Posted: March 25, 1998

[March 19, 1998]

[name and address redacted]

Re: Advisory Opinion No. 98-1

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you asked whether a contractual arrangement for distribution and billing services between Company A and Company B (the "Arrangement") constitutes grounds for sanction under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), for exclusion under sections 1128(b)(6) [claims substantially in excess of usual charges] and 1128(b)(7) [fraud, kickbacks, and other prohibited activities] of the Act, or for civil monetary penalties under sections 1128A(a)(1)(A) [items or services not provided as claimed], 1128A(a)(1)(B) [false claims], or 1128A(a)(7) [kickbacks] of the Act.

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the facts and agreements among the parties regarding the Arrangement.

In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented.

Based on the information you have provided, we conclude that payments under the Arrangement potentially constitute prohibited remuneration under the anti-kickback statute and may subject the parties to sanction under sections 1128B(b), 1128(b)(7), and 1128A(a)(7) of the Act. As further explained below, because we lack sufficient information to render an opinion, we reach no conclusion regarding the applicablility of sections 1128(b)(6), 1128A(a)(1)(A), or 1128A(a)(1)(B) of the Act. We note, however, that the Arrangement contains features that suggest that some or all of these authorities may be implicated.

I. FACTUAL BACKGROUND

A. The Parties

Company A is a manufacturer of, among other things, orthopedic “soft goods” products, including splints, cervical collars, supports, joint immobilizers, neoprene products, cast shoes, walkers, post-op shoes, traction products, anti-embolism stockings, cold packs, and elastic bandages. Company A sells its soft goods products directly to orthopedic physicians, among other customers. Typically, these physicians purchase a supply of orthopedic products for their offices sufficient to meet the anticipated needs of their patients. They prescribe the products where medically indicated and dispense them incident to the medical treatment provided to the patient. The physicians submit claims to third-party payers, including Federal and state health care programs.

Company B is a State X-based corporation engaged in the business of providing marketing consulting and medical billing in connection with home medical equipment.

2. The Arrangement

On July 1, 1997, Company A entered into an agreement with Company B pursuant to a contract entitled “Independent Contractor Agreement (Third Party Billing)” for certain distribution, marketing, and billing services.[1] Under the Arrangement, Company A will consign soft goods products to Company B, which will, in turn, consign them to physicians, except as otherwise noted in the discussion of the “Company B Loaner Program” below. Because they will be supplied to Company B and subsequently to physicians on a consignment basis, the products will remain Company A’s property until they are sold to a patient. Company A personnel will provide Company B with initial introductions to current customer accounts. Company B will assume responsibility for marketing to and servicing those accounts, as well as for developing new ones under a program it calls the “Company B Program.”

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[1] Company A has represented that the contract has been executed, but not implemented. Payments under the contract have not been made, except for one payment to Company B for consulting services not yet performed. Company A has represented that it will discontinue further implementation of the agreement if this Office concludes that the Arrangement could result in sanctions.

Under the Arrangement, Company B will bill, submitting claims to contracted insurance carriers, including the Medicare and Medicaid programs. Company B will accept assignment and bill Medicare and Medicaid under its own supplier numbers. On a regular basis, Company B will forward reimbursements to Company A, less Company B's fee, which ranges from 20 - 25% of collected revenues, depending on the dollar value of business generated in a calendar year.[2]

Company B will contract with payers and bill for Company A's products according to a fee schedule devised by Company B (the "Company B Contract Price List"). The Company B Contract Price List reflects, among other things, the Medicare fee schedule ceiling for each item under a column designated "Medicare Price". In nearly all cases, the "Medicare Price" listed exceeds the price at which Company A currently sells the identical product to any other purchaser (the "Company A List Price"). In many cases, the Company B "Medicare Price" exceeds the Company A List Price by 4-5 times, and in one case by over 13 times. The Company B Contract Price List price to private paying patients is lower than the Medicare Price in almost all cases.

The contract also provides that Company B will provide 100 person-days of consulting services to train Company A employees about sales and reimbursement issues. Company A will pay Company B $1,000 per day plus travel expenses for these services. The contract provides that the specific training requirements and outcomes to be achieved will be determined in advance of any training activities.

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[2]To ensure collections, Company B plans to charge patients' credit cards directly where their insurance carriers do not pay outstanding claims for over 90 days. We express no opinion on the legality of this procedure here; however, charging patients in this manner raises legal concerns in connection with assignment agreements under the Medicare program.

