The Stark II Amendments and Their Relationship with the Fraud & Abuse/Anti-Kickback Provisions A Case Study Approach

Introduction

On March 26, 2004, the Stark II Phase II regulations were published and on July 26, 2004 they went into effect. These regulations construe the meaning of 42 USC §1395nn (the "Stark" law). It is important to always remember that the Stark law operates as a strict liability prohibition, meaning without a statutory exception to its provisions all transactions creating an unlawful financial relationship are prohibited. These types of financial relationships will virtually always be intertwined with the law and regulations concerning illegal remuneration under 42 USC 1320a-7b (the Anti-Kickback law). That statute imposes criminal penalties for giving money or things of value in return for referrals. It is important to note that the Fraud and Abuse provisions have an attached mens rea of "knowingly and willfully," meaning the statute is intent based.

This paper will discuss transactions involving physician ownership of certain entities, land use, and physician recruitment and retention. It will discuss how the Stark and Fraud and Abuse regulations interrelate. From the outset, the most important concept to understand is that the Stark regulations create "exceptions" to the rule. If one meets an exception, they are safe; if one does not meet an exception, they are in violation of the law. On the other hand, the Fraud and Abuse or Anti-Kickback regulations create "safe harbors." This means that if one meets a safe harbor, their transaction should not be in violation of the law; however, safe harbors are not

Normand F. Pizza, Esq. - Milling Benson Woodward LLP
909 Poydras Street, Suite 2300, New Orleans, La. 70112
504-569-7000; 504-569-7001 (fax)

exclusive grounds to avoid the Fraud and Abuse provisions. This is because of the intent element. If one does not have the intent to provide illegal remuneration, they are not in violation of the law. However, if your agreement is not anchored in a safe harbor, you may be required to prove that you did not have the intent to encourage a referral.[1] Finally, simply meeting the letter of the law for each safe harbor will not mean that there is complete compliance with the law. If there is intent to provide illegal remuneration even if a safe harbor is met, there will still be a violation of the Fraud and Abuse laws.

CASE EXAMPLES

Hospital Joint Venture with Physicians Who Operate a Diagnostic Imaging Center

Hospital seeks to jointly own with a physician or physicians a diagnostic imaging center ("IC"). The prospective physician owners will be in a position to refer patients to the Imaging Center. Both the Stark II, Phase II Regulations and the Fraud and Abuse provisions apply.

The Stark Regulations are found at 42 CFR 411.356. The Fraud and Abuse Safe Harbors are located at 42 CFR 1001.952. Stark provides for additional exceptions in "Rural" areas. Fraud and Abuse Safe Harbors are relaxed in Medically Underserved Areas (MUAs). Both Rural and MUA are defined terms.[2]

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[1] Advisory Opinions 03-02 and 03-03 deal with proposed arrangements between a hospital and an ASC. Advisory Opinions 03-12 and 03-13 treat proposed ventures involving imaging services. These Opinions make clear that the failure to meet the requirement of a Safe Harbor does not mean that the Anti-Kickback Law has been violated.

[2] The location of a MUA and a Rural area can be found online. For Rural, see http://www.census.gov/population/www/estimates/metroarea.html. For MUA, see http://bphc.hrsa.gov/databases/newMUA/.

A joint venture for a diagnostic imaging center in an area that is both rural and medically underserved must meet the following requirements. Under Stark, physician referral to a rural provider of designated health services in which he has an ownership interest meets the exception if substantially all (at least 75%) of all designated health services performed by the entity are furnished to individuals residing in a rural area.

The Fraud and Abuse Safe Harbor excepts from the definition of illegal remuneration returns from investment interests when the entity is held by either active or passive investors and requires the entity to be located in a medically underserved area. Also the following eight standards must be met:

1. No more than 50% of the investment interests may be held by those in position to make referrals,

2. The terms of the investments must be the same for those who are not in position to make referrals,

3. The terms of investment are not related to past or future expected volume of referrals,

4. There can be no requirement to make referrals,

5. The entity cannot market products or services to passive investors differently from non-investors,

6. 75% of the dollar volume of business must be derived from those in a medically underserved area or medically underserved population,

7. The entity cannot make loans or guarantee loans which are used to obtain the investment interest, and

8. The amount of the return on invested capital must be directly proportional to the investment interest.

Contrast this with a situation where the joint venture is located in an area which is neither rural nor medically underserved. The Stark exceptions are wholly concerned with the venture being located in a rural area. If more than 25% of the patients treated at the Imaging Center come from outside the area, the venture cannot meet the Stark exception. The investors cannot refer to the Imaging Center. If the Imaging Center is drawing 75% of its patients[3] from a Rural area, it is likely that it is also a MUA[4], but it is not guaranteed. So a separate check of the medically underserved status must be made.

