Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

July 31, 2014

Via Email and US Mail

Mike McKillip, Project Analyst
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Duke University Health System Comments Regarding the Prostate Health Center's CON Application to Acquire One Additional Linear Accelerator
Project ID J-10300-14

Dear Mr. McKillip:

Enclosed please find public comments filed on behalf of the Duke University Health System regarding the Prostate Health Center's CON Application to acquire one additional linear accelerator (Project ID J-10300-14). I am also sending a copy of the comments and referenced exhibits by mail for your convenience. Please let me know if you have any questions of if there is any further information we can provide you. Thank you for your attention to these comments.

Sincerely,

Catharine W. Cummer

Catharine W. Cummer

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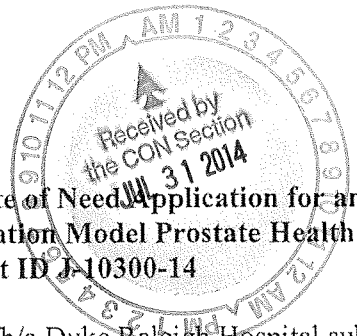

Public Comments regarding Certificate of Need Application for an Additional Linear Accelerator for Demonstration Model Prostate Health Center
Project ID J-10300-14

The Duke University Health System, Inc. d/b/a Duke Raleigh Hospital submits these comments regarding the Prostate Health Center's certificate of need application for a second linear accelerator in Raleigh, North Carolina (Project ID J-10300-14). The application is not conforming with several statutory criteria and should be disapproved.

Criterion 1

This application is not conforming with Criterion 1, as the application is not consistent with the need determinations and policies of the State Medical Facilities Plan, which expressly regulates the inventory and need for linear accelerators.

The 2014 State Medical Facilities Plan establishes a need for two linear accelerators, one in Service Area 20 and one in Service Area 21, pursuant to a fixed review schedule. The Plan expressly states, "It is determined that there is no need for any additional linear accelerators anywhere in the state and no reviews are scheduled." 2014 SMFP, p. 135. In the past, when the SHCC chose to establish a need for a dedicated linear accelerator for a prostate demonstration project, it did so in the linear accelerator chapter. No such need exists in this year's plan.

The Prostate Health Center maintains that because it originally acquired its existing linear accelerator pursuant to a special need determination created for a dedicated linear accelerator for a prostate demonstration project, it does not need to await a further determination of need to acquire additional equipment. This position is contrary to long-standing certificate of need precedent and to the terms of the prostate demonstration project itself.

The 2009 need determination pursuant to which the Prostate Health Center acquired its existing equipment expressly specified a need for one dedicated linear accelerator, not for a radiation oncology center with unlimited linear accelerators:

> In response to a petition, there is included in this North Carolina 2009 State Medical Facilities Plan a statewide need determination for one dedicated linear accelerator that shall be part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men.
>
> The Linear Accelerator Demonstration Project shall include the following components:
>
> - Development of a multidisciplinary prostate health center to provide urology services, medical oncology services, biofeedback therapy, chemotherapy, brachytherapy and living skills counseling and therapy in the same building.
> - Location of the prostate health center in close proximity to minority communities.
> - A medical director who shall be either a urologist certified by the American Board of Urology, a medical oncologist certified by the American Board of Internal Medicine, or a radiation oncologist certified by the American Board of Radiology.
> - Commitment to sponsor regular case conferences and tumor boards.
> - Written policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.

- Written strategies that include specific activities designed to assure the services will be accessible by indigent patients without regard to their ability to pay.
- Written description of patient selection criteria, including referral arrangements for high-risk patients.
- An organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives, such as the NC Minority Prostate Cancer Awareness Action Team.
- An Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that meets regularly and provides feedback about effective practices or changes that need to be made.
- Commitment to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
    - The total number of patients treated;
    - The number of African-Americans treated;
    - The number of other minorities treated; and
    - The number of insured, underinsured and uninsured patients served by type of payment category.
- Documentation of arrangements made with a third party researcher (preferably a historically black university) to evaluate the efficacy of the model during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year of the project.

2009 SMFP, p. 121. As set forth in the need determination, it was created in response to a petition, the process for which is clearly established in each year's plan. After a competitive application process and appeal, the Prostate Health Center was awarded a certificate of need for a single linear accelerator, subject to conditions to comply with the goals of the demonstration project. It has been in operation for a single year.

Each year, the State Health Coordinating Council evaluates the need for additional linear accelerators in each service area. It considers any petitions for adjustments to the need or for dedicated or demonstration projects, just as it did in 2009. For 2014, the SHCC determined that there is a need for a single additional linear accelerator in the service area in which the Prostate Health Center is located, the review cycle for which begins September 1. This additional linear accelerator is not limited to any prostate demonstration project or other dedicated need. If the Prostate Health Center believes it can demonstrate the need for that linear accelerator, it is free to file an application and face a review and comparative analysis with any other applicant in the review beginning September 1. It is similarly free to petition to create a need determination for an additional dedicated prostate linear accelerator. It cannot, however, simply ignore the need determinations in the Plan and expand its inventory of linear accelerators.[1]

Following the Prostate Health Center's argument, any provider who originally developed regulated assets pursuant to a special need determination or a demonstration project would never

[1] Not only did Cary Urology refrain from petitioning the SHCC for an additional dedicated prostate linear accelerator, in fact, Cary Urology opposed the petition to establish the need in the 2014 SMFP for an additional linear accelerator in its service area.

need to petition for, nor await, a further need determination again to expand its capacity. This would include providers of dedicated MRI scanners (breast or extremity) or single-specialty ambulatory surgery centers, for example. While there are several SMFP policies that expressly create exemptions from need determinations in other settings, the SHCC has never promulgated a similar policy that would have exempt demonstration projects from need determinations. There is no evidence that the SHCC intended to abdicate any further oversight of the need for such services, simply by authorizing a demonstration project to operate a single linear accelerator.

To the contrary, it is clear that the SHCC expressly intended to evaluate the demonstration project after several years of operation before determining whether any additional linear accelerators dedicated for this purpose were appropriate in the state. The prostate demonstration project is subject to very specific conditions, including that it arrange with a third party researcher "to evaluate the efficacy of the model during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State" and "[t]he report and recommendations of the researcher shall be provided to the Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year of the project." 2009 SMFP, p. 121. The Prostate Health Center is required to report each year the number of insured, underinsured and uninsured patients served by type of payment category. These conditions were designed to evaluate whether this model would, in fact, benefit patients in the state. As set forth below, recent research and the Prostate Health Center's own experience reflect the inherent problems with the model.

This application does not comply with Criterion 1 and must be denied.

Criteria 3, 4, and 6

Even if the application were properly filed pursuant to a need determination, it does not comply with Criterion 3, 4, 5, or 6, in that there is no need for the proposed service of a dedicated linear accelerator operated by a urology group; the utilization projections are unreasonable; and the project would therefore be unnecessarily duplicative of existing services in the service area.

Urologist ownership of linear accelerators leads to costly higher referrals for IMRT

In July 2013, the United States Government Accountability Office published a striking study concluding that physicians who could self-refer prostate cancer patients for radiation oncology – that is, urologists and other physicians who owned linear accelerators to which they could refer their prostate cancer patients – were significantly more likely to refer patients for IMRT and less likely to refer them to other, less costly treatments than non-self-referring physicians:

> Among all providers who referred a Medicare beneficiary diagnosed with prostate cancer in 2009, those that self-referred were 53 percent more likely to refer their patients for IMRT and less likely to refer them for other treatments, especially a radical prostatectomy or brachytherapy. Compared to IMRT, those treatments are less costly and often considered equally appropriate but have different risks and side effects. Factors such as age, geographic location, and patient health did not explain the large differences between self-referring and non-self-referring providers. These

> analyses suggest that financial incentives for self-referring providers—specifically those in limited specialty groups—were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT.

GAO 13-525, Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny (July 2013) ("GAO Report," submitted with these comments, introductory page.