A further element of the Arrangement is an "Company B Loaner Program" applicable to Company A products supplied to Medicare patients. This program was developed in response to an interpretation of the supplier standards under 42 C.F.R. § 424.57(c) issued by the Durable Medical Equipment Regional Carrier (DMERC) for Region D. Under the DMERC interpretation, payment can only be made to a supplier when the supplier provides a product directly to the patient. This interpretation prohibits suppliers from leaving equipment in a physician's office for dispensing by the physician to a beneficiary for home use. Under the Company B Loaner Program, physicians generally will order Company A orthotic supplies for Medicare patients from Company B, which will arrange for Company A to ship the products directly to the patients' homes. Company B will telephone patients first to alert them to the forthcoming deliveries.[3] The products shipped by Company A will be treated as a consignment of goods to Company B. In a substantial number of cases, the patient will need to have a product dispensed immediately in the physician's office from the physician's consignment inventory. Such products dispensed in the physician's office for immediate use will be treated as "loaned" to the patient until the patient receives an identical replacement product by mail. Upon receipt of the replacement product, the patient will be asked to return it to the physician to restock the physician's inventory. Because the "loaned" product will not typically be reusable, in most instances the patient will continue to use the "loaned" product and will return the new, unused product to the physician. Patients who fail to return a product to the physician will be charged "rent" for the use of the product.[4]

II. LEGAL ANALYSIS

1. Anti-kickback Law and Prior Guidance

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by the Federal health care programs. 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Under the statute, referrals include, but are not limited to, arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made by a Federal health care program.

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[3]In addition, under the Medicare supplier rules, a supplier must, among other things, respond to beneficiary questions or complaints and disclose certain consumer information to beneficiaries. See 42 C.F.R. § 424.57(c) and (f).

[4]The processing of the paperwork related to the Company B Loaner Program will be handled by a Company B affiliate called Company C.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 476 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. This Office may also initiate administrative proceedings to exclude persons from the Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[5]

A number of statutory and regulatory "safe harbors" protect certain arrangements that might otherwise technically violate the anti-kickback statute from prosecution. See 42 U.S.C. §1320a-7b(b)(3); 42 C.F.R. § 1001.952. Pertinent here is a regulatory safe harbor that protects certain personal services and management contracts that, among other conditions, (i) fix in advance the aggregate compensation to be paid under the contract; (ii) base the compensation on fair market value; and (iii) do not determine compensation in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Medicare or a state health care program. For part-time, periodic, or sporadic services, the safe harbor requires that the schedule and precise length of the intervals for the performance of services be set forth in the contract. See 42 C.F.R. § 1001.952(d).

This Office has long been concerned about potentially abusive marketing arrangements involving health care goods and services paid for in whole or in part by Federal health care programs. In our preamble to the 1991 final safe harbor rules, 56 Fed. Reg. 35952 (July 29, 1991), we explained that the anti-kickback statute "on its face prohibits offering or acceptance of remuneration, *inter alia*, for the purposes of 'arranging for or recommending purchasing, leasing, or ordering any . . . service or item payable under Medicare or Medicaid.' Thus, we believe that many marketing and advertising activities may involve at least technical violations of the statute." 56 Fed. Reg. at 35974. Since publication of the 1991 rule, we have continued to learn of abusive relationships involving marketing activities that adversely affect the Federal health care programs and their beneficiaries.

(i) Percentage Compensation

As a threshold matter, the Arrangement does not qualify for safe harbor protection under the personal services and management contracts safe harbor, since the majority of the compensation to be paid by Company A to Company B is calculated based on a percentage of reimbursements collected by Company B for its sales of Company A products. Thus, the amount of compensation to be paid to Company B under the contract is not fixed in advance and is determined in a manner

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[5]Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under all three provisions.

that takes into account the value or volume of business generated between the parties, including Federal health care program business. See 42 C.F.R. § 1001.952(d).

Because compliance with a safe harbor is not mandatory, the fact that the Arrangement does not fit within a safe harbor does not mean that the Arrangement is unlawful. Percentage compensation arrangements are potentially abusive, however, because they provide financial incentives that may encourage overutilization of items and services and may increase program costs. Here, the percentage compensation arrangement is problematic for the following reasons:

- The Arrangement includes significant financial incentives that increase the risk of abusive marketing and billing practices. The percentage amount of Company B's compensation is a factor in evaluating the Arrangement's financial incentives. Moreover, the compensation is based on a percentage of the volume or value of business generated between the parties. Whereas Company A is not a Medicare supplier, Company B will be a supplier and will actually bill the Federal health care programs. The "Medicare Prices" shown on the Company B Contract Price List are in many cases substantially in excess of Company A's list prices. To the extent that revenues under the Arrangement exceed -- in some instances by substantial amounts -- the revenues derived from prices currently charged by Company A to its list price purchasers, both Company A and Company B stand to profit substantially.

