The Florida Senate

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Committee on Health Regulation

REFERRALS BETWEEN HEALTH CARE PROVIDERS IN DELIVERY OF RADIATION THERAPY SERVICES

Statement of the Issue

It is well-recognized that the referral of a patient by a health care provider to another provider of health care services in which the referring provider has an investment interest (known as self-referral) represents a potential conflict of interest. The Legislature has found that these referral practices may limit or eliminate competitive alternatives in the health care services market, may result in overutilization of health care services, may increase costs to the health care system, and may adversely affect the quality of health care. However, the Legislature has also recognized that it may be appropriate under certain circumstances for such referrals to occur. Accordingly, the Legislature enacted law addressing financial arrangements between referring health care providers and providers of health care services in 1992 that is now codified in s. 456.053, F.S., the Patient Self-Referral Act of 1992. This law is similar to s. 1877 of the federal Social Security Act,[1] which is also known as the Ethics in Patient Referrals Act, or the "Stark Law" in reference to U.S. Representative Pete Stark, who sponsored the legislation.

The federal and state laws both generally prohibit self-referrals while providing certain exceptions. Florida's Patient Self-Referral Act of 1992 contains an exception to the prohibition against self-referrals for health care items or services provided by a sole provider or within a group practice setting. During the 2011 Regular Legislative Session, some members of the Legislature expressed interest in revising the definition of "group practice" in s. 456.053, F.S., in relation to the provision of radiation therapy services. The definition was not amended during the 2011 Regular Legislative Session, but members of the Florida Senate expressed an interest in a more thorough exploration of the potential public benefit and effect of such an amendment.

This issue brief examines radiation therapy, the patient populations receiving radiation therapy, the Stark Law, the Patient Self-Referral Act of 1992, self-referral laws in other states, and the potential public benefit or detriment of altering the status quo with respect to physician self-referrals for radiation therapy services.

Discussion

Radiation Therapy

Radiation therapy is one of numerous options for treating cancer that may be chosen based on the many circumstances involved in any particular cancer case. Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells. X-rays, gamma rays, and charged particles are types of radiation used for cancer treatment. The radiation may be delivered by a machine outside the body (external beam radiation therapy) or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy). Systemic radiation therapy uses radioactive substances, such as radioactive iodine, that travel in the blood to kill cancer cells. About half of all cancer patients receive some type of radiation therapy sometime during the course of their treatment.[2]

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[1] *See* 42 U.S.C. 1395nn.

[2] National Cancer Institute, U.S. Dept. of Health and Human Services, *Radiation Therapy for Cancer Fact Sheet,* June 30, 2010, p. 1, available at: http://www.cancer.gov/cancertopics/factsheet/Therapy/radiation (last visited Aug. 17, 2011).

Radiation therapy kills cancer cells by damaging their DNA, which incorporates the molecular structures inside cells that contain genetic information passed from one generation of cells to the next. Radiation therapy can either damage DNA directly or create charged particles (free radicals) within the cells that can in turn damage the DNA. Cancer cells whose DNA is damaged beyond repair stop dividing or die. When the damaged cells die, they are broken down and eliminated by the body's natural processes.[3]

When a patient and his or her physicians decide to proceed with radiation therapy, a radiation oncologist develops the patient's treatment plan typically using detailed imaging scans that show the location of the patient's tumor and the normal areas around it. These scans are usually computed tomography (CT) scans, but they can also include magnetic resonance imaging (MRI) scans, positron emission tomography (PET) scans, and ultrasound scans.[4] The radiation oncologist then determines the exact area that will be treated, the total radiation dose that will be delivered to the tumor, how much dose will be allowed for the normal tissues around the tumor, and the safest angles (paths) for radiation delivery. Other medical professionals working with the radiation oncologist (including physicists and dosimetrists) use sophisticated computers to design the details of the radiation plan that will be used and to monitor the ongoing delivery of the radiation treatment.[5]

