

April 29, 2013

The Honorable Max Baucus
Chairman
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Orrin Hatch
Ranking Member
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Baucus and Ranking Member Hatch:

The undersigned organizations urge you to preserve the in-office ancillary services exception (IOASE) to the “Stark” law and reject the Administration’s proposal to restrict the IOASE for advanced imaging, radiation therapy and physical therapy. There is widespread agreement that improving the U.S. healthcare system will require more care coordination, not less. The IOASE recognizes that referral within a group practice promotes continuity of care in a setting that is lower cost and more convenient to the patient.

Ancillary services are essential tools used on a daily basis by practices seeking to provide comprehensive services to their patients. Limiting the IOASE would force patients to receive ancillary services in a new and unfamiliar setting, increase inefficiencies, present significant barriers to appropriate screenings and treatments, and make health care less accessible. In its June 2011 Report to Congress, MedPAC recommended against limiting the Stark law exception for ancillary services, citing potential “unintended consequences, such as inhibiting the development of organizations that integrate and coordinate care within a physician practice.”

There is no quantifiable analysis to support the Administration’s estimate that repealing IOASE would result in \$6.1 billion in savings over 10 years; indeed, limiting the IOASE also would result in care being shifted into more expensive settings, raising costs to Medicare beneficiaries and the program substantially. In response to a question for the record at the Finance Committee hearing, Acting Administrator Tavenner provided no data analysis whatsoever on savings from radiation therapy and physical therapy, and merely quoted a previous GAO study that advanced imaging was costing Medicare \$109 million a year. Attached is quantitative analysis for radiation therapy, pathology, advanced medical imaging and physical therapy which shows that repealing IOASE would raise, not lower, costs.

The medical profession has taken significant steps to ensure that only medically necessary and appropriate ancillary services are performed. These steps include the development and implementation of training guidance, appropriate use criteria, practice guidelines, and decision support tools which assist physicians in delivering the most appropriate care. Congress and the Department of Health and Human Services have heavily regulated the provision of such services, through the Stark law and elsewhere. Physicians and group practices relying on this exception must meet complex billing, supervision, and location requirements.

The changing healthcare climate has yielded consolidation of services. As a result, many practitioners are seeking employment with hospitals or other entities. An alternative strategy is formation of single or multi-specialty physician practices, which provide economies of scale, coordination of clinical pathways, improved communication among specialists and quality control over ancillary services. Our organizations seek to protect Medicare beneficiaries and taxpayers alike by providing high quality, ethical care in a setting that benefits the patient and facilitates care coordination. We therefore urge you to preserve the IOASE contained in the “Stark” law.