- Company B will have opportunities to unduly influence referral sources and patients. The Arrangement involves active marketing, including direct contacts, by Company B and Company A to physicians who order and dispense orthotic products. In addition, the Arrangement provides Company B with opportunities to market directly to Medicare patients.

- The Arrangement contains no safeguards against fraud and abuse. The Arrangement is particularly susceptible to abusive practices because the orthotic products at issue are paid for by third-party payers and patients, including the government, instead of by the physicians who order and dispense them.[6] A recent OIG study confirmed that orthotics are subject to significant abuse. See Medicare Orthotics (OEI-02-95-00380, 10/97).

These reasons are sufficient to persuade us that the Arrangement poses an unacceptable risk of fraud and abuse so as to preclude a favorable advisory opinion; however, the determination of an

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[6] Although we have received no information indicating that the Arrangement involves any improper payments from Company B to physicians to induce them to order Company A products, we note that the Arrangement contains no apparent safeguards against such payments.

actual anti-kickback violation in any given case depends on the totality of the facts and circumstances, and no one fact or aspect of the Arrangement is necessarily determinative.[7]

(ii) Training Services

Company A has also requested our opinion with regard to whether the training fees to be paid by Company A to Company B violate the anti-kickback statute. As a threshold matter, the training fee portion of the contract does not satisfy the safe harbor requirement that for periodic, sporadic, or part-time services, the schedule and precise length of the intervals for the performance of the services be set in advance. However, as noted above, compliance with a safe harbor is not required.

Again, the initial inquiry is whether there is remuneration being offered, paid, solicited, or received to induce the referral of Federal program business. In this case, the issue is whether the contractual amount of $100,000 represents fair market value for the training services. Pursuant to 42 U.S.C. § 1320a-7d(b)(3), we are unable to make that determination. However, given that Company B's own staff will assume primary responsibility for marketing and distributing Company A's orthotic products under the Company B Program, the need for training of Company A's employees by Company B is unclear. It is possible that the training fees may represent disguised compensation for Company B's activities that generate business, including Federal program business.

2. Claims Issues and the Loaner Program

As indicated above, Company A has further inquired about the applicability to the Arrangement of certain permissive exclusion and civil monetary penalty provisions involving Federal program claims filing and reimbursement. However, no claims have actually been filed for Federal program reimbursement under the Arrangement, and we have no certified information regarding how, for example, Company B plans to report charges on its claims or code its claims. Accordingly, we make no determination with respect to these issues. We wish to make clear, however, that aspects of the Arrangement described in the materials submitted by Company A, including the Company B Contract Price List and the Company B Loaner Program, raise substantial questions with respect to claims filing and coding under the Arrangement. These questions further support our view the Arrangement may pose more than a minimal risk of fraud or abuse.

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[7] We have adopted for purposes of this opinion Company A's characterization of the Arrangement as one in which Company B is paid a fee for marketing and billing services. We note that there are two other plausible interpretations of the Arrangement. The Arrangement may be viewed as one in which Company B pays remuneration to Company A in the form of a percentage of collections on Company A's products. Alternatively, the Arrangement could be viewed as a joint venture between Company A and Company B. In both scenarios, amounts paid to Company A could be construed as payment for referrals of existing physician customers and their patients.

3. Conclusion

The advisory opinion process permits this Office to protect specific arrangements that "contain[] limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused." See Preamble to the 1991 final rule for safe harbors, 62 Fed. Reg. 7350, 7351 (February 19, 1997). The Arrangement contains no such limitations, requirements, or controls. To the contrary, the Arrangement provides multiple opportunities and financial incentives for marketing and billing activities that may lead, individually or collectively, to more than a minimal risk of Federal health care program abuse.[8]

Therefore, for the above-stated reasons, we conclude that the Arrangement may involve prohibited remuneration under the anti-kickback statute and thus potentially be subject to sanction under section 1128B(b) of the Act, to exclusion under section 1128(b)(7) of the Act, and civil monetary penalties under section 1128A(a)(7). Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process. In addition, although we have insufficient information to make a determination, we are concerned that the Arrangement may potentially involve activities that would subject the parties to exclusion under section 1128(b)(6) or civil monetary penalties under section 1128A(a)(1)(A) or 1128A(a)(1)(B).

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, modify or terminate this opinion.

Sincerely,

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[8] Our conclusion regarding the risk of abuse in relation to the anti-kickback statute should not be construed to mean that a finding of abuse is an implied element necessary to establish a violation of the statute.

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General