If the IC venture does not fall within a MUA, it can still attempt to meet the Small Entity "60/40" Safe Harbor. Its requirements are as follows:

1. No more than forty percent (40%) of the investment interests of the entity may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity,

2. No more than forty percent (40%) of the gross revenue of the entity may come from referrals or business otherwise generated from investors.

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[3] Stark requires 75% of the venture's patients come from the Rural area. There is no reference to the venture's revenues. The Safe Harbor for a MUA is for 75% of patient revenues to come from patients in the MUA.

[4] A medically underserved area can be in an urban area as well as a rural area. Check the website for status as a MUA.

The Small Investment (60/40) Safe Harbor does not refer to the place (rural, urban, MUA) where the patient revenues are derived.

AMBULATORY SURGICAL CENTER

Special exceptions have been created specifically for ambulatory surgical centers. These exceptions are not concerned with the entity being located in either a rural or medically underserved area. The services provided in an ASC are not Designated Health Services under Stark. So the analysis of whether the ASC violates law must be done by examining the Anti-Kickback Law and Regulations and state law.

The hospital and physicians want to form a joint venture ASC. Illegal remuneration, under the regulations, will not include payment for an investment interest as long as the entity is a certified ASC, its operating and recovery room space is used exclusively as an ASC, and patients who are referred to the entity are fully informed of the investor's interest. Also, the regulations for the specific type of ASC must be met. The regulations would define our example, not surprisingly, as a hospital/physician ASC. If one investor is a hospital, the entity must meet the requirements for the hospital/physician ASC as well as the other investors must fit the requirements for either a surgeon-owned, a single-specialty, or a multi-specialty ASC; the requirements for a group practice or surgical group practice; or be investors not employed by the entity or any investor, not in a position to provide items or services to the investors, and are not in a position to make referrals to the entity or its investors.

Although this paper will not go into the exact specifics of the above entities, a few

general comments are necessary. Surgeon-owned, single-specialty, and multi-specialty ASCs all have requirements about the investment interests not relating to referrals, percentages of income that come from the performance of procedures, prohibitions on loaning of funds for the investment, proportionality of payment received to investment interest, billing practices to Medicare, and non-discrimination. Group practice regulations require equity interests in your own practice or group practice that are only held by licensed health care professionals. The interests must also be in the whole group and not a subdivision thereof.

The hospital/physician ASC must also meet the following requirements: the investment terms cannot be related to volume of referrals, the entity cannot make loans to obtain investment interest, payments must be directly proportional in relation to the investment interest, the entity cannot discriminate against those receiving care under Federal Health Care programs, space cannot be leased at hospital investor's facility unless the requirements for rental of office space are met, there cannot be separate billing to Medicare for ancillary services, the hospital may not include ASC costs in its cost report, and the hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.

SPECIALTY HOSPITALS

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA 2003") altered the "Whole Hospital" exception so as to disqualify specialty hospitals from the Whole Hospital exception for an 18 month period beginning December 8, 2003 and ending June 8, 2005. This moratorium on physician investment and specialty hospitals also applies to

hospitals in Rural areas. The act defines a specialty hospital as one in the 50 states or the District of Columbia that is primarily or exclusively engaged in the care and treatment of one of the following:

1. Patients with cardiac conditions;
2. Patients with an orthopedic condition;
3. Patients receiving a surgical procedure;
4. Patients receiving any other specialized category of services designated by the Secretary (and so far there are no such designations by the Secretary).

The following are not specialty hospitals :

1. Psychiatric hospitals;
2. Rehabilitation hospitals;
3. Children's hospitals;
4. Long term care hospitals;
5. Certain cancer hospitals.

Some specialty hospitals are grandfathered. Grandfathering occurs if the hospital was in operation or under development as of November 18, 2003, and a) the number of physician investors has not increased; b) specialized services furnished by the hospital have not changed; c) any increase in the number of beds has occurred only on the main campus of the hospital and does not exceed the greater of 5 beds or 50% of the beds in the hospital.

Parties may submit advisory opinion requests to CMS to determine if the specialty

hospital was under development as of November 18, 2003. CMS advises that it will consider the following in these determinations:

a) When architectural plans were completed;

b) When funding was received;

c) Whether zoning requirements were met; and

d) Whether the necessary approvals from appropriate state agencies were received.