Sincerely,

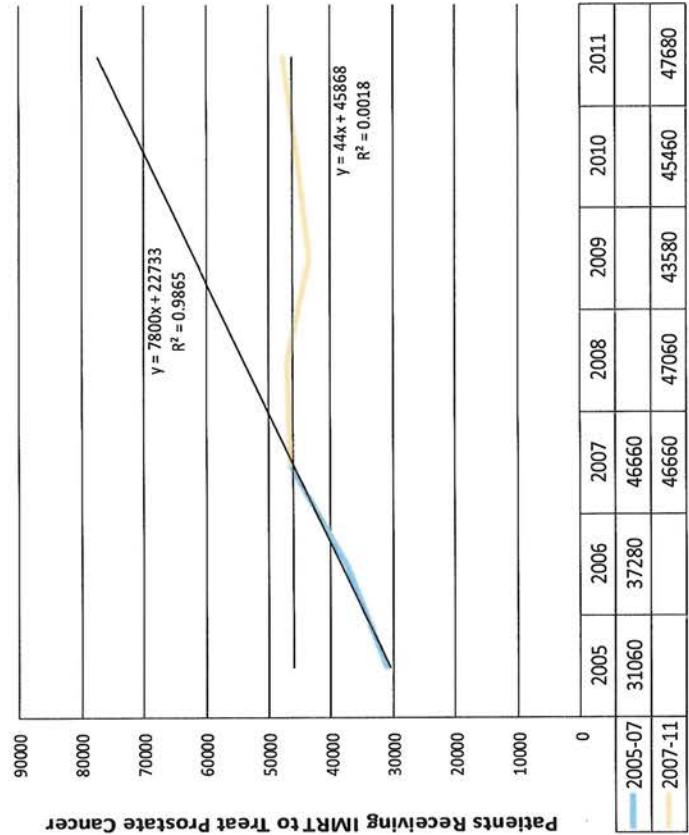
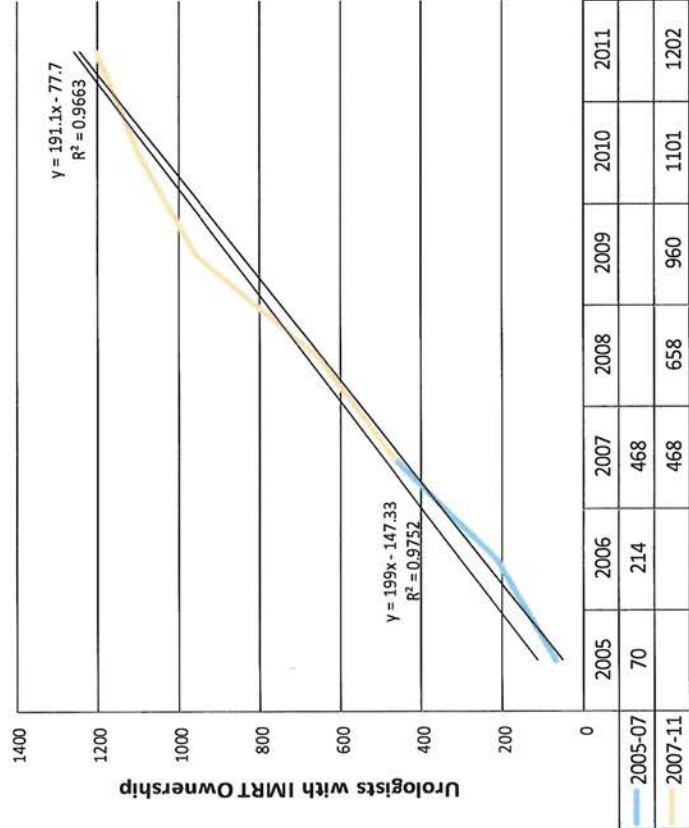
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Neuromuscular & Electrodagnostic Medicine
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Gastroenterology
American College of Surgeons
American Gastroenterological Association
American Medical Group Association
American Society for Gastrointestinal Endoscopy
American Society of Echocardiography
American Society of Neuroimaging
American Society of Nuclear Cardiology
American Urological Association
Association of Black Cardiologists
Cardiology Advocacy Alliance
Congress of Neurological Surgeons
Large Urology Group Practice Association
Medical Group Management Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery

cc: Senate Finance Committee Members

UTILIZATION OF IMRT TO TREAT PROSTATE CANCER DOES NOT CORRELATE WITH UROLOGY OWNERSHIP

The facts:

- ✓ Literature indicates that IMRT utilization began increasing in the early part of the last decade - before urology ownership of this technology - and increased through 2007^{1,2}
- ✓ From 2007-11, despite a nearly 160% increase in the number of urologists in practices with ownership of IMRT (468 to 1202), IMRT utilization to treat prostate cancer during this period increased by only 2.2%³
- ✓ Statistical analysis demonstrates that there is no correlation between urology ownership of IMRT and the number of patients receiving this treatment for prostate cancer