This finding was supported by another study published last year in the New England Journal of Medicine:

> [T]his study shows that men treated by self-referring urologists, as compared with men treated by non–self-referring urologists, are much more likely to undergo IMRT, a treatment with a high reimbursement rate, rather than less expensive options, despite evidence that all treatments yield similar outcomes. The findings raise concerns regarding the appropriate use of IMRT, especially among older Medicare beneficiaries, for whom the risks of undergoing intensive irradiation probably exceed the benefits. Recent evidence suggests that the IMRT self-referral arrangement is becoming more common; by the end of 2011, approximately 19% of urology practices had incorporated IMRT services into their practice. Permitting urologists to self-refer for IMRT may contribute to increased use of this expensive therapy.

Jean M. Mitchell, "Urologists' Use of Intensity-Modulated Radiation Therapy for Prostate Cancer," New England Journal of Medicine, 2013; 369:1629-1637 (October 24, 2013). *See also* Justin E. Bekelman et al., "Effect of Practice Integration between Urologists and Radiation Oncologists on Prostate Cancer Treatment Patterns, The Journal of Urology, 2013: DOI: 10.1016/j.juro.2013.01.103 (prostate cancer patients of urologists who own linear accelerators are more likely to receive radiation treatment in lieu of surgery than patients treated by urologists without an ownership stake in the equipment).

Citing the GAO Report, the American Society for Radiation Oncology (ASTRO) has concluded that "[c]ontrary to the claims of limited specialty [urology] groups, GAO's report confirms that these practices are not truly integrated health care centers, but that they are moneymaking schemes intended to increase volume and achieve high profits." (see August 1, 2003 ASTRO Press Release, submitted with these comments). Therefore, compelling evidence supports a conclusion that there is no need for additional urologist-owned linear accelerators as proposed by the Prostate Health Center.

Moreover, as part of the American Board of Internal Medicine's Choosing Wisely initiative, created to promote conversations across multiple medical specialties between patients and physicians to help patients choose care that is supported by evidence and truly necessary, ASTRO has also published a recommendation that all physicians discuss active surveillance without therapy as an option before initiating management of low-risk prostate cancer. Perhaps reflecting this recommendation to consider active surveillance in lieu of therapy for some prostate patients, the 2013 GAO report showed that overall Medicare utilization for prostate-cancer related IMRT (including services provided in hospital outpatient departments and non-self-referring physician offices) began to decrease slightly starting in 2007. GAO Report, Appendix II. The exception was "switchers" who developed the ability to self-refer patients for

IMRT; these switchers became 46.6% more likely to refer patients for IMRT after the switch, and 52.2% less likely to refer patients for brachytherapy. GAO Report, p 40.

The Prostate Health Center's referral rate for radiation therapy increased after acquisition of a linear accelerator

The Prostate Health Center appears to have followed this trend of "switchers" referring significantly more patients for linear accelerator treatments after acquisition of a linear accelerator, despite the national trend of overall flat or declining radiation oncology utilization for prostate patients. In its 2009 application, Cary Urology stated that in its experience, approximately 50% of new prostate cancers are appropriately treated with radiation therapy. (See 2009 application for Project ID J-8331-09, pp. 114 and 193). Including post-surgery EBRT patients, Cary Urology projected a total of 125 patients would receive EBRT either alone or combination with brachytherapy and/or surgery in the first year of service (including prostate, GU, and palliative care patients), or approximately 46% of all patients. See 2009 application, pp. 200 and 202. 9% of all patients were projected to get brachytherapy in the first year of the project. The remainder were projected to have surgery, medical oncology, or a "watchful waiting" approach.

The Prostate Health Center's 2014 application documents a striking shift in that referral pattern. After the acquisition of a physician-owned linear accelerator to which to refer patients, the Center now reports that 205 patients, or more than 70% of the total, received radiation oncology treatments on its linac (with an additional 3.5% electing radiation therapy elsewhere). 2014 Application, p. 125. Fewer than 4% of all patients (9 out of 285) received brachytherapy (which as the GAO Report points out is a much cheaper alternative), a significant decrease from the prior treatment rate. The Prostate Health Center offers no explanation for this radical increase in linear accelerator utilization rates for its patients, and the corresponding decrease in brachytherapy, surgery, and watchful waiting.

The GAO Report and other research call into serious doubt any utilization projections based on a self-referring urology practice's own volumes, as they become a self-fulfilling prophecy. In this case, the Prostate Health Center projects future utilization based on its new, elevated utilization rate for linear accelerator treatments for prostate patients. 2014 Application, p. 125. However, this utilization rate is unreasonable given its historical experience prior to owning a linear accelerator and in light of nationwide stagnant prostate radiation oncology utilization . The fact that the Prostate Health Center has exceeded its original projections for its first year of operation is a cause for significant concern and heightened scrutiny, not the basis for approving the acquisition of additional equipment to which it can self-refer.

Criterion 13(c)

One of the key issues to be evaluated in the prostate demonstration project is the payer mix of the population served by the demonstration project. Based on its experience since it has begun

service, the Prostate Health Center documents a surprisingly low percentage of its patients to be served by Medicaid.

	2009 Application	**Actual/2014 Application**
Self-Pay	0.8%	1.30%
Medicare	61.2%	59.03%
Medicaid	**6.8%**	**0.46%**
Commercial/Managed Care	24.4%	11.9%
Other (BCBS/Other)	6.8%	27.31%
TOTAL	100%	100%

The Prostate Center's Medicaid population in particular is significantly lower than projected, an unexpected result for a demonstration project to reach out to an underserved population. In fact, its Medicaid population now constitutes a smaller percentage of its radiation oncology patients than the percentages both of its entire practice and specifically of brachytherapy services were at the time of its application in 2009 (1.8% and 6.8% respectively). 2009 Application, p. 246.

The Prostate Health Center therefore does not conform with Criterion 13(c) regarding access for underserved patients, a key metric for this demonstration project in particular.

Limits on use

While the Prostate Health Center claims the right to apply to increase its capacity based on its "demonstration project" status, its application does not include a commitment to limit its linear accelerator services to prostate and urologic cancers as it did in its original application. That application expressly stated that "[t]he proposed linear accelerator will be used exclusively for the treatment of prostate and urologic cancers":

> Furthermore, the proposed project is consistent with the intent of the need determination as detailed in the verbiage on page 121 of the *SMFP* describing the need determination for the linear accelerator as "part of a demonstration project for a model multidisciplinary prostate health center focused on the treatment of prostate cancer, particularly in African American men". A project for a linear accelerator that will be involved in the treatment of multiple site cancers, other than urological cancers, cannot truly be 'focused on the treatment of prostate cancer'. The proposed linear accelerator will be used exclusively for the treatment of prostate and urologic cancers. The Prostate Health Center physicians and Staff will be focused on the treatment of prostate cancer. The Prostate Health Center Tumor Board will focus on prostate cancer. The Center proposes an organized African American prostate cancer education/outreach program to partner with and complement the NC Minority Prostate Cancer Awareness Action Team initiatives.

2009 Application, p. 146.

This restriction is appropriate for a demonstration project for a linear accelerator dedicated for a multidisciplinary prostate center. However, the Prostate Health Center does not expressly

commit to the same exclusive use for the second proposed linear accelerator, which would be inconsistent with its claim that it is simply expanding its existing service. Even if it could demonstrate need for this project and conformity with the SMFP's need determinations and other statutory and regulatory criteria, any acquisition of additional radiation oncology equipment for this demonstration project should be expressly limited to its use for urological cancer patients.

Conclusion

Given nationwide prostate IMRT utilization trends, the risks to patients and increased costs associated with self-referral, and the changes in the Prostate Health Center's utilization patterns, increasing capacity for such a dedicated service is not in the best interests of patients in North Carolina, and this application should be denied.

United States Government Accountability Office

Report to Congressional Requesters

July 2013

MEDICARE

Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny

GAO-13-525

July 2013

GAO Highlights

Highlights of GAO-13-525, a report to congressional requesters

MEDICARE

Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny

Why GAO Did This Study

Questions have been raised about self-referral's role in Medicare Part B expenditures' rapid growth. Self-referral occurs when a provider refers patients to entities in which the provider or the provider's family members have a financial interest. Services that can be self-referred under certain circumstances include IMRT, a common and costly treatment for prostate cancer. GAO was asked to examine Medicare self-referral trends among radiation oncology services. This report examines (1) trends in the number of and expenditures for prostate cancer-related IMRT services provided by self-referring and non-self-referring provider groups from 2006 through 2010 and (2) how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer. GAO analyzed Medicare Part B claims and developed a claims-based methodology to identify self-referring groups and providers. GAO also interviewed officials from the Centers for Medicare & Medicaid Services (CMS), which administers Medicare, and other stakeholders.

