the FOA physicians to make referrals to McLaren. According to the Complaint, the parties presented Medicare and Medicaid claims for payment which included certifications that the services reflected therein were provided in compliance with all laws and regulations regarding the provision of health care services, when allegedly the defendants knew or should have known that the services were not compliant because (in the Government's view) the payments were above fair market value.

In its Complaint, the Government seeks the imposition of "civil penalties required by law," as well as reimbursement for the allegedly false claims submitted by the parties. Under the False Claims Act, a person convicted of violating the statute is liable for civil monetary penalties of not less than $5,000 and not more than $10,000, plus three times

### NOTEWORTHY

On January 9, 2001, the IRS issued temporary regulations under the intermediate sanctions provisions of Section 4958 of the Tax Code - provisions which essentially tax insiders and managers on the amount of "excess benefits" (generally the difference from fair market value) they receive from tax-exempt entities. These regulations are effective for three years, beginning January 10, 2001. The regulations generally, though not universally, provide some additional flexibility as well as constructive guidance and some helpful examples for tax-exempt organizations. They also continue to place a premium, however, on adequate documentation and a reasonable approach to transactions. Issuance of the new regulations also may increase the likelihood of active enforcement of the intermediate sanctions provisions.

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the amount of damages the Government sustains because of that person's act.

**Underlying Facts**. According to the Government, the material facts underlying the parties' arrangement are as follows. Prior to entering into their lease/medical director transactions with McLaren, FOA furnished physical therapy (**"PT"**) and occupational therapy (**"OT"**) services from a medical office building owned by FOR, known as the "Bristol Road Building." The group, however, had determined in 1992 or 1993 to discontinue providing PT and OT services directly to its patients. In 1993, the FOA physicians and McLaren began negotiating the terms under which McLaren would establish a PT/OT clinic in the Bristol Road Building. In connection with that process, FOA's accountant purportedly prepared a memo indicating that "FOA would lose $150,000 in annual income if it discontinued its physical and occupational therapy practices as planned, ... and if the FOA physicians wished to recover that lost revenue, FOR should not accept a lease for less than $18 per square foot ..." The Complaint asserts that negotiations between McLaren and the FOA physicians considered a number of potential options for the lease arrangement's financial structure, involving varying per square foot rental amounts and varying medical directorship compensation (i.e., the higher the rental rate, the lower the medical director fee). Ultimately, in July 1994, McLaren allegedly entered into a five-year lease agreement with FOR (with an option to renew for an additional five years) pursuant to which the hospital would lease approximately 21,000 square feet at the Bristol Road Building for $17.00 gross/square foot per year, subject to annual four percent increases. According to the Complaint, in October 1994, McLaren entered into a 10-year medical director agreement with Dr. Walter (one of the FOA physicians) providing for a $25,000 per year medical directorship fee.

Three particular factors appear to underlie the Government's contention that (i) the compensation paid to the FOA physicians exceeded fair market value, and (ii) such payments were offered to induce the these physicians to refer to the McLaren PT/OT clinic at the Bristol Road Building.

First, according to the Complaint, during the month immediately prior to the McLaren-FOR lease agreement, FOR entered into an agreement with another entity (a durable medical equipment supplier) to lease approximately 3,500 square feet of space in the same building for $3.00/square foot less than the rate charged to McLaren.

Second, in a real estate tax appeal action filed by FOR, FOR argued that the Township of Flint assessed the value of the Bristol Road Building for tax purposes at an amount in excess of its true value. FOR asserted that the tax-assessed value on the property was excessive, in part, because the rental amount under FOR's lease with McLaren was above market prices for comparable lease space in the community. To support its position, FOR introduced a valuation report prepared by its appraiser, who determined market rent at the building to be $12.50 gross per square foot; further, in a 1996 deposition, a McLaren representative purportedly stated that "McLaren's $17.00 per square foot gross rent for the space at the Bristol Road Building was 'too high' and thus was not reflective of fair market value."

Third, the Government argues that during the term of lease arrangement, the number of PT and OT referrals made by FOA physicians to McLaren have increased substantially while referrals of such services to other Flint area PT and OT providers decreased. Further, on a number of occasions during the lease term, the Medical Director at the McLaren Family Care Centers, an affiliate of McLaren, allegedly wrote to the FOA physicians (a) stating that, notwithstanding reminders to the FOA staff, FOA physicians nonetheless have "ordered" that patients go to non-McLaren affiliated facilities for PT services, and (b) requesting, purportedly on behalf of McLaren, that all FOA patients in need of PT be referred to McLaren.