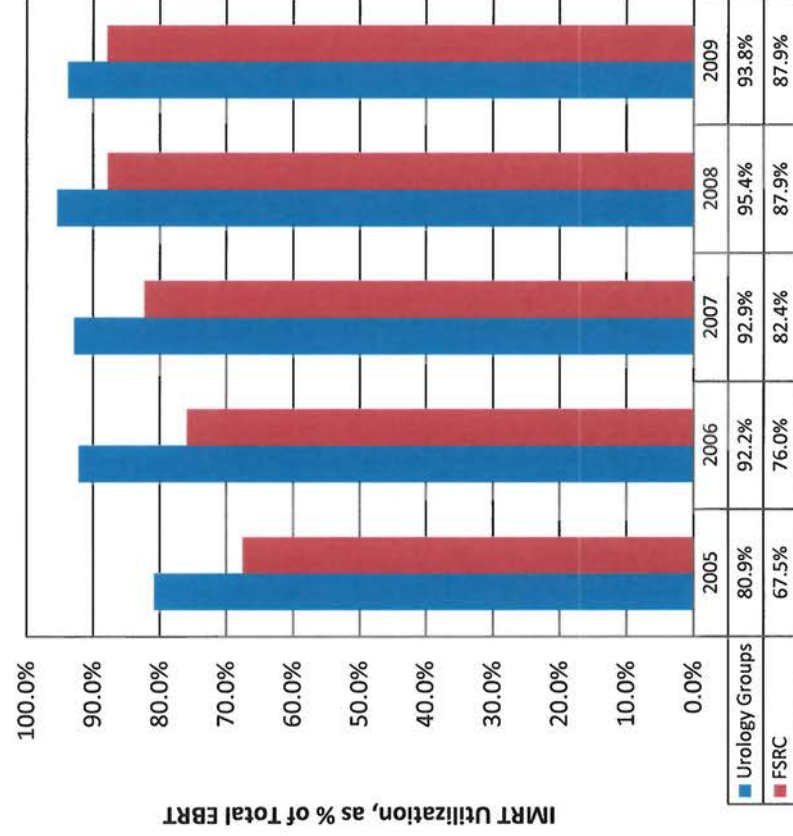
1. Nguyen PL, Gu X, Lipsitz SR, et al. Cost implications of the rapid adoption of newer technologies for treating prostate cancer. J Clin Oncol. 2011;29(12):1517-1524.
2. Dinan MA, Robinson TJ, Zagar TM, et al. Changes in initial treatment for prostate cancer among Medicare beneficiaries, 1999-2007. Int J Radiat Oncol Biol Phys. 2012 Apr 1;82(5):e781-6.
3. Kapoor DA, Olsson CA. Urology Ownership and Utilization of IMRT to Treat Prostate Cancer in the Medicare Population, 2005-2011. *manuscript in preparation*

ELIMINATION OF THE IOASE WILL INCREASE COSTS AND REDUCE ACCESS TO CANCER CARE

- The facts:

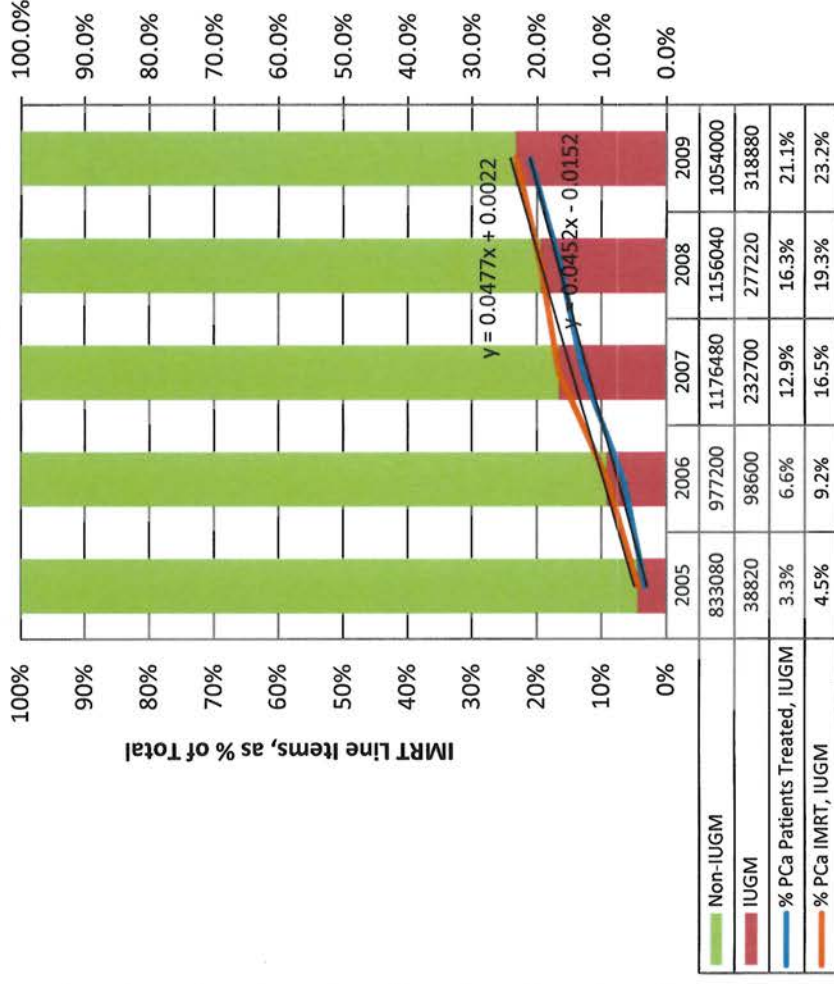
- ✓ By 2009, the utilization of IMRT by physician practices was virtually identical regardless of site of service
- ✓ Changes in utilization of IMRT by urology group practices were statistically identical to changes in market share
- ✓ In 2013, daily treatment costs of IMRT in the hospital is 19.3% higher than in the physician office setting
- ✓ As utilization rates are the same across sites of service and line item counts are more expensive, elimination of the IOASE will result in higher costs and decreased access to life saving cancer treatment