What GAO Recommends

Congress should consider directing the Secretary of Health and Human Services, whose agency oversees CMS, to require providers to disclose their financial interests in IMRT to their patients. GAO also recommends that CMS identify and monitor self-referral of IMRT services. HHS disagreed with GAO's recommendation. Given the magnitude of GAO's findings, GAO maintains CMS should identify and monitor self-referral of IMRT services.

View GAO-13-525. For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

The number of Medicare prostate cancer–related intensity-modulated radiation therapy (IMRT) services performed by self-referring groups increased rapidly, while declining for non-self-referring groups from 2006 to 2010. Over this period, the number of prostate cancer–related IMRT services performed by self-referring groups increased from about 80,000 to 366,000. Consistent with that growth, expenditures associated with these services and the number of self-referring groups also increased. The growth in services performed by self-referring groups was due entirely to limited-specialty groups—groups comprised of urologists and a small number of other specialties—rather than multispecialty groups.

Providers substantially increased the percentage of their prostate cancer patients they referred for IMRT after they began to self-refer. Providers that began self-referring in 2008 or 2009—referred to as switchers—referred 54 percent of their patients who were diagnosed with prostate cancer in 2009 for IMRT, compared to 37 percent of their patients diagnosed in 2007. In contrast, providers who did not begin to self-refer—that is, non-self-referrers and providers who self-referred the entire period—experienced much smaller changes over the same period. Among all providers who referred a Medicare beneficiary diagnosed with prostate cancer in 2009, those that self-referred were 53 percent more likely to refer their patients for IMRT and less likely to refer them for other treatments, especially a radical prostatectomy or brachytherapy. Compared to IMRT, those treatments are less costly and often considered equally appropriate but have different risks and side effects. Factors such as age, geographic location, and patient health did not explain the large differences between self-referring and non-self-referring providers. These analyses suggest that financial incentives for self-referring providers—specifically those in limited specialty groups—were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT. Medicare providers are generally not required to disclose that they self-refer IMRT services, and the Department of Health and Human Services (HHS) lacks the authority to establish such a requirement. Thus, beneficiaries may not be aware that their provider has a financial interest in recommending IMRT over alternative treatments that may be equally effective, have different risks and side effects, and are less expensive for Medicare and beneficiaries.

Change in the Percentage of Medicare Prostate Cancer Patients Providers Referred for IMRT after a Diagnosis of Prostate Cancer in 2007 or 2009

Type of provider	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2007	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2009	Percentage point change from 2007 to 2009	Percentage more or less likely providers were to refer patients for IMRT in 2009 compared to 2007
Switchers	37.0%	54.2%	17.2	46.6%
Non-self-referrers	31.4	33.1	1.7	5.5
Self-referrers	55.7	52.9	-2.8	-5.1

Source: GAO analysis of CMS data.

Note: Switchers did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. The percentage by which providers were more or less likely to refer patients for IMRT in 2009 compared to 2007 is equivalent to the percentage point change from 2007 to 2009 divided by the percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2007.

Contents

Tables

Figures

Abbreviations

3D-CRT	three-dimensional conformal radiation therapy
ASTRO	American Society for Radiation Oncology
AUA	American Urological Association
CMS	Centers for Medicare & Medicaid Services
EBRT	external beam radiation therapy
FFS	fee-for-service
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
IMRT	intensity-modulated radiation therapy
IOAS	in-office ancillary services
LUGPA	Large Urology Group Practice Association
NPI	national provider identifier
PPACA	Patient Protection and Affordable Care Act
PSA	prostate-specific antigen
SEER	Surveillance Epidemiology and End Results
TIN	taxpayer identification number

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
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July 19, 2013

Congressional Requesters

Expenditures for Medicare Part B services—which include physician and other outpatient services—have grown rapidly, increasing annually at 5.9 percent, on average, from 2007 through 2011. In comparison, the national economy grew by less than half that rate during the same period. Policymakers have questioned whether some of the growth in spending for Part B services may be attributed to self-referral, which occurs when providers refer their patients to entities—such as themselves or a group practice—in which they or a member of their families have a financial relationship.[1] While federal law generally prohibits self-referral under Medicare, there are exceptions for certain services and arrangements.[2] Among the Medicare diagnostic and therapeutic services that may be self-referred under one of these exceptions is intensity-modulated radiation therapy (IMRT), a form of external beam radiation therapy (EBRT) commonly used to treat prostate cancer. While there are multiple effective treatments for prostate cancer, IMRT is one of the most costly options. In 2010, expenditures for prostate cancer–related IMRT services accounted for about 55 percent of the $1.27 billion that Medicare paid for all IMRT services under Medicare Part B.

Questions have been raised about the effect of self-referral arrangements on the utilization of IMRT services reimbursed under Medicare Part B. Critics of such self-referral arrangements suggest that there may be a financial incentive to overutilize IMRT because diagnosing providers can earn more by self-referring IMRT services than if patients were referred

[1]Providers in our analysis that could self-refer could include physicians and other providers, such as nurse practitioners and physician assistants.

[2]Compliance with the physician self-referral law, commonly known as the Stark law, is outside the scope of this report. The Stark law prohibits physicians from making referrals for certain designated health services paid for by Medicare, to entities with which the physicians or immediate family members have a financial relationship, unless the arrangement complies with a specified exception, such as in-office ancillary services. 42 U.S.C. § 1395nn(b)(2). The requirements of the in-office ancillary services exception are found at 42 C.F.R. § 411.355(b) (2012).

for other treatments.[3] Other treatments for prostate cancer are often considered equally appropriate, as experts have not established a "gold standard" for the treatment of cancer that has not spread beyond the prostate (i.e., localized prostate cancer), which represents a large majority of newly diagnosed prostate cancers.[4] Proponents of self-referral arrangements contend that the self-referral of IMRT services does not affect clinical decision making and that patients benefit from self-referral through, for example, improved coordination among the providers who diagnose and treat patients.

You asked us to examine Medicare self-referral trends among radiation oncology services. In this report, we (1) compare trends in the number of and expenditures for prostate cancer–related IMRT services provided by self-referring and non-self-referring provider groups from 2006 through 2010 and (2) examine how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer.

To compare trends in the number of and expenditures for prostate cancer–related IMRT services provided by self-referring and non-self-referring groups in provider offices from 2006 through 2010, we analyzed IMRT delivery claims from the Medicare Part B Carrier file.[5] We identified

[3]For example, see Benjamin P. Falit, Cary P. Gross, and Kenneth B. Roberts, "Integrated Prostate Cancer Centers and Over-Utilization of IMRT: A Close Look at Fee-For-Service Medicine in Radiation Oncology," *International Journal of Radiation Oncology • Biology • Physics* 76, no. 5 (April 2010): 1285-88.

[4]For instance, for a subset of localized prostate cancers that are low risk, IMRT, brachytherapy, and a radical prostatectomy are all among the treatments considered appropriate. According to the National Cancer Institute, 81 percent of men who were diagnosed with prostate cancer from 2002 through 2008 in 18 geographic areas that provided cancer data to the National Cancer Institute were diagnosed with localized prostate cancer, while the rest were diagnosed at an unknown stage (3 percent) or after the cancer had spread regionally (12 percent) or distantly (4 percent). See http://seer.cancer.gov/statfacts/html/prost.html, accessed December 18, 2012.