Radiation therapy is sometimes given with curative intent, i.e. with the goal of curing the cancer, either by eliminating a tumor, preventing cancer recurrence, or both. In such cases, a patient may receive radiation therapy before, during, or after surgery, or patients may receive radiation therapy alone, without surgery or other treatments. Some patients may receive radiation therapy and chemotherapy at the same time. Radiation therapy may also be given with palliative intent. Palliative treatments are not intended to cure. Instead, they are intended to relieve symptoms and reduce the suffering caused by cancer. The timing of radiation therapy depends on the type of cancer being treated and the goal of treatment (cure or palliation).[6]

The following are types of cancer that are the most commonly treated with radiation therapy:[7]

- Bladder Cancer
- Bone Metastases
- Brain Metastases
- Brain Tumors
- Breast Cancer
- Colon Cancer
- Gynecologic Cancer
- Head and Neck Cancer
- Lung Cancer
- Lymphomas
- Prostate Cancer
- Skin Cancer

External Beam Radiation Therapy (EBRT)

External beam radiation therapy is most often delivered in the form of photon beams (either X-rays or gamma rays). A photon is the basic unit of light and other forms of electromagnetic radiation. The amount of energy in a photon can vary. For example, the photons in gamma rays have the highest energy, followed by the photons in X-rays. Many types of EBRT are delivered using a machine called a linear accelerator or LINAC, which uses electricity to form a stream of fast-moving subatomic particles. This creates high-energy radiation that may be

[3] *Ibid.*
[4] *Ibid,* p. 2.
[5] *Ibid,* p. 3.
[6] *Ibid,* p. 2.
[7] American Society for Radiation Oncology, *Answers to Your Radiation Therapy Questions,* available at http://www.rtanswers.org/treatmentinformation/index.aspx (last visited Aug. 17, 2011).

used to treat cancer.[8] Patients who receive most types of EBRT usually are treated up to 5 days a week for several weeks. Typically, one fractional dose of the planned total dose of radiation is given each day.[9]

EBRT is a rapidly-advancing form of cancer treatment and many methods of EBRT are currently being used and tested. The most pertinent for the purpose of this issue brief are:

- Three-Dimensional Conformal Radiation Therapy (3D-CRT)
  3D-CRT is a form of EBRT that uses computers and special imaging techniques to show the size, shape, and location of the tumor as well as surrounding organs. Radiation beams can then be precisely tailored to the size and shape of the tumor. Because the radiation beams are precisely directed, 3D-CRT allows nearby normal tissue to receive less radiation and thereby suffer less damage and heal more quickly.[10]

- Intensity Modulated Radiation Therapy (IMRT)
  IMRT is an advanced, specialized form of 3D-CRT that allows radiation to be more exactly shaped to fit the tumor. With IMRT, the radiation beam can be broken up into many "beamlets" and the intensity of each beamlet can be adjusted individually.[11] Unlike other types of radiation therapy, IMRT is planned in reverse, a technique called inverse treatment planning. With inverse treatment planning, the radiation oncologist chooses the radiation doses for different areas of the tumor and surrounding tissue, and then a computer program calculates the required number of beams and angles of the radiation treatment.[12] In contrast, during traditional (forward) treatment planning, the radiation oncologist chooses the number and angles of the radiation beams in advance and computers calculate how much dose will be delivered from each of the planned beams.