**Lessons to be Learned**. The final chapter has yet to be written in this case, and the providers ultimately may prevail when their defenses are heard. Nevertheless, irrespective of the answers to be filed in this case or the ultimate disposition of the case, readers should note the substantial risks associated with hospitals entering into transactions with physicians in which, at a minimum, the processes for establishing fair market value are susceptible to challenge, or as the government contends in U.S. v. McLaren, the financial arrangement between the parties is, by design, constructed to induce an ongoing referral relationship. These risks are heightened when, as in this case, the physician-

lessors are in a position to, and likely will, make referrals to the business operated by the hospital-lessee at the leased space. Additional factors that increase the likelihood of regulatory scrutiny of hospital-physician transactions (which the Complaint suggests were present in McLaren's arrangement) include:

(i) discrepancies in rental rates among tenants in a physician-owned building, especially when the rental rate paid by a tenant who potentially might expect to receive referrals from the physician-lessors is higher than the rate charged to tenants who are not potential referral recipients;

(ii) the appearance that the lease rate may have been determined by reference to factors other than commonly accepted principles for establishing fair market value (such as market comparables); for example, in U.S. v. McLaren, the Complaint suggests that the aggregate compensation to the FOA physicians was established, at least in part, through an "opportunity cost" approach, in which total compensation was designed to "make the physicians whole" for the income that they would forego by discontinuing the provision of PT and OT services; and

(iii) the absence of safeguards to ensure that physicians receiving remuneration from a hospital do not materially alter their referral patterns or, significantly more damaging, the existence of documentation or other evidence supporting the Government's inference that there was an understanding or expectation of referrals between the parties in connection with the arrangement.

**NOTEWORTHY**

On December 28, 2000, the Department of Health and Human Services published in the Federal Register the final rule regarding Standards for Privacy of Individually Identifiable Health Information. The final rule governs the use and disclosure of protected health care information. Protected health care information is individually identifiable information transmitted by electronic media or transmitted or maintained in any other form or medium. These standards apply to health plans, health care clearinghouses and health care providers that transmit health information in electronic form. They address when consent or authorization is required for using or disclosing an individual's protected health care information. They also include requirements governing business associate relationships, preemption of state law, proper forms of consents and authorizations, patient access to and amendment of health information and disclosure of protected health information in the context of fundraising, marketing and patient directories. The standards generally take effect on February 26, 2003 but will require initiating action now to ensure compliance. We are preparing a detailed analysis of these standards and their practical implications for distribution to our clients and friends. For more information or to request a copy of our analysis, please contact Linda Ross at (313) 465-7526 or at lsr@honigman.com.

## FEDERAL COURT PROVIDES GUIDANCE AS TO WHAT CONSTITUTES PROPER DISCLOSURE UNDER THE DISCOUNT EXCEPTION TO THE ANTI-KICKBACK STATUTE

*By: Patrick G. LePine*

A recent ruling by the United States Court for the District of Massachusetts is very instructive to health care providers attempting to structure transactions to fit within the discount exception to the Medicare and Medicaid Anti-kickback Statute (the "Discount Exception"). In United States v Shaw, a federal district court interpreted what constitutes "proper disclosure" under the Discount Exception.

National Medical Care ("NMC") provided, through its various subsidiaries, products and services to patients diagnosed with end-stage renal disease ("ESRD"). Dr. K. Glenn Shaw ("Shaw") was the past president of NMC Medical Products, Inc. ("MPD"), a wholly-owned subsidiary of NMC that manufactured, sold, and distributed products used in kidney dialysis, a primary treatment of ESRD. MPD sold these dialysis-related products both to NMC-owned clinics, called Bio-Medical Applications ("BMAs") and to

dialysis facilities not owned by NMC. NMC also had another division called LifeChem that provided clinical laboratory blood testing services both to the BMAs and to dialysis clinics not owned by NMC.

On February 10, 1999, a grand jury charged Shaw with a conspiracy to commit an offense against the United States. The grand jury charged, specifically, that Shaw conspired to violate the anti-kickback statute by inducing clinics to order and to arrange for ordering laboratory blood testing services from LifeChem, which services were paid for primarily by the Medicare program. According to the court, Shaw conspired to pay remuneration (in the form of rebates and special pricing) to independent dialysis clinics to induce those clinics to use LifeChem's laboratory services for, among other things, non-routine tests and medically unnecessary tests that were in whole or in part reimbursable under the Medicare program, all in violation of the anti-kickback statute. Shaw contended that the alleged remuneration described in the indictment was protected under the Discount Exception and, thus, did not constitute illegal remuneration.

**NOTEWORTHY**

On January 3, 2001, the Health Care Financing Administration issued the first of two parts of the final Stark II rule, which governs referrals by physicians for "designated health services" under the Medicare program to entities or persons with which the physician (or a member of his or her immediate family) has a "financial relationship. Phase I of this final rulemaking, which has a 90-day comment period, deals with those paragraphs of the Stark Law setting forth (i) the statute's general prohibition, (ii) the exceptions pertaining to both ownership and compensation relationships, and (iii) definitions that are used throughout the Stark Law. The regulations in Phase 1 become effective on January 4, 2002 (except for the rulemaking addressing referrals to home health, which becomes effective on February 5, 2001). HMSC is preparing an in-depth analysis of the final rule, with an emphasis on the practical implications of the regulations for health care entities' transactions with physicians.