[5]IMRT delivery codes represent individual treatment sessions during which patients receive radiation. In addition to receiving radiation, patients receive several different types of services during a course of IMRT. Our analysis of self-referred prostate cancer–related IMRT services is limited to those services performed in physician offices. We focused on this setting because our work showed rapid growth in this setting compared to hospital outpatient departments and because the financial incentive for providers to self-refer is most direct when the service is performed in a physician office. Services performed by non-self-referring groups in the physician office setting could include services provided in places such as freestanding cancer centers. Throughout this report, we refer to services billed through the Carrier file as services performed in physician offices.

prostate cancer–related IMRT services using diagnosis codes on the claims. Because there is no indicator or "flag" on the claim that identifies whether services are self-referred or non-self-referred and the Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, has no other method for identifying whether a service was self-referred, we developed a claims-based methodology for identifying provider group practices as self-referring or non-self-referring.[6] Specifically, we classified groups as self-referring if the providers who administered IMRT for the group had a financial relationship with the same entity as the provider who referred the IMRT service.[7] Additionally, in order to be considered self-referring, groups had to meet other volume-related criteria, such as self-referring at least half of the courses of IMRT therapy the group provided. To ensure that how we defined our criteria were reliable, we tested alternative thresholds for defining self-referring groups and found that the observed patterns were similar regardless of the threshold used. We also analyzed trends in the utilization of prostate cancer–related IMRT services by whether the service was performed by a limited-specialty or multispecialty group. We defined groups as limited specialty in a given year if more than 75 percent of its office visits were performed by urologists, nonphysician practitioners (e.g., physician assistants), or providers whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists. The remaining groups were comprised of providers from a large number of different specialties and were considered multispecialty groups. We examined the trends in prostate–cancer related IMRT services performed in hospital outpatient departments for context.

To examine how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer, we performed two separate analyses using the Medicare Part B Carrier and hospital outpatient files. First, we compared the percentage of prostate cancer patients that self-referring and non-self-referring providers referred for IMRT and other treatments within a year of being diagnosed in 2007 or 2009. We classified referring providers as self-referring if they were the

[6]An indicator or "flag" could be, for example, a modifier that a provider lists on a claim to indicate that a service is self-referred. Providers currently use modifiers to provide additional information about a service to CMS.

[7]Providers could have a financial relationship with the same entity if, for example, they are part of the same group practice.

performing provider on a claim that was paid to a self-referring provider group in the year of, before, or after a beneficiary's prostate cancer diagnosis. All other providers were considered non-self-referring. In addition, we examined how, if at all, the referral patterns for non-self-referring and self-referring providers were affected by beneficiary characteristics such as age, geographic location (i.e., urban or rural), and beneficiary health.[8] As part of our examination of beneficiary health, we examined how, if at all, provider referral patterns were affected by clinical characteristics of patients' prostate cancers, which were obtained from the New York State Cancer Registry, for beneficiaries who lived in New York and were diagnosed with prostate cancer in either 2007 or 2009. The results of the New York analysis are not generalizable to the entire Medicare population. We used clinical information from the New York State Cancer Registry because such information is not available on Medicare claims, and we determined that the geographic areas included in another common source of such information—Surveillance Epidemiology and End Results (SEER) data—did not sufficiently overlap with areas in which IMRT self-referral was prevalent during our study period. Second, we determined whether the percentage of providers' prostate cancer patients referred for IMRT and other treatments changed after they began to self-refer. Specifically, we identified a group of providers, which we called "switchers," that did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. We then analyzed the change in the percentage of switchers' newly diagnosed prostate cancer patients referred for IMRT and other treatments before and after switchers began to self-refer. We compared the change for this group of providers to the change among providers who did not begin to self-refer IMRT services during this period. For both analyses, we counted IMRT and other treatments regardless of the setting in which they were performed.

We took several steps to ensure that the data used to produce this report were sufficiently reliable. Specifically, we assessed the reliability of the CMS data we used by interviewing officials responsible for overseeing these data sources, reviewing relevant documentation, and examining the data for obvious errors. We determined that the data were sufficiently

[8]We defined urban areas as metropolitan statistical areas, a geographic entity defined by the Office of Management and Budget as a core urban area of 50,000 or more population; all other settings were considered rural.

reliable for the purposes of our study. (See app. I for more details on our scope and methodology.)

We conducted this performance audit from May 2010 through July 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Prostate cancer patients choose among multiple treatments that are often considered equally appropriate but can have different risks and side effects. The treatments can also vary in cost, with IMRT being one of the most costly options.

Diagnosis and Treatment of Prostate Cancer

Cancer of the prostate—a gland located at the base of the urinary bladder—is the second most common cancer among men in the United States, with approximately 1 in 6 men receiving a diagnosis of prostate cancer in his lifetime.[9] In 2010, there were an estimated 218,000 new cases of prostate cancer and approximately 32,000 deaths due to prostate cancer. Most men in the United States are diagnosed with prostate cancer as a result of an abnormal digital rectal exam or prostate-specific antigen test. After an abnormal test result, beneficiaries often undergo a prostate biopsy, during which a provider—typically a urologist—removes small amounts of prostate tissue. Another provider then examines the tissue to determine whether a beneficiary has prostate cancer.

IMRT is one of multiple treatment options available to patients with prostate cancer. The type of treatment a prostate cancer patient chooses depends on a number of different factors such as life expectancy, overall health, personal preferences, provider recommendations, and the clinical characteristics of a patient's prostate cancer. For many men, multiple

[9]National Cancer Institute. See http://seer.cancer.gov/statfacts/html/prost.html, accessed December 18, 2012. Skin cancer is the most common form of cancer.

treatment options are considered equally appropriate.[10] For instance, IMRT, brachytherapy, and a radical prostatectomy are all among the treatments considered appropriate for men with low-risk prostate cancer.[11] Even though such treatments are often considered equally appropriate, the risks and side effects for each treatment are different. Compared to IMRT, prostate cancer patients undergoing a radical prostatectomy have a higher rate of short term urinary problems and erectile dysfunction but do not face bowel-related side effects, which are experienced by some men undergoing IMRT.[12] Compared to IMRT, prostate cancer patients undergoing brachytherapy have lower rates of bowel-related side effects but about 1 in 10 patients undergoing brachytherapy experience acute urinary retention. Also, several studies have reported that physician recommendations play a large role in influencing a patient's decision,[13] and another study found that the use of a particular prostate cancer treatment decreased after its payment was reduced, suggesting that financial incentives may have influenced treatment decisions.[14] Currently, providers who self-refer IMRT services are generally not required to disclose to their patients that they have a

[10]Men can also receive a combination of therapies, such as brachytherapy combined with EBRT.

[11]National Comprehensive Cancer Network, *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™): Prostate Cancer* (June 2011).

[12]Institute for Clinical and Economic Review, "Management Options for Low-Risk Prostate Cancer: A Report on Comparative Effectiveness and Value" (Sept. 16, 2009).

[13]Steven B. Zelladt et al., "Why Do Men Choose One Treatment over Another? A Review of Patient Decision Making for Localized Prostate Cancer," *Cancer* 106, no. 9 (May 1, 2006): 1865-74.

[14]Vahakn B. Shahinian, Yong-Fang Kuo, and Scott M. Gilbert, "Reimbursement Policy and Androgen-Deprivation Therapy for Prostate Cancer," *The New England Journal of Medicine* 363, no. 19 (Nov. 4, 2010): 1822-32.

financial interest in the service.[15] Some common prostate cancer treatments are summarized in table 1.

Table 1: Prostate Cancer Treatments

Treatment	Description
Radical prostatectomy	A radical prostatectomy is a surgical procedure in which the entire prostate gland is removed. A prostatectomy can be performed with or without robotic assistance.
Three-dimensional conformal radiation therapy (3D-CRT)	3D-CRT is a form of external beam radiation therapy (EBRT) during which multiple doses of radiation from an external source are administered over several weeks. In 3D-CRT, radiation beams are shaped in an attempt to maximize the amount of radiation the tumor receives and reduce the amount of radiation to which normal tissue is exposed.
Intensity-modulated radiation therapy (IMRT)	IMRT is a newer and an even more precise form of EBRT that allows even more radiation to be delivered to the tumor while sparing normal tissue.
Brachytherapy	Brachytherapy is a treatment that involves the implantation of radioactive sources directly inside the prostate.
Active surveillance	Active surveillance is a regimen of following a patient's condition without giving any treatment, unless the patient's condition changes. An exact regimen has not been established for active surveillance. However, typical protocols involve periodic physical examination, prostate-specific antigen testing, and repeat prostate biopsies.
Hormone therapy	Hormone therapy is a treatment that removes or blocks the actions of male sex hormones, which can cause prostate cancer to grow, in order to stop the growth of prostate cancer. Drugs, surgery, or other hormones are used to reduce hormone production or block their effects.