  Using IMRT, it is possible to further limit the amount of radiation received by healthy tissue near the tumor. In some situations, this may also safely allow a higher dose of radiation to be delivered to the tumor, potentially increasing the chance of a cure while diminishing the damage to healthy cells.[13] The National Comprehensive Cancer Network's clinical oncology practice guidelines for prostate cancer describe IMRT as "state-of-the-art" for EBRT.[14]

Of the 223 locations in Florida that are licensed by the Florida Department of Health to own and operate EBRT equipment for treating cancer in humans, 31.4 percent are hospital-based or hospital-owned, 30.9 percent are health care clinics, and 37.7 percent are physician practices. Seven of the physician practices indicate that they perform EBRT for the treatment of fewer than three different types of cancer, one of which is a dermatology practice while the other six specialize in urology.[15]

The Stark Law

Enacted in 1989, the federal Stark Law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare[16] to an entity with which that physician, or an immediate family member, has a financial relationship such as ownership, investment, or compensation, unless an exception applies. The Stark Law establishes a number of specific exceptions and grants the secretary of the federal Department of

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[8] *Supra,* note 2, pp. 3-4.
[9] *Supra,* note 2, p. 7.
[10] American Society for Radiation Oncology, *Treatment Types: External Beam Radiation Therapy,* available at http://www.rtanswers.org/treatmentinformation/treatmenttypes/externalbeamradiation.aspx (last visited Aug. 17, 2011).
[11] *Ibid.*
[12] *Supra,* note 2, p. 4.
[13] *Supra,* note 10.
[14] National Comprehensive Cancer Network, *NCCN Guidelines, Version 4.2011, Prostate Cancer,* June 21, 2011, p. MS-7, available at http://www.nccn.org/professionals/physician_gls/f_guidelines.asp (last visited Aug. 17, 2011).
[15] Non-scientific research conducted by staff of the Senate Committee on Health Regulation, Aug. 15-17, 2011, based on EBRT licensure information provided by the Florida Department of Health.
[16] Medicare is a federal health insurance program for people who are 65 years of age or older, people under age 65 with certain disabilities, and people of any age with end-stage renal disease or amyotrophic lateral sclerosis. Medicare has four parts: Part A, which is hospital insurance; Part B, which is medical insurance for non-hospital services; Part C, which is coverage by Medicare Advantage Plans; and Part D, which is prescription drug coverage.

Health and Human Services (DHHS) the authority to create regulatory exceptions for financial relationships that do not pose a risk of abuse for the Medicare program or Medicare enrollees.

Under the Stark Law, the following items and services are DHS:[17]

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Outpatient speech-language pathology services
- Radiology and certain other imaging services
- *Radiation therapy services and supplies* [emphasis added]
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

An exception to the Stark Law allows physicians to provide ancillary services such as diagnostic imaging, radiation therapy, clinical laboratory tests, and physical therapy to patients in their offices. This provision is known as the in-office ancillary services (IOAS) exception and functions similarly to the exception within Florida law pertaining to a sole provider or group practice.

The Stark Law's prohibitions against physician self-referrals pertain only to DHS that are reimbursed under Medicare. The Stark Law does not prohibit physician self-referrals in a general sense when health care products or services are billed to a non-Medicare payer, nor does it apply to non-DHS reimbursed under Medicare.[18]

The Patient Self-Referral Act of 1992 (PSRA)

Florida's PSRA[19] addresses the issue of the referral of patients by a health care provider for services or treatments when the referring health care provider has a financial interest in the service or treatment to be provided. The PSRA provides definitions relating to financial arrangements between referring health care providers and providers of health care services.

For the purpose of this issue brief, the PSRA's key definitions include:

- Designated health services (F-DHS) – Clinical laboratory services, physical therapy, comprehensive rehabilitative services, diagnostic imaging services, and *radiation therapy services* [emphasis added].
- Direct supervision – Supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.
- Group practice – A group of two or more health care providers legally organized as a partnership, professional corporation, or similar association:
    - In which each health care provider who is a member of the group provides substantially the full range of services that the provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;