Utilization of IMRT by Site of Service



*FSRC=Free Standing Radiation Centers

IMRT Utilization and Market Share, Integrated Groups



*IUGM=Metropolitan Statistical Areas containing Urology practices with IMRT Ownership

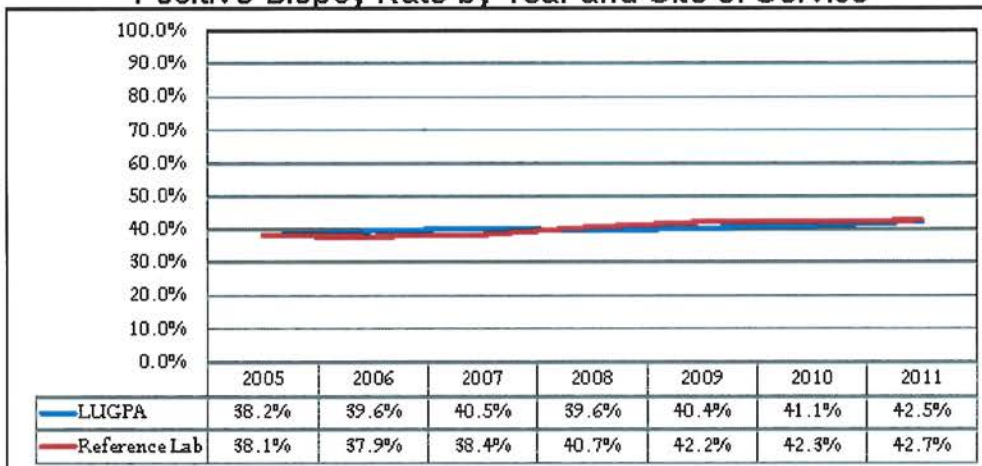
Pathology – No evidence of Overutilization for Prostate Biopsies

In April 2012, Dr. Jean Mitchell published an article funded by the American Clinical Lab Association and the College of American Pathologists in Health Affairs claiming urologists in integrated groups performed prostate biopsies on many men who were unlikely to have prostate cancer and also collected double the number of specimen vials per biopsy than those who sent their samples to reference labs (6 vs. 12).

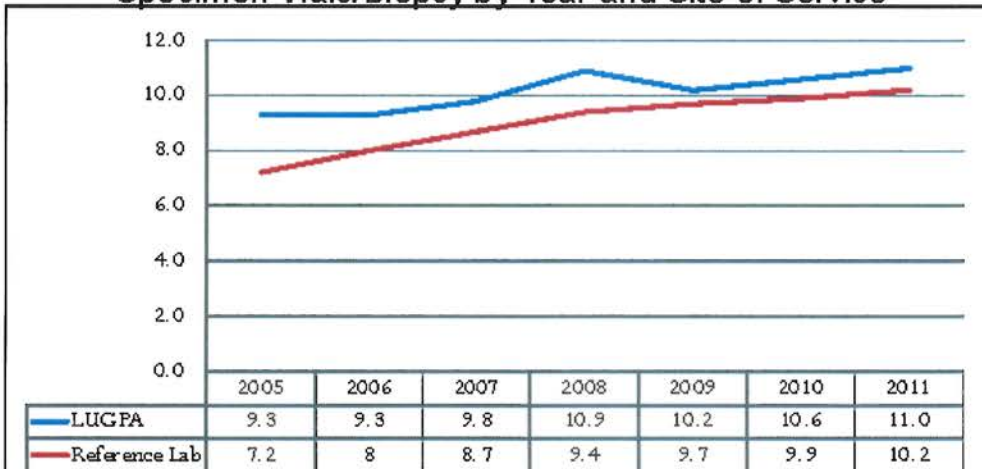
In fact, the standard of care at the time of the study (2005-2007) was, and still is, to obtain 10 to 12 cores. By 2006, the literature was large enough to support an exhaustive meta-analysis review of 87 studies by Eichler and colleagues, which confirmed the superiority of 10-12 cores. Schemes of 12 cores demonstrated a 31% improvement in cancer detection rate when compared to the 6-core sextant approach. The National Cancer Care Network clinical guidelines recommend that 12 cores always be done.