[15]A physician with an ownership or investment interest in a hospital and who is a member of that hospital's medical staff is required to disclose this financial interest when referring patients to that hospital under an exception to the general prohibition on Medicare self-referral (Stark law). According to Physician Hospitals of America, an advocacy group for physician-owned hospitals, approximately 265 hospitals—or less than 5 percent of all hospitals—were physician-owned as of July 2012. See 42 C.F.R. § 411.362 (2012) for more information on additional requirements concerning physician ownership and investment in hospitals under the Stark law. The Patient Protection and Affordable Care Act (PPACA) created a new disclosure requirement for physicians who self-refer certain other in-office ancillary services under the Stark Law. Pub. L. No. 111-148, § 6003, 124 Stat. 119, 697(2010). Specifically, referring physicians for certain advanced imaging services are required to inform their patients in writing at the time of the referral that the patient may obtain the service from another entity and provide the patients with a list of providers who furnish the service in the area in which the patient resides. 42 U.S.C. § 13955nn(b)(2). No such requirement exists for physicians who self-refer IMRT services. CMS noted in the preamble to the final rule detailing this disclosure requirement that the agency does not have the authority to expand the disclosure requirements to services other than the radiology services referenced in PPACA. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,170, 73,444 (Nov. 29, 2010).

Treatment	Description
Other treatments	Other treatments for prostate cancer include stereotactic body radiotherapy / stereotactic radiosurgery (forms of EBRT during which beneficiaries receive larger daily doses of radiation over a shorter period of time), cryosurgery (freezing prostate cancer by injecting gases through thin needles inserted into the prostate), and proton beam therapy (a form of EBRT that involves the use of particles—protons—rather than photons, which are used in the majority of EBRT treatments).

Source: GAO analysis of published literature.

Medicare Reimbursement for IMRT Services and Costs of Treatment Options for Prostate Cancer

Medicare reimbursement rates for IMRT delivery services varied over time, and rates are not directly comparable between settings. Beneficiaries receive approximately 45 separate IMRT delivery services over several weeks during a course of IMRT to treat prostate cancer. Medicare beneficiaries predominantly receive IMRT delivery services in two settings—physician offices or hospital outpatient departments. The Medicare reimbursement per IMRT delivery service increased from approximately $319 to $421 from 2006 to 2010 and then to $484 by 2013 for services performed in hospital outpatient departments.[16] For services performed in physician offices, the reimbursement rate decreased from approximately $690 to $511 from 2006 to 2010 and then to $406 by 2013.[17] The reimbursement rates for IMRT delivery services performed in physician offices and hospital outpatient departments are not directly comparable. For instance, if an IMRT delivery service was performed in a hospital outpatient department, payment includes the technical component for image guidance,[18] which is almost always furnished with an IMRT service. In physician offices, image guidance is reimbursed separately.

[16]These payment rates are those hospitals receive under the Hospital Outpatient Prospective Payment System. Not all hospitals are paid under this system.

[17]These expenditures do not include the payment reductions that may result from implementation of the Budget Control Act of 2011. Pub. L. No. 112-25, 125 Stat. 240.

[18]The technical component is intended to cover the cost of performing a test, including the costs for equipment, supplies, and nonphysician staff.

Researchers have consistently found that courses of IMRT, which include IMRT delivery and other services,[19] are more costly than other treatments for prostate cancer, with the exception of proton therapy.[20] Researchers have found IMRT to be more costly despite differences among studies in design and methodology, such as the services counted toward total treatment costs, the duration of time during which costs are studied (e.g., first year costs vs. lifetime costs), and the patient population studied. One recent study found that, among men diagnosed with prostate cancer in 2005, the cost to Medicare per course of treatment was approximately $14,000 to $15,000 higher for men receiving IMRT ($31,574) than for men who received brachytherapy ($17,076) or a prostatectomy ($16,469 or $16,762, depending on the type of prostatectomy).[21] Despite the 2013 reduction in the Medicare reimbursement rate for IMRT delivery services performed in physician offices, we found that IMRT remains substantially more expensive than other treatments for prostate cancer, with the exception of proton therapy.[22]

[19]Episodes of IMRT for prostate cancer include other services such as a radiotherapy dose plan, weekly management services, and weekly radiation physics consultations.

[20]For instance, see: Matthew R. Cooperberg et al., "Primary treatments for clinically localised prostate cancer: a comprehensive lifetime cost-utility analysis," *BJU International* 111, no. 3 (March 2013): 437-50; or Chirag Shah et al., "Brachytherapy provides comparable outcomes and improved cost-effectiveness in the treatment of low/intermediate prostate cancer," *Brachytherapy* 11 (2012): 441-45.

[21]P. L. Nguyen et al., "Cost implications of the rapid adoption of newer technologies for treating prostate cancer," *Journal of Clinical Oncology*, 29, no. 12 (2011): 1517-24. Because Medicare beneficiaries often face cost-sharing requirements, more expensive treatments likely lead to higher beneficiary costs.

[22]To determine the effect of the payment reduction, we calculated the cost of a course of IMRT to treat prostate cancer using 2013 Medicare reimbursement rates and previously published methodologies. For an example of a methodology used, see Andre Konski et al., "Using Decision Analysis to Determine the Cost-Effectiveness of Intensity-Modulated Radiation Therapy in the Treatment of Intermediate Risk Prostate Cancer," *International Journal of Radiation Oncology • Biology • Physics* 66, no. 2 (2006): 408-15.

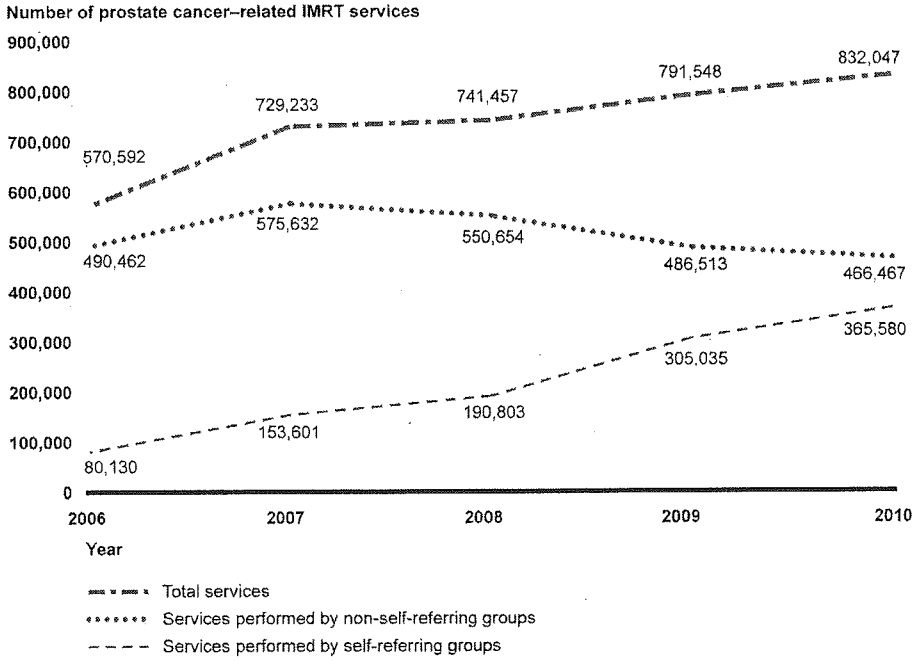
Number of and Expenditures for Prostate Cancer–Related IMRT Services Provided by Self-Referring Groups Grew Rapidly, while Declining for Non-Self-Referring Groups

We found that the number of and expenditures for Medicare prostate cancer–related IMRT services performed by self-referring groups grew rapidly from 2006 through 2010. In contrast, the number of and Medicare expenditures for prostate cancer–related IMRT services performed by non-self-referring groups declined over the period.