The Discount Exception protects "a discount or other reduction in price obtained by a provider of services or other entity under a federal health care program ***if the reduction in price is properly disclosed and appropriately reflected*** in the costs claimed or charges made by a provider or entity under a Federal health care program." Shaw argued that the discounts he offered were protected under the Discount Exception because he had disclosed the discounts to the purchasers of the tests. However, the purchasers apparently did not reflect the discounts in their costs claimed or charges made. Shaw contended that "MPD attempted in good faith to comply with the statutory requirements" by enabling the purchasers of the tests to report to Medicare the reductions in prices they were receiving on the goods and services purchased. Further, Shaw contended that MPD's communication to the purchasers of the discounted tests regarding the price reductions constituted adequate disclosure under the Discount Exception and that it was the purchasers' responsibility to appropriately reflect those reductions in the costs claimed to the Medicare program. In response, the government argued that the Discount Exception requires that for discounts to be properly disclosed within the meaning of the statutory exception, "the material terms of the discounts" must appear on the face of the transaction between the supplier and the purchaser of the discounted goods or services.

The court noted that the purpose of the Discount Exception was "to encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs." However, for competitively lower prices (in the form of discounts or other reductions) to be exempt from criminal liability under the anti-kickback statute, the low prices must inure to the benefit of the Medicare and Medicaid programs. The court concluded that the essential component of the Discount Exception is that the applicable federal or state health care program share in and benefit from the reduced cost of the services or goods being provided at a discount or other reduced price. The court then stated that "the only way to pass on these benefits, however, is if Medicare and Medicaid are made aware of the competitively low costs so that the federal or state system reimburses the provider the percentage of only the reduced price" and, that is the purpose of the phrase, "properly disclosed and appropriately reflected" in the Discount Exception.

The court acknowledged that Shaw and the government were at cross-purposes as to the meaning of what constitutes proper and appropriate disclosure under the Discount Exception. The court rejected Shaw's argument that MPD, as the supplier of the goods and services at issue, was responsible only for disclosing the amount and method of the price reductions to the purchasers (and that the purchasers were solely responsible for reporting the reduced costs to Medicare or Medicaid). The court reasoned that Shaw's interpretation was based on an incorrect grammatical reading of the statutory exception. The court also rejected the government's argument that "proper disclosure" within the meaning of the Discount Exception required "full disclosure of the material terms of the transaction" as reading too much into the exception; by its terms the Discount Exception requires only "full and accurate disclosure of the price reduction," not disclosure of all of the materials terms of the transaction. In denying Shaw's motion to dismiss, the court ruled as follows:

> "In order for the statute (1) to prohibit both offers and acceptances of illegal remunerations and (2) to encourage certain discounts and other reductions in price that would increase competition and reduce health care costs, the discount exception must apply to both those who offer and those who accept discounts and other reductions in price. ... Thus both parties to the transaction, the seller-supplier and buyer-provider must properly disclose and appropriately reflect the reductions in price in order to find shelter under the discount exception."

Left unanswered by the court was what steps a seller, seeking the protection of the Discount Exception, must take to properly disclose and appropriately reflect any reductions in price offered to a buyer. The discount safe harbor to the Anti-kickback Statute specifically sets forth three sets of disclosure standards (depending upon the status of the buyer), one of which must be met by a seller seeking the protection offered by the discount safe harbor. In most situations, the discount safe-harbor requires the seller to: (a) fully and accurately report the discount on the invoice, coupon or statement submitted to the buyer; (b) inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligation to report such discount; and (c) refrain from doing anything that would impede the ability of the buyer to fully and accurately report the discount to Medicare or other applicable health care program. Arguably, a seller seeking to comply with the Discount Exception would be protected if the seller were to disclose and appropriately reflect the reductions in price offered to a buyer in a manner consistent with the requirements set forth in the discount safe harbor.

**NOTEWORTHY**

An Executive Order issued by President Bush may delay the effective date of certain federal regulations that had not yet taken effect by January 20, 2001.

To date, the court's ruling in United States v Shaw has not been appealed. Further, there is no appellate court decision interpreting the Discount Exception or incorporating the court's reasoning in Shaw. Nevertheless, health care providers structuring transactions to fit within the Discount Exception should review such transactions in light of this decision.

**OF FURTHER NOTE**

Health care providers also should note that the Shaw court recognized the independent status of the statutory discount exception vis a vis the discount safe harbor. The court explicitly acknowledged that the discount safe harbor and the statutory discount exception are "separate and independent bases for which certain activities may be excluded from criminal liability under the anti-kickback statute."

The question of whether the discount safe harbor had "swallowed" the statutory discount exception had been raised by commentators because the OIG on several occasions has indicated its belief that the discount safe harbor protects all discounts which Congress intended to provide protection for under the statutory discount exception. Because the terms of the discount safe harbor are quite complicated, the statutory discount exception, in many instances, allows a provider greater flexibility in structuring a particular arrangement.

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