Mitchell's study of less than 10,000 biopsies found that integrated groups had positive biopsy rates between 21 percent to 27 percent – 14% lower than her control group. In response, the Large Urology Group Practice Association collaborated with Bostwick Laboratories to undertake the largest study ever performed on prostate biopsy utilization – analyzing data from 2005-2011 with 29 urology practices representing 74.4% of all urology practices with full service pathology labs and compared this with data from 919 practices nationwide and a total of about 438,000 patients and 4.2 million specimens. The analysis found the positive biopsy rate to be statistically identical at 40.3 percent. From 2005-2011, the average difference in vials per biopsy between integrated groups and reference labs was 1.2 vials per biopsy and from 2009-2011 it was 0.6 vials, which is not statistically significant.

Positive Biopsy Rate by Year and Site of Service



Specimen Vials/Biopsy by Year and Site of Service



Appropriate in-office advanced diagnostic imaging reduces costs.

As the delivery of medicine has evolved, many physician groups have incorporated medical imaging and other ancillary services (including radiation oncology and pathology) into their practices. The in-office ancillary services exception (IOASE) to the physician self-referral law allows patients to be treated in an integrated setting, which improves access to care, enhances convenience for patients, streamlines communications between providers and allows the development of disease-specific expertise. These benefits reduce cost and improve quality by eliminating duplication of services and reducing treatment delays. Moreover, the provision of ancillary services by integrated physician practices is critical to the economic feasibility of the independent practice of medicine by physicians and crucial to competition in the health care marketplace. Furthermore, alternative payment strategies which encourage assumption of risk by providers depend on integration of these professional services.

Recently, the President has submitted a budget to Congress that proposes to repeal the IOASE as it applies to advanced diagnostic imaging and certain other services. The proposal in the President's budget to preclude physicians from providing in-office advanced diagnostic imaging to Medicare patients is based on two premises: (1) in-office use of imaging results in significant overutilization; and (2) eliminating in-office advanced diagnostic imaging would result in substantial savings. Both of these premises are in dispute.

The sole basis for the Administration's proposal and the accompanying budget projections – according to Acting CMS Administrator Tavenner, is the 2012 GAO report, "Higher Use of Advanced Imaging by Providers Who Self-Refer Costing Medicare Millions." This report suggests that utilization of MRI and CT is \$109 million higher per year for physicians who provide these procedures within their practices than for those who refer to facilities outside their practices. Based solely on this flawed GAO analysis, the President's budget projects that this change would result in a budget savings of \$6 billion over 10 years (and provides no basis for savings in radiation or physical therapy, which are also impacted by the proposal).

There are several important points to note about the GAO report.

1. **GAO does NOT recommend repealing the IOASE.** GAO's refusal to endorse such a policy is consistent with the Medicare Payment Advisory Commission (MedPAC) refusal to endorse such a policy in its June 2011 report on this issue. This means that both investigatory arms of Congress have rejected repealing the IOASE as it applies to advanced diagnostic imaging.
2. **Eliminating In-Office Advanced Diagnostic Imaging Will Not Result in Budget Savings.** The GAO fails to quantify the probable result of prohibiting private practices from providing advanced diagnostic imaging: Most of these services will end up in the more expensive hospital setting because that is where they are now predominantly being provided. As shown below, this shift would cost Medicare more than \$100 million a year in higher costs. Specifically, the GAO estimates that if the referral rate of physician owners of MRI/CT services were the same as the referral rate for non-owners, there would have been approximately 20% fewer MRIs and CTs performed for Medicare patients in 2010. But what about the remaining 80%, which the GAO acknowledges still would be

performed even if the financial incentives involved in self-referral were eliminated? If these studies were referred to hospital and non-hospital facilities in rough proportion to the national ratio of hospital vs. non-hospital CT and MRI (approximately 80% hospital/20% non-hospital), no savings would be achieved. In fact, in the aggregate, the Medicare program likely would incur significantly higher costs due to the shift of MRI and CT services to higher cost settings.