[17] Centers for Medicare & Medicaid Services, *Physician Self Referral: Overview,* available at https://www.cms.gov/physicianselfreferral/ (last visited Aug. 9, 2011).
[18] The Secretary of the federal Centers for Medicare & Medicaid Services is authorized to deny payment of Medicaid federal matching funds for self-referrals that violate the Stark Law within a state Medicaid program. However, Medicaid providers are not precluded by the Stark Law from making self-referrals or from billing state Medicaid programs for DHS. *See* Federal Register, vol. 63, no. 6, January 9, 1998, p. 1704, available at http://www.gpo.gov/fdsys/pkg/FR-1998-01-09/pdf/98-282.pdf (last visited Aug. 17, 2011), *and* Federal Register, vol. 66, no. 3, January 4, 2001, p. 858, available at http://www.gpo.gov/fdsys/pkg/FR-2001-01-04/pdf/01-4.pdf (last visited Aug. 17, 2011).
[19] *See* s. 456.053, F.S.

  - For which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and
  - In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.
- Referral – Any referral of a patient by a health care provider for health care services, including, without limitation:
  - The forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies F-DHS or any other health care item or service; or
  - The request or establishment of a plan of care by a health care provider, which includes the provision of F-DHS or other health care item or service.

With certain exceptions, the PSRA specifies that a health care provider may not refer a patient for the provision of F-DHS to an entity in which the health care provider is an investor or has an investment interest.[20]

Florida's Group Practice Exception

A number of exceptions are imposed upon the PSRA's definition of "referral," including the provision that certain orders, recommendations, or plans of care do *not* constitute a referral by a health care provider, including those by a provider who is a sole provider or who is a member of a group practice for F-DHS or other health care items or services that are prescribed or provided solely for the referring provider's or group practice's own patients, and that are provided or performed by or under the direct supervision of such referring provider or group practice.[21]

The PSRA contains further prohibitions related to billing. It prohibits any entity from presenting a claim for payment for a service furnished pursuant to a prohibited referral, and if an entity collects any amount that was billed in violation of this prohibition, the entity must refund that amount in a timely manner. The PSRA creates a civil penalty of up to $15,000 per incident for knowingly violating the prohibition against billing or for failing to provide a refund. And, any health care provider or entity that enters into an arrangement or scheme, such as a cross-referral arrangement, designed to assure referrals that would violate the PSRA, is subject to a civil penalty of up to $100,000 for each such arrangement or scheme. A violation of the PSRA by a health care provider also constitutes grounds for disciplinary action by the applicable regulatory board.[22]

Unlike the Stark Law, which applies prohibitions only to DHS reimbursed by the Medicare program, the PSRA applies to all physician referrals made in Florida.

Physician Self-referral Laws in Other States

At least 18 states aside from Florida have enacted laws that contain general prohibitions against health care provider referrals to an entity in which the health care provider is an investor or has an investment interest that are substantially similar to the Stark Law and Florida's PSRA, all of which include exceptions relating to IOAS or services provided in group practice settings.[23]

Recent state-level activity includes:

- Maryland – The physician self-referral law in Maryland provides that a health care practitioner may not refer a patient to a health care entity in which the practitioner, or the practitioner's immediate family, owns a beneficial interest, or with which the practitioner, or the practitioner's immediate family, has a compensation arrangement that could financially incent the practitioner to make such referrals.[24] The Maryland law includes exceptions to this prohibition, including for a practitioner who refers a patient to

[20] *See* s. 456.053(5)(a), F.S.
[21] *See* s. 456.053(3)(o)3.f., F.S.
[22] *See* s. 456.053(5)(c)-(g), F.S.
[23] American College of Radiology, *State-by-State Comparison of Physician Self-Referral Laws, a*vailable at http://www.acr.org/SecondaryMainMenuCategories/GR_Econ/FeaturedCategories/state/compare_laws.aspx (last visited Aug. 17, 2011).
[24] *See* Title 1, Subtitle 3, Section 1-302(a), Maryland Code, Health Occupations.