Number of Prostate Cancer–Related IMRT Services Performed Increased among Self-Referring Groups—Specifically, Limited-Specialty Groups—and Decreased among Non-Self-Referring Groups

From 2006 through 2010, the number of prostate cancer–related IMRT services performed by self-referring groups increased rapidly, while the number performed by non-self-referring groups decreased. The number of prostate cancer–related IMRT services performed by self-referring groups increased from approximately 80,000 to 366,000, an annual growth rate of 46 percent (see fig. 1). Consistent with that growth, the number of self-referring groups also increased rapidly over the period. In contrast, the number of prostate cancer–related IMRT services performed by non-self-referring groups in physician offices decreased from approximately 490,000 to 466,000, an annual decrease of 1 percent.

Figure 1: Number of Medicare Prostate Cancer–Related IMRT Services Performed by Self-Referring and Non-Self-Referring Groups in Physician Offices, 2006-2010



Source: GAO analysis of CMS data.

The rapid increase in prostate cancer–related IMRT services performed by self-referring groups coincided with several other trends from 2006 through 2010. First, the number of prostate-cancer related IMRT services performed in hospital outpatient departments and by self-referring and non-self-referring groups all grew from 2006 to 2007. After 2007, the rapid increase in prostate cancer–related IMRT services performed by self-referring groups coincided with declines in these services within hospital outpatient departments and among non-self-referring groups. Overall utilization of prostate cancer–related IMRT services therefore remained relatively flat across these settings after 2007, indicating a shift away from hospital outpatient departments and non-self-referring groups and toward self-referring groups. (See app. II for information on the trends in IMRT services performed in hospital outpatient departments.) Second, while the number of prostate cancer–related IMRT services provided to Medicare fee-for-service (FFS) beneficiaries has stabilized since 2007, the

percentage of newly diagnosed Medicare beneficiaries receiving IMRT has increased.[23] While seemingly contradictory, these two trends occurring simultaneously can in part be explained by (1) a decrease in the total number of Medicare FFS beneficiaries from 2006 through 2010[24] and (2) a decrease in the number of men newly diagnosed with prostate cancer.[25] Third, the increasing percentage of prostate cancer patients receiving IMRT may partially be explained by a shift from an older form of EBRT—3D-CRT—to a newer form—IMRT, though the largest effect of this substitution likely occurred earlier in our study period as IMRT largely replaced 3D-CRT by 2007.[26]

Our analysis showed that, from 2006 through 2010, the growth in prostate cancer–related IMRT services performed by self-referring groups was entirely due to an increase in the services performed by limited-specialty groups (see fig. 2). Limited-specialty groups were comprised of urologists and a small number of other specialties.[27] Over our study period, the number of prostate cancer–related IMRT services performed by limited-specialty self-referring groups increased over fivefold, from approximately

[23]Specifically, our analysis of the distribution of treatments among men newly diagnosed with prostate cancer indicates that 33.7 percent and 36.8 percent of men diagnosed with prostate cancer in 2007 and 2009, respectively, were referred for IMRT.

[24]As a result of increased enrollment in Medicare Advantage, the number of Medicare FFS beneficiaries aged 65 and older decreased from 2006 to 2010, going from approximately 27.6 million to 26.4 million.

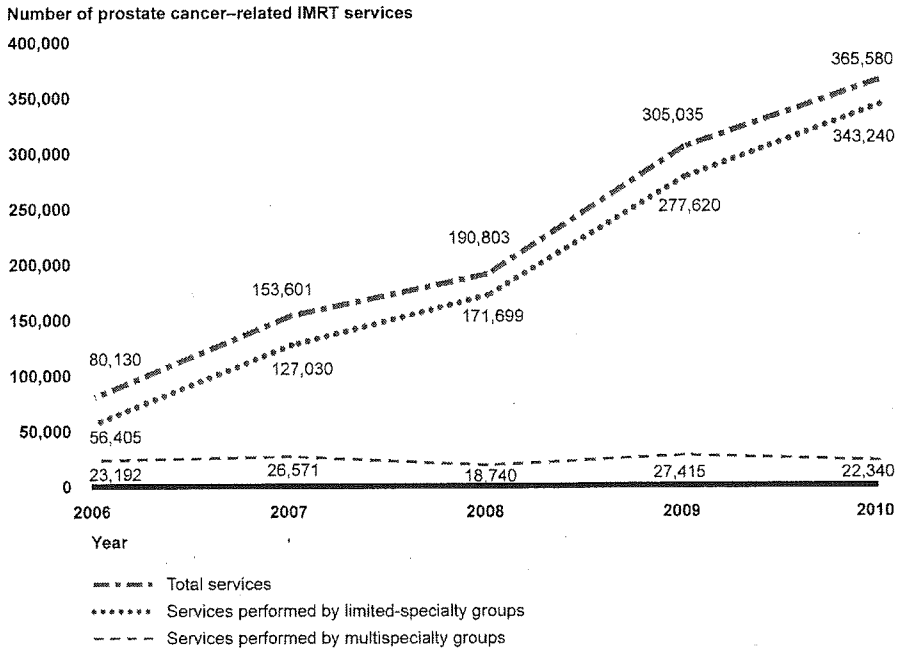
[25]In our analysis of the distribution of treatments among men newly diagnosed with prostate cancer, we found a 19 percent decrease in the number of Medicare FFS beneficiaries who were diagnosed with prostate cancer and met our other inclusion criteria in 2009 compared to 2007—58,289 and 71,834, respectively. In accordance with that, the number of prostate biopsies provided to Medicare FFS beneficiaries, which some researchers have used as a proxy for prostate cancer diagnoses, stayed relatively flat from 2006 to 2007 but then decreased by approximately 20 percent from 2007 through 2010. Others have also noted a decline in reported prostate cancer incidence over a similar period. For instance, see: David H. Howard, "Declines in Prostate Cancer Incidence After Changes in Screening Recommendations," *Archives of Internal Medicine* 172, no. 16 (Sept. 10, 2012): 1267-68.

[26]Bruce L. Jacobs et al., "Growth of High-Cost Intensity-Modulated Radiotherapy for Prostate Cancer Raises Concerns About Overuse," *Health Affairs* 31, no. 4 (April 2012): 750-59.

[27]In 2010, urologists performed approximately 89.1 percent of office visits billed under limited-specialty groups, compared to 5.7 percent for multispecialty groups. Additionally, the average number of specialties that billed office visits under limited-specialty groups in 2010 was 3.3, compared to 36.2 for multispecialty groups.

56,000 to 343,000. In contrast, the number of such services performed by multispecialty self-referring groups, which were comprised of a large number of different provider types, declined slightly, going from approximately 23,000 to 22,000.

Figure 2: Number of Medicare Prostate Cancer–Related IMRT Services Performed by Limited-Specialty and Multispecialty Self-Referring Groups, 2006-2010



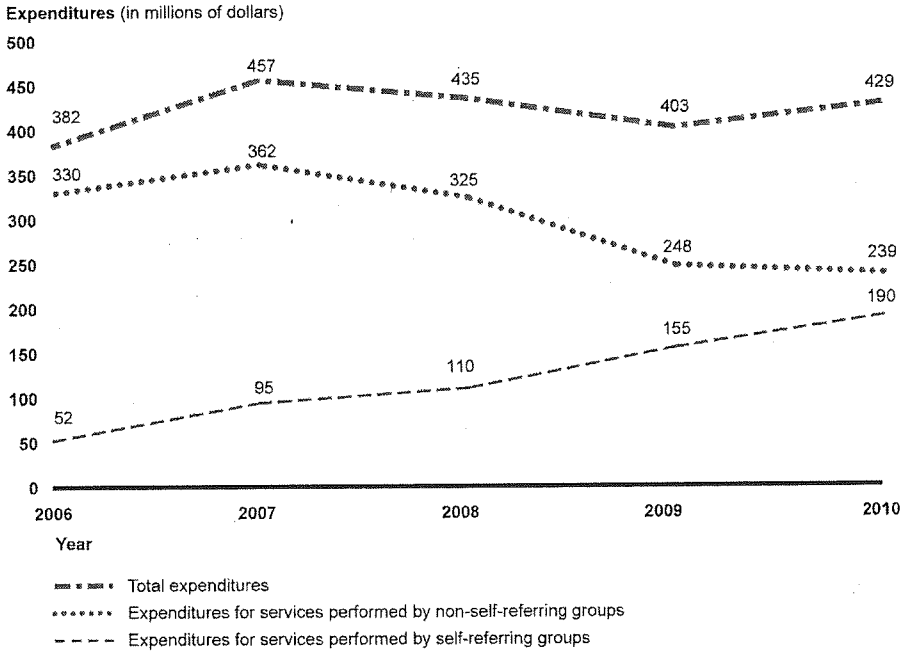
Source: GAO analysis of CMS data.