For example, if physician ownership of MR and CT services were banned in 2010, and formerly self-referring physicians were to refer MRI and CT services to other facilities at the same rate as other non-self-referring physicians, an estimated additional 556,697 MRIs would be referred to other facilities, at least 80% of which (445,358 MRI studies) would have been referred to hospital outpatient departments where Medicare would pay \$35.6 million more for these studies.¹ Likewise, if physician ownership of CT services were outlawed, an estimated 1,166,275 CT studies would be referred elsewhere, 933,020 of which likely would be referred to higher cost hospital outpatient departments, at an estimated increased cost to Medicare of \$77 million.² Altogether, Medicare would incur increased hospital outpatient costs of over \$112 million for CT and MRI services previously provided in lower cost settings, more than offsetting the projected cost savings of eliminating the “excess” utilization that, according to the GAO, results from physician ownership.

Significantly, this is an extremely conservative estimate of the cost of banning physician ownership of CT and MR facilities, since this calculation only takes into account the shift in the site of service of currently self-referred studies. Unfortunately, eliminating physician-owned facilities from the marketplace would have much more far-reaching effects. The GAO report itself suggests that physician-owned facilities provide services to many patients who are not “self-referred” but who are referred by community physicians with no financial ties to the facility. If physician-owned facilities close, many of the studies ordered by outside physicians also would likely shift to higher cost hospital settings and a higher cost to Medicare and private payers and patients. In fact, in many communities, eliminating physician-owned facilities may leave hospitals with a virtual monopoly on the provision of critical advanced diagnostic imaging services, enabling them to not only provide advanced imaging services to the Medicare program at significantly higher cost, but also further increasing their leverage to with private payers for other services. .

3. **The Department of Health and Human Services (HHS) rejected two of the three GAO recommendations as either inadvisable or unworkable.** HHS only supports the GAO recommendation to apply appropriateness criteria to advanced diagnostic imaging services. That concept has potential merit, but as the majority of imaging costs are incurred in the hospital setting, any such criteria should be applied to all physicians that refer for imaging, whether office or hospital based

¹ For the most common MRIs (MRI of the lumbar spine, neck and upper and lower extremities) the differential between the amount paid to physicians offices (TC) and the amount paid to hospitals ranges from about \$25 to about \$116. It is estimated that the average differential for the top five most frequently performed MRIs is about \$80 per study.

² For the most common CTs (CT of the abdomen and pelvis), the differential between the amount paid to physicians' offices (TC) and the amount paid to hospitals ranges from about \$80-\$84. It is estimated that the average differential for the top three most frequently performed CT codes is about \$83 per study.

4. **The GAO Report does not examine whether or to what extent the diagnostic imaging procedures ordered by either physicians whose practices own imaging facilities or those who refer to other providers were medically appropriate.**
5. **The GAO Report disguises the current downward utilization trends in the use of non-hospital advanced imaging.** In fact, both utilization and spending per Medicare beneficiary for CT and MRI in non-hospital settings has declined since 2009.
6. **The GAO Report exaggerates the growth of physician self-referral** by including in the definition of self-referring physicians those who are employed by faculty practice plans, hospitals or other providers; non-physicians such as PAs and nurse practitioners who typically have no financial interest in increasing utilization of CT or MR; and numerous others who are not self-referring under current federal law.
7. **The GAO Report distorts the potential impact of physician self-referral on advanced imaging utilization rates.** The GAO fails to note that, even based on its own expansive definition of self-referral, physician ownership may increase overall CT and MRI utilization by under 2%. (based on GAO figures.)
8. **The GAO Report overstates the difference in the growth rates of self-referred and non-self-referred studies.** The GAO excludes from its analysis advanced images ordered by non-self-referring physicians that are provided in hospital outpatient departments--the primary site of service for these images.
9. **The GAO Report fails to provide an objective analysis of the financial implications of limiting physician ownership.** The GAO calculation of the "cost" of self-referral assumes that self-referring physicians refer more because they own the equipment involved and that their referral rates would equal the referral rates of non-owners if self-referral were banned. The GAO report fails to acknowledge that it is those physicians who refer more patients for advanced imaging who are more likely to acquire advanced imaging equipment and that eliminating self-referral may have little or no impact on their practice patterns.

