

AFROC



ASSOCIATION OF FREESTANDING RADIATION ONCOLOGY CENTERS

Our Voice in Washington

The Source

October 2008

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AFROC SELECTS NEW MANAGEMENT COMPANY

AFROC has selected Drohan Management Group (DMG) as the organization's new service and support team. DMG began its partnership with AFROC October 1, 2008, and will provide full-service management for the group.

DMG is a full-service Association Management Company based in Reston, VA. The company has been operational since 1986, and its executives have over 200 years of combined experience in the association field. DMG has a staff of 40 and manages 20 national and international organizations on both full-service and project bases.

New AFROC Mailing Address and contact information:

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2008 DUES

The third and final invoices for 2008 AFROC dues were mailed in June. To assure that your name will remain on our mailing list, please let us hear from you.

It is estimated that 95% of your dues can be taken as a business expense.

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AFROC's 21st Annual Conference

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LEGISLATIVE NEWS

AFROC SUBMITS COMMENTS ON PROPOSED 2009 PHYSICIAN FEE SCHEDULE

AFROC recently submitted comprehensive comments on the proposed CY 2009 Physician Fee Schedule, objecting to CMS's plans to revalue certain procedures (including IMRT) whose utilization is growing rapidly. In addition, AFROC requested exclusion of radiation oncology services (including especially IGRT) from the list of services that would require physicians' practices to register as IDTFs. In this regard, AFROC pointed out to CMS that IGRT is not a diagnostic service and should not be regulated in the same way as diagnostic MRI, CT, and other diagnostic imaging services.

For the same reasons, AFROC objected to CMS's proposal to subject IGRT and potentially other radiation oncology services to the anti-markup prohibition, which are supposed to be applicable only to diagnostic services. If this prohibition were extended to IGRT services, radiation oncology centers could be precluded from obtaining Medicare payment for the equipment and overhead involved in the provision of IGRT and any other radiation oncology services that CMS determined to be "diagnostic" services under the Medicare Act.

Finally, AFROC also submitted comments in response to CMS's solicitation of data on malpractice costs associated with technical component services; however, it is anticipated that further data may be needed on this issue.

OIG CASTS DOUBT ON LEGALITY OF PART-TIME LEASES OF RADIATION ONCOLOGY FACILITY BY UROLOGISTS

On August 26, 2008 the Office of the Inspector General (OIG) of the Department of Health and Human Services posted Advisory Opinion No. 08-10, which addresses the legality of certain types of lease arrangements between a radiation oncology facility and referring urologists. While the OIG did not determine that the particular arrangement involved in the Advisory Opinion was illegal, the OIG does express significant concerns that the arrangement has the potential to violate the

anti-kickback provisions of the Medicare fraud and abuse law.

Under the proposed arrangement, a freestanding radiation oncology center that provides IMRT proposed to enter into an arrangement with area urology practices, some of which currently refer their patients to the center for IMRT and some of which do not. The proposed arrangement called for each urology group to enter into a part-time block lease with the center, under which the center was to provide the facility and personnel associated with the provision of IMRT to that urology group's patients. Radiation oncologists associated with the center were to provide professional services to each urology practice's patients, on an independent contractor basis, during the time that the center was leased to that particular urology practice. Bills for both the technical and professional components were proposed to be submitted in the name of the urology group, by the center, acting as the urology group's agent.

Each urology group would pay the Facility fixed fair market value rent for the space, equipment, personnel expenses and administrative expenses and would pay the radiation oncologist(s) on an independent contractor basis for his or her professional services.

The radiation oncology center requesting the Advisory Opinion indicated that the arrangement was structured to meet the Stark Law requirements applicable to "in office ancillary" services, since each urology group would see patients at least six hours per week in the same building where the IMRT services were provided.

While the OIG expressed no view on whether or not the arrangement qualified for a Stark Law exception, it did indicate concerns about the arrangement under the anti-kickback provisions of the Medicare/Medicaid anti-fraud and abuse law. Under the Federal anti-kickback statute it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. The potential criminal liability flows to both parties of an impermissible arrangement. The statute is violated when even just one purpose of the remuneration was to obtain money for the referral of services.

The OIG Advisory Opinion does not provide an opinion on whether the amount paid for the space, equipment



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and personal services by the Center fit under the applicable safe harbors for those payments. Rather, the OIG compared the arrangement under consideration to other types of “contractual joint ventures” under which a provider provides “turnkey arrangements” to a referral source. The OIG pointed out the following features of the arrangement, which it considers troubling:

- The urologists would not participate in performing the IMRT;
- The urologists would contribute little in the way of capital, money, or human resources and, therefore, would assume very little risk;
- The urologists would be in a position to ensure the success of the joint venture by referring patients to the Facility and by selecting IMRT as the therapy for the patients;
- The center is an established provider of the same services involved in the proposed venture and can provide IMRT in its own right and bill Medicare (and other payers) in its own name; and
- The center and the urology group would share in the economic benefit of the IMRT arrangement, and so the arrangement appears to allow the Facility to do indirectly what it can’t do directly -- offer the urologists remuneration for referring patients to it.

The OIG indicates that the “compensation” that violates the statute in this case is not the compensation that flows between each urology practice and the center-- which was stipulated to reflect fair market value--but

rather the compensation that the urology group receives through the difference between the payment it makes to the center for the services and the reimbursement it receives from the payers such as Medicare for patients it refers.

For more information, see the Advisory Opinion at:

<http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-10A.pdf>.