Notes: In 2006 and 2008, less than 1 percent of total services could not be attributed to either limited-specialty or multispecialty groups. We defined groups as limited specialty in a given year if more than 75 percent of its office visits were performed by urologists, nonphysician practitioners (e.g., physician assistants), or providers whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists. The remaining groups were comprised of providers from a large number of different specialties and were considered multispecialty groups.

Expenditures for Prostate Cancer–Related IMRT Services Performed by Self-Referring Groups Increased Rapidly, while Declining for Non-Self-Referring Groups

Medicare expenditures for prostate cancer–related IMRT services performed by self-referring groups increased rapidly from 2006 through 2010, while decreasing for services performed by non-self-referring groups. Specifically, expenditures for prostate cancer–related IMRT services performed by self-referring groups increased from $52 million to $190 million, an average increase of 38 percent a year (see fig. 3). In contrast, expenditures for prostate cancer–related IMRT services performed by non-self-referring groups in physician offices declined by an average of 8 percent a year. For comparison, expenditures for prostate cancer–related IMRT services performed in hospital outpatient departments grew an average of 7 percent a year during the period we studied. (For more information about hospital outpatient department expenditure trends, see app. II.)

Figure 3: Changes in Medicare Prostate Cancer–Related IMRT Expenditures for Services Performed by Self-Referring and Non-Self-Referring Provider Groups in Physician Offices, 2006-2010



Source: GAO analysis of CMS data.

Self-Referring Providers Referred Their Prostate Cancer Patients for IMRT More Frequently than Non-Self-Referring Providers

Self-referring providers were more likely to refer their Medicare prostate cancer patients for IMRT and less likely to refer them for other treatments when compared to non-self-referring providers. In addition, after providers began self-referring IMRT services, they substantially increased the percentage of their prostate cancer patients they referred for IMRT, in contrast to providers who did not begin to self-refer IMRT services during the same period.

Self-Referring Providers Were 53 Percent More Likely to Refer Their Prostate Cancer Patients for IMRT than Non-Self-Referring Providers

Self-referring providers were more likely to refer their prostate cancer patients for IMRT and less likely to refer them for other treatments compared to non-self-referring providers. Self-referring providers referred approximately 52 percent of their patients who were newly diagnosed with prostate cancer in 2009 for IMRT, while non-self-referring providers referred 34 percent of their patients for IMRT (see table 2). Self-referring providers also referred a lower percentage of their prostate cancer patients for nearly all other types of treatments compared to non-self-referring providers, with the largest differences among patients being referred for brachytherapy or a radical prostatectomy.[28] Other differences were smaller—self-referring providers were about 8 percent less likely to refer their patients for active surveillance compared to non-self-referring providers. (For alternative groupings in which beneficiaries are sorted into discrete treatment categories, see app. III.)

[28]Other than IMRT, the only type of treatment for which self-referring providers did not refer a lower percentage of their prostate cancer patients compared to non-self-referring providers was proton therapy.

Table 2: Percentage of Self-Referring and Non-Self-Referring Providers' Medicare Patients Referred for a Given Treatment after a Diagnosis of Prostate Cancer in 2009

Prostate cancer treatment	Percentage of non-self-referring providers' patients referred for a given treatment (N=48,298)	Percentage of self-referring providers' patients referred for a given treatment (N=9,991)	Percentage point difference	Percentage more or less likely self-referring providers were to refer patients for a given treatment compared to non-self-referring providers
Intensity-modulated radiation therapy	33.7%	51.7%	18.0	53.5%
Active surveillance	22.9	21.0	-1.9	-8.2
Radical prostatectomy	18.0	13.1	-4.9	-27.0
Hormone therapy only[a]	11.4	7.7	-3.8	-32.9
Brachytherapy	14.0	7.0	-7.0	-50.0
Other treatments[b]	6.0	3.2	-2.8	-46.5
Three-dimensional conformal radiation therapy / other external beam radiation therapy	2.4	1.1	-1.3	-55.2

Source: GAO analysis of CMS data.

Notes: Treatment categories do not sum to 100 percent because, with the exception of active surveillance and hormone therapy only, a patient was counted in more than one treatment category if he received a combination of therapies. Including combinations involving hormone therapy, self-referring and non-self-referring providers referred nearly equal percentages of their patients for a combination of treatments—27 percent and 26 percent, respectively.

[a]Prostate cancer patients also commonly receive hormone therapy in conjunction with other treatments. Self-referring providers referred 31.9 percent of their prostate cancer patients for any hormone therapy, while non-self-referring providers referred 33.7 percent.

[b]"Other treatments" consists of cryoablation, stereotactic body radiotherapy / stereotactic radiosurgery, and proton therapy. Self-referring providers were less likely to refer their patients for cryoablation and stereotactic body radiotherapy / stereotactic radiosurgery compared to non-self-referring providers, but both types of providers referred the same percentage of their patients for proton therapy—approximately 1 percent.

The difference between self-referring and non-self-referring providers in the percentage of their prostate cancer patients referred for IMRT was largely due to self-referring providers who belonged to limited-specialty groups. Self-referring providers who belonged to a limited-specialty group referred approximately 52 percent of their patients diagnosed with prostate cancer in 2007 or 2009 for IMRT.[29] In contrast, self-referring

[29]Because only a small percentage of beneficiaries were referred by providers who belonged to a multispecialty group, we combined beneficiaries diagnosed with prostate cancer in 2007 or 2009. Of that population, approximately 92 percent were referred by a provider who belonged to a limited-specialty group, compared to 8 percent who were referred by a provider who belonged to a multispecialty group.

providers who belonged to a multispecialty group referred approximately 36 percent of their patients diagnosed with prostate cancer in 2007 or 2009 for IMRT, only moderately higher than the 33 percent of non-self-referring providers' patients diagnosed with prostate cancer in 2007 or 2009 who were referred for IMRT.

Differences in the percentage of prostate cancer patients referred for IMRT between self-referring and non-self-referring providers persisted after accounting for differences in age, geographic location (i.e., urban or rural), and beneficiary health, including clinical characteristics of prostate cancers for a subset of beneficiaries who lived in New York.

Age

Differences between self-referring and non-self-referring providers in the percentage of prostate cancer patients that were referred for IMRT could not be explained by differences in age. The average age when a beneficiary was diagnosed with prostate cancer was the same for patients of both self-referring and non-self-referring providers, and, regardless of their patients' ages, self-referring providers were more likely to refer their patients for IMRT compared to non-self-referring providers. The average age when a beneficiary was diagnosed with prostate cancer was 74 years old for patients of both self-referring and non-self-referring providers. Depending on the age range, self-referring providers were anywhere from 48 percent to 62 percent more likely to refer their patients for IMRT compared to non-self-referring providers. For more information about how the percentage of prostate cancer patients referred for IMRT and other treatments by self-referring and non-self-referring providers changed on the basis of the age of a beneficiary, see appendix IV.

Geographic Location

Differences between self-referring and non-self-referring providers in the percentage of prostate cancer patients that were referred for IMRT could not be explained by differences in geographic location. Self-referring providers were more likely to refer their patients for IMRT compared to non-self-referring providers, regardless of differences in geographic location.[30] Self-referring providers were 52 percent more likely to refer their patients that lived in urban areas for IMRT compared to non-self-referring providers. Similarly, self-referring providers were 42 percent

[30]Approximately 84 percent of self-referring providers' prostate cancer patients lived in urban areas compared to approximately 68 percent of non-self-referring providers' patients.

more likely to refer their patients that lived in rural areas for IMRT compared to non-self-referring providers.