Even based on its faulty analysis the GAO does not recommend banning physician ownership of advanced imaging equipment. Neither should Congress.

Physician-owned Physical Therapy Services Cost Medicare Less Than Therapy in Other Settings

MedPAC Data

MedPAC physical therapy data, collected over the course of seven years, examined the total spending on physical therapy (PT) services by outpatient therapy locations compared to physician office locations. Data published by MedPAC indicate that **spending for outpatient therapy services in physician office settings is much lower than spending for similar services performed in outpatient therapy settings.** The percentage of total Medicare spending decreased in the physician office settings and increased significantly in outpatient therapy settings.

According to MedPAC, spending for outpatient therapy in physician office settings decreased from 9% in 2002 to 4% in 2011 as a percentage of total Medicare spending, while spending on physical therapists in private practice increased from 18% to 30% (see MedPAC Basics on Outpatient Therapy Services 2005 and MedPAC Payment Basics Outpatient Therapy Services, October 2012) . MedPAC also found that overall spending for outpatient therapy services paid under the physician fee schedule grew from \$1.4 billion to \$2.2 billion between 2003 and 2008. The share of spending provided incident to a physician's service declined by nearly half (from 30 percent to 16 percent) while the share of payments delivered by therapists who bill Medicare independently grew from 70 to 84 percent (MedPAC Report June 2010).

MedPAC also has expressed concern about the negative consequences of closing the in-office ancillary services (IOAS) exception and has declined to recommend any changes to the exception. In their June 2011 report, they stated:

“...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.”

DOPTA REPORT

A 2009 study “Developing Outpatient Therapy Payment Alternatives (DOPTA)” published by RTI International and funded by CMS, examined the use of physical therapy (PT) across treatment settings. The conclusion was that the spending trends show that physician owned PT services cost significantly less per visit and are able to better contain Medicare expenditures. The study compared Medicare reimbursement for PT services between settings and subsequently the cost per episode of treatment when the same ICD-9 code is used. **The study concluded that physician owned physical therapy services on average cost less per episode of treatment compared to independently owned physical therapy services (PTPP).**

The study compared 2009 Medicare claims data for outpatient therapy services. More specifically, the cost of a single setting PT episode with lumbago (low back pain) is compared across treatment settings. In a PTPP setting, 1,662,583 episodes occurred; the average number of visit days was 11.5, at an average cost of \$887. In a physician owned setting, 397,451 episodes occurred; the average number of visit days was 7.6, at an average cost of \$531. **Receiving treatment in a physician owned PT setting was on average 40% or \$356 less expensive when compared to a PTPP setting.**

Physical Therapy Expenditure Trends

In a physician owned setting, expenditures decreased by 31.3% between CY 2004-CY 2006. Expenditures then decreased again between CY2006 – CY2009 by 7.0%. **Between 2004 and 2009 physical therapy expenditures increased by 57.4% in PTPP settings and decreased by 38.3% in physician owned settings.**

Single-setting PT episodes by setting, CY 2009

Setting	Number of single-setting episodes	Most frequent ICD-9	ICD-9 description	Mean episode days	Mean episode paid	Mean claim lines
Total	4,559,017	V57.1	Physical therapy nec	11.2	\$801	25.6
Hospital	1,256,276	V57.1	Physical therapy nec	8.3	\$496	14.0
S/NF	732,805	719.7	Difficulty in walking	17.0	\$1,159	39.5
CORF	55,735	781.2	Abnormality of gait	12.5	\$1,212	40.1
ORF	446,888	724.2	Lumbago	12.1	\$943	30.4
HHA	2,835	781.2	Abnormality of gait	9.1	\$665	21.2
PTPP	1,662,583	724.2	Lumbago	11.5	\$887	27.9
OTPP	--	--	--	--	--	--
Physician	397,451	724.2	Lumbago	7.6	\$531	19.3
NPP	4,444	724.2	Lumbago	6.7	\$426	13.9

SOURCE: RTI International analysis of 2009 Medicare claims data for outpatient therapy services (See source file OutpatientTherapyEpisodes__bySetting_CY2009.xls. CMS contract #500-2005-00291/0012).