another practitioner in the same group practice and for IOAS.[25] Maryland's definition of IOAS specifically provides that, except for a radiologist group practice or an office consisting solely of one or more radiologists, an IOAS does *not* include MRI services, radiation therapy services, or CT scan services.[26] Recent Maryland case law has upheld the Maryland Board of Physicians' interpretation that the statute's exception for referrals within a group practice covers only the referral of a patient between physicians in a group practice where professional decision-making about the patient's continued care is transferred to the second physician, and therefore does not supersede the IOAS definition that excludes certain services from the IOAS exception. Maryland does not allow a physician who owns a beneficial interest in a group practice to refer a patient within the group practice for those services or tests that were already chosen by the referring physician.[27] However, Maryland allows a referral for those services or tests provided within a group practice by an employee of the group practice who does not own a beneficial interest or have a compensation arrangement related to the referral.[28]

- Oregon – In the 2011 session of the Oregon State Legislature, HB 3522 was introduced which would have virtually duplicated Maryland's self-referral law, including Maryland's exclusion of MRI, CT scans, and radiation therapy from the definition of services that qualify for an IOAS exception.[29] However, the bill did not receive a hearing and died in committee when the session adjourned on June 30.
- Pennsylvania – Pennsylvania has enacted a limited physician self-referral law that pertains only to health care delivered via worker's compensation insurance. A bill currently pending before the General Assembly of Pennsylvania, HB 319, would create a general physician self-referral law pertaining to all physician referrals in the state. If enacted, the bill will place into Pennsylvania law the exceptions to the prohibition against physician self-referral that are contained in all present and future provisions of the federal Stark Law.[30]
- Washington State – Washington has a physician self-referral prohibition for its Medicaid program only. During the 2007-2008 biennial session of the Washington State Legislature, HB 2691 was introduced that would have recreated much of the Maryland self-referral law into Washington law, including Maryland's exclusion of MRI, CT scans, and radiation therapy from the definition of services that qualify for an IOAS exception. The bill was the subject of one work session in the House Committee on Health Care & Wellness on February 13, 2008, but did not progress any further.[31]

Examination of the IOAS Exception by the Medicare Payment Advisory Commission (MedPAC)

MedPAC is an independent congressional agency established by the federal Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program. In addition to advising Congress on payments to providers in Medicare's traditional fee-for-service program and health plans participating in the Medicare Advantage program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.[32]

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[25] *See* Title 1, Subtitle 3, Section 1-302(d), Maryland Code, Health Occupations.
[26] *See* Title 1, Subtitle 3, Section 1-301(k)(2), Maryland Code, Health Occupations.
[27] *Potomac Valley Orthopaedic Associates, et al. v. Maryland State Board of Physicians, et al.*, 12 A.3d 84 (Md. 2011).
[28] Maryland Board of Physicians, Declaratory Ruling No. 2006-1, pp. 27-29, available at http://www.mbp.state.md.us/forms/2006-1.pdf (last visited Aug. 17, 2011).
[29] Bill text available at http://www.leg.state.or.us/11reg/measpdf/hb3500.dir/hb3522.intro.pdf (last visited Aug. 17, 2011).
[30] Bill text and history available at http://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?syear=2011&sind=0&body=H&type=B&BN=0319 (last visited Aug. 17, 2011).
[31] Bill text and history available at http://dlr.leg.wa.gov/billsummary/default.aspx?year=2007&bill=2691 (last visited Aug. 17, 2011).
[32] MedPAC meets publicly to discuss policy issues and formulate its recommendations to Congress. In the course of these meetings, MedPAC commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. Two reports (issued in March and June each year) are the primary outlets for Commission recommendations. In addition to annual reports and occasional reports on subjects requested by Congress, MedPAC advises Congress through other avenues, including comments on reports and proposed regulations issued by the secretary of the Department of Health and Human Services (DHHS), testimony, and briefings for congressional staff.