CMS FINALIZES CHANGES THAT CURTAIL PHYSICIAN “SELF REFERRAL”

On July 31, 2008, CMS published the final FY2009 Inpatient Prospective Payment Systems and FY 2009 Rates (“Final IPPS Rule”), which includes a number of extremely important changes to the regulations implementing the federal physician self-referral prohibition (the “Stark Law”). These regulations will limit the availability of Stark law exceptions for referring physician investments in “turn-key” transactions and for percentage and other volume-related leases of space and equipment.

“Turn- Key” and “Under Arrangements” Joint Ventures

Many joint ventures that include referring physicians (such as urologists or medical oncologists) are organized as “turnkey” businesses whose purpose is to construct the facility, obtain the equipment, and hire the employees necessary to operate a radiation oncology facility. The business is then leased or provided on a turnkey basis to a radiation oncology practice or hospital, which function as the “provider” of the services. (If the services are furnished to a hospital, they are often billed under the provisions that allow hospital billing for services furnished “under arrangements” with the hospital. “Under arrangements” transactions preclude the non-hospital supplier from billing any entity other than the hospital for the services provided.)

Under the regulations that have been in effect until now, the returns to the referring physician owners of a turnkey operation were characterized as “indirect compensation” to the referring physicians. The Stark Law exception available for “indirect compensation” arrangements is very broad, making investment in turnkey operations an attractive option for referring

physicians seeking to profit from referrals without incurring Stark Law exposure.

Under the revised regulations, such turnkey joint ventures must meet the exception requirements applicable to “direct” financial relationships. These exception requirements are much more restrictive, and referring physician ownership is generally prohibited unless the joint venture is located in a rural area or meets the group practice exception requirements (which cannot be met if a number of otherwise unassociated practices are involved).

New “Stands in the Shoes” Requirements

The revised regulations also preclude referring physicians who are part-owners of their practices from taking advantage of the more liberal “indirect compensation” exception by having compensation run to them through their practices. Under the revised regulations, a physician who has an ownership interest in his or her practice “stands in the shoes” of his or her physician organization (i.e. his or her practice) for the purpose of Stark Law analysis. On the other hand, physician employees who do not have an ownership interest in their practices and therefore have no ability or right to receive the financial benefits of ownership or investment (such as dividends, the distribution of profits, or sale proceeds) – are not required to stand in the shoes of their physician organizations.

CMS acknowledges that because of these changes, some arrangements may need to be modified during the term of the arrangement to become Stark Law-compliant and is modifying the regulations that requires the term of an arrangement be “set in advance” in order to facilitate the necessary amendments. CMS delayed the effective date of the provisions applicable to “turn key” operations (including “under arrangements” transactions) until October 1, 2009.

Percentage-based and “Per Click” Leases of Space and Equipment

In addition, CMS has limited the extent to which percentage-based payments and “per click” or “per service unit” formulas are permissible under the Stark Law exceptions. The Stark Law exceptions involved are those that require compensation to be “set in advance” and “not vary based on the value or volume of

referrals or other business generated between the parties”: The primary exceptions affected are those for space and equipment leases. Existing lease agreements where the rental rate is determined using a percentage-based or “per click/unit of service” compensation formula must be restructured to comply with the new language by October 1, 2009.

CMS believes that block time leases, depending upon how they are structured, may meet the requirements of the space and equipment lease exceptions. However, CMS indicates that it is continuing to study the ramifications of block time leasing arrangements and may address these arrangements in the future.

Ownership or Investment Interest in Retirement Plans

While the Stark Law specifically excludes an interest in a retirement plan, the final Stark Law regulations makes it clear that if the retirement plan invests in a provider of radiation oncology or other services covered by the Stark Law, the exclusion does not apply.

Period of Disallowance

The “period of disallowance” refers to the period of time when a financial relationship fails to satisfy all of the requirements of a Stark Law exception. During the period of disallowance, a physician may not refer a Medicare patient for radiation oncology services or other DHS to the entity with whom the physician has a prohibited financial relationship, and the entity may not bill Medicare for any DHS referred to it by the physician. CMS has historically interpreted the period of disallowance as beginning on the date the arrangement first fell out of compliance and ending on the date the arrangement came into compliance or ended.

In the final Phase III regulation, CMS indicates that when noncompliance with an exception exists because one party is paying for items or services in excess or less than fair market value, the period of disallowance will continue until all of the overpayment (or underpayment) is rectified.

Alternative Methods of Compliance with Signature Requirements in Certain Exceptions

Many exceptions to the Stark Law require the parties to sign a written agreement. The final Phase III

regulations indicate that parties may obtain a missing signature within a defined period of time (ninety days from the beginning of the financial relationship if the failure to obtain the signature was inadvertent or thirty days from the beginning of the financial relationship if the failure to obtain the missing signature was intentional or knowing). This provision may only be used by a health care entity once every three years with respect to the same referring physician.

Burden of Proof

The Phase III regulations indicate that in any appeal of a denial of payment made on the basis of a violation of the Stark Law, the provider bears the initial burden of proof.

Conclusion

In general, the revised Stark Law regulations will close a number of the “loopholes” that have been utilized most commonly to enable medical oncologists, urologists, and other referring physicians to obtain a financial benefit for their referrals. Because a number of the most important changes will not become effective until October of 2009, it is anticipated that, over the next year, there may be substantial restructuring of existing arrangements with referring physicians.

Significantly, however, the new regulations do not substantially alter the “in office ancillary services” exception--commonly known as the “group practice” exception. For this reason, physician groups that meet the regulatory definition of a “group practice” may still own and operate radiation oncology centers, so long as certain billing, supervision, and place of service requirements are met.



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