In the comments to the Stark II, Phase II regulations, the following was stated:

> "In this Phase II rulemaking, we are adopting the January 1998 proposed rule for the hospital ownership exception without change, except for conforming amendments to the corporate provisions, Section 507 of MMA."

The existing regulation in Stark II, Phase I was that with respect to DHS provided by a hospital, an ownership or investment interest in a hospital (and not merely a subdivision of the hospital) is not a financial relationship within the meaning of Stark if the referring physician is authorized to perform services at the hospital. But please note this caveat that is also set forth in the Stark II, Phase II regulations:

> "Notwithstanding, physician ownership of hospitals may implicate the Anti-Kickback Statute, Section 1128B(b) of the act, depending on the circumstances. For example, specialty hospital ventures in which investment opportunities are substantially limited to physicians in a position to refer to the specialty hospital may implicate the Anti-Kickback Statute."

Land Lease

Another issue under both the Stark and the Fraud and Abuse provisions is land/office space rental. If the Imaging Venture is not drawing patients from a Rural area, physicians ask if it is possible to participate in the venture. Stark stops referring doctors from owning a part of the venture. But they may be able to lease the facility to the joint venture that operates the Imaging Center. Such a lease would fall under the rental of office space exemptions/safe harbors of the Stark and the Fraud and Abuse laws. Stark excludes from the definition of financial relationship payments for office space which meet the following conditions: the agreement must be in writing for a term of at least one year, the space rented must not be more than is necessary, the rental charges must be consistent with fair market value and not take into account the volume or value of referrals, and the agreement must be commercially reasonable as if no referrals were made.

A similar provision exists under the Fraud and Abuse safe harbors. Remuneration does not include payments by a lessee to a lessor for use of premises as long as the lease is in writing and covers all of the premises to be leased for the term of the lease and specifies the premises covered, if the lease is only for certain intervals those intervals must be specified, the term of the lease must be for at least one year, the aggregate rental value must be set in advance and be consistent with fair market value, and the space rented cannot be more than what is reasonably necessary.

Remember, in this situation it does not matter whether the rental is in a rural area or a medically underserved area or whether the lessor-entity is an IC or an ASC. Only the above stated provisions must be met.

Physician Recruitment - Stark II, Phase II Regulations

The next that will be addressed is that of physician recruitment. Certain payments from a hospital to a physician to establish a practice in an area would appear to create an unlawful financial relationship or illegal remuneration due to the potential influence for the physician to refer patients to the paying hospital. However, in certain instances these payments can be made because an exception/safe harbor has been granted by Stark or the Fraud and Abuse provisions. The Stark exceptions are found at 42 CFR 411.357(e) and the Fraud and Abuse safe harbors are found at 42 CFR 1001.952(n).

Take for example a physician who is recruited from 2 miles away. Stark grants an exclusion from the definition of unlawful financial relationship for payments made to physicians to induce them to relocate. However, as part of the definition of relocate, a physician must move his practice a minimum of 25 miles. Therefore, in this example, the Stark exception could not be met.

However, now let us assume the practice will be moved 25 or more miles. The definition of relocate also requires that 75% of the revenues of the new operation be from new patients. If this requirement is met, then the physician will have "relocated." Stark further requires that the arrangement be in writing and not be conditioned on referrals or determined by potential referrals, and further requires that the physician can establish staff privileges at other hospitals. If these requirements are met, the payment will meet a Stark exception and will not constitute an unlawful financial relationship.

Continuing the example, we must now apply the Fraud and Abuse analysis. Payments may be made to a practitioner for him to move to a health professional shortage area (HPSA) for his specialty. For example, if our practitioner is a cardiologist he must move to a HPSA for cardiologists according to the Fraud and Abuse provisions. The following requirements must also be met – there must be a written arrangement, 75% of the revenues must be from new patients, the benefits of the arrangement cannot last longer than three years or be renegotiated during that time, there cannot be a requirement to make referrals, the payments cannot be based on referrals, the physician shall be allowed to have staff privileges at other hospitals, Medicare patients cannot be treated in a discriminatory manner, 75% of the revenues generated must be from patients in an HPSA, MUA, or medically underserved population, and finally, payments cannot be made which benefit someone, other than the recruited practitioner, in a position to make referrals. If all these requirements are met, then the payment will also meet the Fraud and Abuse safe harbor.

