Pharmacy Joint Venture Raises Anti-Kickback Concerns

Joint ownership in a new long-term care pharmacy by owners of various long-term care facilities may generate prohibited remuneration under the federal anti-kickback statute (the “AKS”), under certain circumstances related to the management of operations, personnel and services. This was the finding of the Office of Inspector General (“OIG”) in Advisory Opinion No., 11-03 which was issued on April 7, 2011.

The entity that requested the opinion was an existing long-term care pharmacy (the "Existing Pharmacy") that provided pharmaceutical products and services to skilled nursing facilities, intermediate care facilities, assisted living facilities, and residential care facilities (the "LTC Facilities"). It was proposed that an employee of the Existing Pharmacy, its director of business integration (the "Employee"), would form a new long-term care pharmacy (the "New Pharmacy") and that he would own such New Pharmacy jointly with one or more of the owners of the LTC Facilities doing business in Existing Pharmacy's market area (the "Facility Owners"). Presumably, in the ordinary course of business and without the existence of the New Pharmacy, it would be these LTC Facilities that would refer patients to the Existing Pharmacy.

Employee would be awarded the initial shares in New Pharmacy at a nominal price. Facility Owners would receive dividends or distributions from the New Pharmacy in proportion to their share of ownership in New Pharmacy.

Existing Pharmacy would enter into a management agreement with New Pharmacy to do the following:

1. Provide all personnel in day-to-day services necessary for New Pharmacy to serve the LTC Facilities customers;
2. Make all decisions associated with New Pharmacy's operations;
3. Provide New Pharmacy with any office space it might need;
4. Direct the purchase of supplies and non-capital equipment New Pharmacy would need to operate;
5. Provide storage space for the inventory of New Pharmacy;
6. Supply non-controlled substances directly to New Pharmacy's customers;
7. Provide billing services for the New Pharmacy.

New Pharmacy would not have any employees. It would store its entire inventory either with its LTC Facilities customers or at the Existing Pharmacy's facility.

In exchange for the above services New Pharmacy would pay Existing Pharmacy a management fee equal to $1.25 for each prescription. New Pharmacy would also be responsible for the direct costs of pharmacy operations, billing services, consulting pharmacist services, clinical education and overhead expenses, among other expenses.

The OIG restated its continuing concern about certain problematic joint venture arrangements between those in a position to refer business, such as the LTC Facilities, and those furnishing items or services for which Medicare or Medicaid pays, such as the Existing Pharmacy. In other words, a problematic joint venture can occur when a health care provider in one line of business (here the LTC Facilities) expands into a related health care business by contracting with an existing provider of a related item or service to provide the new item or service to the health care provider's existing patient population. In the proposed transaction, the OIG expressed concern that the Facility Owners were expanding into such a related line of business.

In its analysis, the OIG refers to previous guidance it issued on suspect contractual joint venture arrangements. The OIG found that the arrangement analyzed in the previous guidance was very similar to the proposed arrangement. In finding that the proposed transaction was problematic and could generate prohibited remuneration, implicating the AKS, the OIG's looked at the following factors:

1. The Facility Owners would be expanding into a related line of business (long-term care pharmaceutical products and services) that would be dependent on referrals from the LTC Facilities.

2. The Facility Owners would not actually participate in the operation of New Pharmacy but rather would contract out substantially all New Pharmacy operations;

3. Existing Pharmacy is an established provider of the same services that New Pharmacy would provide and is in a position to directly provide pharmaceutical products and services in its own right, to bill insurers and patients in its own name, and to retain all available reimbursement;

4. Existing Pharmacy's employee would participate as owner and organizer of New Pharmacy;

5. The aggregate payment to Existing Pharmacy would vary with the volume of referrals from the LTC Facilities, as would the Facility Owners' income (which would be based upon the net profits and positive cash flow generated by New Pharmacy's operations);

6. Existing Pharmacy and the Facility Owners would share in the economic benefit of New Pharmacy.

For these reasons, the OIG concluded it could not exclude the possibility that the proposed arrangement was designed to permit the Existing Pharmacy to do indirectly what it could not do directly; to pay the Facility Owners a share of the profits from their referrals for pharmaceutical products and services. Given the above, the OIG found there was a significant risk that the proposed arrangement would in fact constitute an improper joint venture structured to reward the Facility Owners for the referrals, thus implicating the AKS.

Entities wishing enter into a joint venture with other entities already operating in their line of business and that are in a position to make referrals should carefully structure the joint venture in light of this new OIG opinion.

If you have questions regarding this Alert, please contact the authors, **Linda A. Malek** at 212.554.7814/lmalek@mosessinger.com, **Samuel J. Servello** at 212.554.7872/ sservello@mosessinger.com or **Osato F. Chitou** at 212.554.7823/ochitou@mosessinger.com.

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Linda A. Malek
Chair
212.554.7814
lmalek@mosessinger.com

Jeffrey M. Davis
212.554.7837
jdavis@mosessinger.com

Cathy J. Frankel
212.554.7848
cfrankel@mosessinger.com

David Rabinowitz
212.554.7815
drabinowitz@mosessinger.com

Abraham Y. Skoff
212.554.7897
askoff@mosessinger.com

Jill E. Anderson
212.554.7836
janderson@mosessinger.com

Samuel J. Servello
212.554.7872
sservello@mosessinger.com

Osato F. Chitou
212.554.7823
ochitou@mosessinger.com

JoAnna R. Nicholson
212.554.7661
jnicholson@mosessinger.com

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The Chrysler Building
405 Lexington Avenue
New York, NY 10174-1299
Tel: 212.554.7800 Fax: 212.554.7700

2200 Fletcher Avenue
Fort Lee, NJ 07024
Tel: 201.363.1210 Fax: 201.363.9210
Abraham Y. Skoff, Esq.
Managing Attorney for New Jersey

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