In its proposed rule for the 2008 Medicare physician fee schedule, the federal Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, noted that discussions between CMS and trade associations and a CMS review of industry trade articles had heightened its awareness of the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices. While declining to issue specific proposals to amend the IOAS exception, CMS solicited comments as to whether changes in the exception were necessary and, if so, what changes should be made.[33]

In October 2009, MedPAC began examining the IOAS exception in the Stark Law.[34] MedPAC cited the CMS request for comments to illustrate the need for its examination of the IOAS.[35] While considering whether to make any recommendations to Congress relating to the IOAS exception, MedPAC contemplated a number of options, one of which was the removal of radiation therapy from the IOAS exception.[36]

Between January 2010 and April 2011, MedPAC researched and analyzed the IOAS exception as it relates to diagnostic imaging, radiation therapy and other types of therapy, and other services provided within physicians' offices and group practice settings. Presentations to MedPAC on this subject were made by MedPAC staff and via public testimony at public meetings on at least five occasions during that period.

At its meeting on April 7, 2011, MedPAC approved four recommendations to Congress as a result of its examination of the IOAS exception, all of which were designed to improve payment accuracy for imaging and other diagnostic tests and ensure the appropriate use of advanced imaging studies within the Medicare program.[37] None of MedPAC's approved recommendations were related to radiation therapy.

In its June 2011 report to Congress, MedPAC elaborated on its examination of the IOAS exception and its reasons for not recommending that radiation therapy and other services be removed from the exception. The report includes the following passage:

> ... we have explored a range of interim approaches to address concerns raised about self-referral. One such option is to narrow the types of services or physician groups covered by the IOAS exception. However, the Commission is concerned that limiting the IOAS exception could have unintended consequences, such as inhibiting the development of organizations that integrate and coordinate care within a physician practice. In addition, it could be difficult to craft a more limited IOAS exception that distinguishes between group practices that improve quality and coordination and those that use additional services of marginal clinical value. Therefore, we do not currently recommend that the exception be changed.[38]

MedPAC further pointed out, however, that while its recommendations did not directly address self-referral of radiation therapy and certain other procedures, the Commission intends to continue tracking the growth of these services and may consider policy options to specifically address them in the future.[39]

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[33] *See* Federal Register, vol. 72, no. 133, July 12, 2007, p. 38181, available at http://www.gpo.gov/fdsys/pkg/FR-2007-07-12/pdf/07-3274.pdf (last visited Aug. 17, 2011).
[34] *See* http://medpac.gov/meeting_search.cfm?SelectedDate=2009-10-08 (last visited Aug. 17, 2011).
[35] Medicare Payment Advisory Commission, *Report to the Congress: Aligning Incentives in Medicare,* June 2010, pp. 213-214, available at http://medpac.gov/documents/Jun10_EntireReport.pdf (last visited Aug. 17, 2011).
[36] *Ibid,* p. 215.
[37] *See* Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System, June 2011Recommendations,* p. 1, available at http://medpac.gov/documents/Jun11_RecommendationsSheet.pdf (last visited Aug. 5, 2011).
[38] Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System,* June 2011, p. 28, available at http://medpac.gov/documents/Jun11_EntireReport.pdf (last visited Aug. 5, 2011).
[39] *Ibid,* pp. 28-29.

Examination of the IOAS Exception by the Government Accountability Office (GAO)

The United States GAO is an independent, nonpartisan agency that works for Congress. The GAO investigates how the federal government spends taxpayer dollars. The GAO's products include reports, testimonies, correspondence, and legal decisions and opinions, which are available to the public. The GAO also produces special publications to assist Congress and executive branch agencies by recommending corrections to problems in government programs and operations and by identifying long-term trends. The head of the GAO, the Comptroller General of the United States, is mandated by law to make appointments to certain health care-related commissions, advisory boards, and governing boards, one of which is MedPAC.