Now what would happen if the physician had just completed his residency or was only in practice for a short amount of time? Both the Stark and the Fraud and Abuse provisions create an exception/safe harbor for those in practice for less than a year. These provisions are less strenuous than those for physicians who had been in practice for longer times. Under Stark, the relocation requirement is removed meaning that the new physician does not have to move his practice 25 miles nor must 75% of the revenues be from new patients. However, the physician is required to establish his practice within the geographic area of the hospital (lowest number of

contiguous zip codes from which the hospital obtains 75% of its inpatients). The same general requirements about a written arrangement, no referrals, and staff privileges still apply.

Under the Fraud and Abuse provisions, the requirements are the same as those for a physician with a previously established practice. The physician must still locate himself in a HPSA for his specialty that is served by the entity recruiting him. However, if the practitioner is not leaving an established practice, meeting the requirement of 75% of revenue from new patients is not necessary.

REMUNERATION PROVIDED BY HOSPITAL TO A PHYSICIAN INDIRECTLY THROUGH PAYMENTS MADE TO ANOTHER PHYSICIAN OR PHYSICIAN PRACTICE

The Stark II, Phase II Regulations provide these new regulations for payments made to a physician or physician practice when a new physician is recruited to the area and will go to work for that physician practice and not for himself. These rules govern payments to the practice. They are as follows:

1. The written agreement is signed by the party to whom the payments are directly made (in other words, to the newly recruited physician).

2. Except for actual costs incurred by the physician or physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

3. In the case of an income guarantee made by the hospital to a recruited physician who joins a physician or physician practice, the costs allocated by the physician or physician

practice to the recruited physician do not exceed the actual additional, incremental costs attributable to the recruited physician. In other words, if overhead for the practice is $1,000,000, there were two physicians in the practice originally and a third physician arrives, the practice cannot simply add the additional costs of the new physician and divide it by three. Only the actual additional, incremental costs can be added to the guarantee.

4. Records of the actual costs in the passed through amounts are maintained for a period of at least five years and made available to the Secretary of Health and Human Services upon request.

5. The remuneration from the hospital under the arrangement is not to be determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

6. The physician or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care. (This has been interpreted by the OIG as meaning that non-competition prohibitions cannot be added to the agreement. The comments to the regulations also detail this prohibition.)

7. The arrangement does not violate the Anti-Kickback section of federal or state law or regulation governing billing or claims submission.

Retention Payments

In contrast to a situation in which payment is given to a physician to move his practice is the situation in which a hospital wants to give payment to prevent a physician or practitioner from moving elsewhere. There is no provision in the Fraud and Abuse safe harbors which exempts this type of transaction meaning one making this type of payment would have to prove lack of intent. However, Stark does have an exception for retention payments which is found at 42 CFR 411.357(t).

First the general requirements that the arrangement must be writing, the arrangement cannot be conditioned on referrals, remuneration cannot be determined by potential referrals, and the physician must have the ability to establish staff privileges at other hospitals are required. Next, the geographic area served by the hospital must be an HPSA although it does not have to be an HPSA for the physician's specialty as was the case with recruitment payments. The physician must have a bona fide firm, written offer from another hospital which would require the physician to move his practice at least 25 miles and outside of the geographic area served by the hospital.

Louisiana State Law

The Louisiana Legislature also has had something to say about the preceding types of transactions – exactly what the feds have to say. Under La. R.S. 37:1745(B), no payment shall be offered for referring or soliciting payments whether payment is made directly or indirectly.

FAIR MARKET VALUE - STARK SAFE HARBOR

Stark II, Phase II Regulations added a so-called Fair Market Value Safe Harbor. It provides as follows:

> An hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using either of the following two methodologies:
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> 1) the hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market;
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> 2) the hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) and at least four of the following surveys and dividing by 2,000 hours. The surveys are:
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> a) Sullivan, Kotter, and Associates, Inc. Physician Compensation and Productivity Survey;
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> b) Hay Group - Physicians' Compensation Survey;
>
> c) Hospital and Health Care Compensation Services - Physician Salary Survey Report;
>
> d) Medical Group Management Association - Physician Compensation and Productivity Survey;
>
> e) ECS Wattson Wyatt - Hospital and Healthcare Management Compensation Report;
>
> f) William M. Mercer - Integrated Health Networks' Compensation Survey.

Note the general definition of Fair Market Value remains unchanged.

Normand F. Pizza, Esq. - Milling Benson Woodward LLP
909 Poydras Street, Suite 2300, New Orleans, La. 70112
504-569-7000; 504-569-7001 (fax)