On April 16, 2010, U.S. Rep. Henry Waxman (who was then chairman of the House Committee on Energy and Commerce), U.S. Rep. Sandy Levin (who was then chairman of the House Committee on Ways and Means), and U.S. Rep. Pete Stark (who was then chairman of the House Ways and Means Subcommittee on Health) sent a letter to the head of the GAO requesting that the GAO conduct a study to evaluate the extent of physician self-referral arrangements for advanced imaging and radiation oncology services provided to Medicare beneficiaries and the effects of such arrangements on Medicare spending.[40]

Citing concerns that the potential financial incentives associated with self-referrals that are allowed under the IOAS exception to the Stark Law could lead to the overutilization of imaging and radiation oncology services, Reps. Waxman, Levin, and Stark suggested that the GAO study should focus on: (1) prevalence, patterns, and trends in physician self-referral for advanced imaging and radiation oncology services, (2) Medicare spending on these physician self-referred services, and (3) the extent to which self-referral may have led to increases in the provision of, and Medicare spending for, advanced imaging and radiation oncology services.

The GAO is currently conducting the study and has not announced when the study will be completed or when a report on the study will be publicly available.

Concerns of Overutilization

As described above, CMS, MedPAC, and members of Congress have publicly expressed concerns about the potential overutilization of certain medical services and tests, such as radiation therapy and advanced diagnostic imaging, that fall under the Stark Law's IOAS exception to the prohibition against self-referrals. At least two national trade organizations representing radiologists[41] or radiation oncologists[42] have gone on record warning MedPAC, members of Congress, and/or the GAO about potential overutilization of these services and tests when provided in group practice settings under the IOAS exception, and urging federal action to eliminate or amend the IOAS exception. Articles have appeared in popular news media to illustrate these concerns specifically related to IMRT.[43,44] However, a recent peer-reviewed journal article has found that trends in radiation and surgery for prostate cancer therapy between 2006 and 2008 were similar with 11.5 percent and 13 percent increases in each modality, respectively. Further, this published study concluded that utilization rates for IMRT are similar in both physician office and hospital facility settings.[45]

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[40] A copy of the letter is on file with staff of the Florida Senate Committee on Health Regulation.
[41] *See* American College of Radiology news release, April 22, 2010, available at http://www.acr.org/SecondaryMainMenuCategories/NewsPublications/FeaturedCategories/CurrentACRNews/SRLetter-to-GAO.aspx (last visited Aug. 17, 2011).
[42] American Society for Radiation Oncology, ASTROnews: Fighting Self-referral, July 11, 2011, available at http://cs.astro.org/blogs/astronews/pages/astronews-fighting-self-referral.aspx (last visited Aug. 17, 2011).
[43] Carreyrou, John, and Tamman, Maurice, *A Device to Kill Cancer, Lift Revenue,* The Wall Street Journal, Dec. 7, 2010, available at http://online.wsj.com/article/SB10001424052748703904804575631222900534954.html (last visited Aug. 17, 2011).
[44] Stein, Rob, *Doctor-owned centers spark criticism, scrutiny,* The Washington Post, Feb. 28, 2011, available at http://www.washingtonpost.com/wp-dyn/content/article/2011/02/28/AR2011022805378.html (last visited Aug. 17, 2011).
[45] Kapoor, Deepak, et al, *Utilization trends in prostate cancer therapy*, The Journal of Urology, September 2011, 186(3):860-864. The study did not differentiate between office IMRT procedures performed by integrated urological practices and those practices with no urology affiliation.

MedPAC's review and study of the issue, however, resulted in no recommendation to change the status quo, due to concerns by MedPAC commissioners that changing the IOAS exception in an attempt to mitigate potential overutilization could result in detrimental unintended consequences. MedPAC also expressed recognition that many of the services and tests in question, when provided under the IOAS exception, enable physicians to diagnose and treat illness with greater speed and precision and, in some cases, with greater convenience for patients.[46] The GAO study proposed by Reps. Waxman, Levin, and Stark could provide lawmakers and policy administrators with scientifically valid research and data to help guide policy decisions in this area.

[46] *Supra,* note 38, p. 27.