Beneficiary Health

Differences between self-referring and non-self-referring providers in the percentage of prostate cancer patients that were referred for IMRT could not be explained by differences in beneficiary health. Self-referring and non-self-referring providers' prostate cancer patients had a similar average health status, and self-referring providers were more likely to refer their patients for IMRT compared to non-self-referring providers, regardless of whether their patients had low-, intermediate-, or high-risk prostate cancer. Self-referring providers' patients had an average risk score—a proxy for health status—of 0.94 in 2009, and non-self-referring providers' patients had an average risk score of 0.92, indicating that the two patient populations had a similar average health status.[31] In cases where we had information on the clinical characteristics of patients' prostate cancer, we found that self-referring providers were more likely than non-self-referring providers to refer their patients for IMRT, although the difference decreased as prostate cancer risk level increased. Specifically, self-referring providers were 91 percent, 41 percent, and 33 percent more likely than non-self-referring providers to refer patients with low-, intermediate-, and high-risk prostate cancer for IMRT, respectively.[32] The difference in IMRT referrals made by self-referring and non-self-referring providers narrowed as patients' prostate cancer risk level increased in part because non-self-referring providers increased IMRT referrals and decreased brachytherapy referrals as cancer risk levels increased. In comparison, self-referring providers referred similarly small percentages of patients for brachytherapy for all three risk levels,

[31]A beneficiary's risk score is a proxy for health status and is equivalent to the ratio of expected health care expenditures for the beneficiary under Medicare FFS relative to the average health care expenditures for all Medicare FFS beneficiaries. For example, a beneficiary with a risk score of 1.05 would have expected expenditures that were 5 percent higher than an average Medicare FFS beneficiary.

[32]Self-referring providers were also 43 percent more likely to refer their patients for IMRT compared to non-self-referring providers for patients who could not be assigned a risk category. Because the New York State Cancer Registry contains some cancer characteristics obtained after patients received treatment, we also reran this analysis twice after restricting the population to patients (1) for whom the extent of the cancer was determined before treatment and (2) who did not receive a radical prostatectomy. For both of these analyses, the results were similar to the original analysis—self-referring providers were between 25 percent and 87 percent more likely to refer their patients for IMRT compared to non-self-referring providers, depending on whether the cancer was low, intermediate, or high risk.

and their IMRT referrals increased only moderately as their patients' risk level increased.[33]

Providers Substantially Increased the Percentage of Their Prostate Cancer Patients They Referred for IMRT after They Began to Self-Refer

Providers that switched from being non-self-referring to self-referring—that is, switchers—referred a greater percentage of their prostate cancer patients for IMRT after they began to self-refer (see table 3). Specifically, switchers referred 37 percent of their patients who were diagnosed with prostate cancer in 2007 for IMRT. After beginning to self-refer, switchers referred 54 percent of their patients who were diagnosed with prostate cancer in 2009 for IMRT. While providers that did not begin to self-refer—that is, self-referrers and non-self-referrers—referred different percentages of their patients who were diagnosed with prostate cancer in 2007 for IMRT, the percentages of their patients they referred for IMRT remained relatively consistent over the same period when switchers dramatically increased the percentage of their patients they referred for IMRT. This suggests that the increase seen among switchers was likely not due to provider characteristics that were relatively stable over time or changes in the way all providers treated prostate cancer in response to such things as changing treatment guidelines. (See app. V for more information about how the percentage of beneficiaries switchers, non-self-referring providers, and self-referring providers referred for a given treatment.)

Table 3: Change in the Percentage of Medicare Prostate Cancer Patients Providers Referred for IMRT after a Diagnosis of Prostate Cancer in 2007 or 2009

Type of provider	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2007	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2009	Percentage point change from 2007 to 2009	Percentage more or less likely providers were to refer patients for IMRT in 2009 compared to 2007
Non-self-referring	31.4%	33.1%	1.7	5.5%
Self-referring	55.7	52.9	-2.8	-5.1
Switcher	37.0	54.2	17.2	46.6

Source: GAO analysis of CMS data.

[33]While the difference between self-referring and non-self-referring providers narrowed, non-self-referring providers were still more likely to refer their patients with intermediate- and high-risk prostate cancer for brachytherapy compared to self-referring providers. This includes brachytherapy as a sole treatment or brachytherapy received in combination with another treatment, such as a form of EBRT.

Notes: We define switchers as those providers that did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. In 2007, switchers, self-referring providers, and non-self-referring providers referred 4,903, 1,776, and 42,471 prostate cancer patients for treatment, respectively. In 2009, switchers, self-referring providers, and non-self-referring providers referred 4,156, 1,244, and 34,107 prostate cancer patients for treatment, respectively.

Conclusions

IMRT has been shown to be an effective treatment option for localized prostate cancer and allows radiation to be delivered to the tumor while minimizing damage to normal tissue. Proponents of self-referral arrangements contend that the self-referral of IMRT services does not affect clinical decision making and that patients benefit from self-referral through, for example, improved coordination among the providers who diagnose and treat patients. However, our review indicates that Medicare providers that self-referred IMRT services—particularly those practicing in limited-specialty groups—were substantially more likely to refer their prostate cancer patients for IMRT and less likely to refer them for other, less costly treatments, especially brachytherapy or a radical prostatectomy, compared to providers who did not self-refer. The relatively higher rate of IMRT referrals among self-referring providers cannot be explained by beneficiary age, geographic location, or health. Consistent with these findings, we also found that after providers began to self-refer IMRT services they substantially increased the percentage of their prostate cancer patients they referred for IMRT, while providers that did not begin to self-refer experienced much smaller changes over the same period. Taken together, our findings suggest that financial incentives were likely a major factor driving the increase of IMRT referrals among self-referring providers in limited-specialty groups.

The greater use of IMRT by self-referring Medicare providers to treat prostate cancer raises two potential concerns. First, because physician recommendations play a large role in influencing a patient's treatment decision, a financial interest in one treatment option may diminish the role that other criteria—such as life expectancy, overall health, patient preferences, and clinical characteristics of the prostate cancer—play in the decision-making process. Despite the fact that several treatment options are often considered equally appropriate, the higher use of IMRT among providers who self-refer seems problematic because prostate cancer treatments differ in terms of their risks and side effects, such as the likelihood of developing sexual, urinary, or bowel-related side effects. To the extent that providers' financial interests are shaping treatment decisions, some patients may end up on a treatment course that does not best meet their individual needs. Second, because IMRT costs more than most other treatments, the higher use of IMRT by self-referring providers

results in higher costs for Medicare and beneficiaries. To the extent that treatment decisions are driven by providers' financial interest and not by patient preference, these increased costs are difficult to justify.

Given self-referral's potential effect on both the Medicare program and beneficiaries, it is imperative that CMS improve its ability to identify and monitor the effects of such services. CMS is not currently well-positioned to address self-referring providers' financial incentive to refer their prostate cancer patients for IMRT, as CMS currently does not have a method for easily identifying such services. Without a way to identify self-referred services, such as a self-referral flag on Medicare Part B claims, CMS does not have the ongoing ability to monitor self-referral and its effects on beneficiary treatment selection and costs to both Medicare and beneficiaries.

In addition, Medicare providers who self-refer IMRT services are generally not required to disclose their financial interest in IMRT. Thus, beneficiaries may not be aware that their provider has an incentive to recommend IMRT over alternative treatments which may be equally effective, have different risks and side effects, and are less expensive for Medicare and beneficiaries. Beneficiaries need to select among different prostate cancer treatment options, and beneficiary knowledge of a referring provider's financial interest in IMRT may be an important consideration in making these selections. Currently, the Department of Health and Human Services (HHS), the agency that administers CMS, lacks the authority to establish a disclosure protocol for providers who self-refer IMRT services.

Matter for Congressional Consideration

To increase beneficiaries' awareness of providers' financial interest in a particular treatment, Congress should consider directing the Secretary of Health and Human Services to require providers who self-refer IMRT services to disclose to their patients that they have a financial interest in the service.

Recommendation for Executive Action

We recommend that the Administrator of CMS insert a self-referral flag on its Medicare Part B claims form, require providers to indicate whether the IMRT service for which a provider bills Medicare is self-referred, and monitor the effects that self-referral has on costs and beneficiary treatment selection.

Agency and Third-Party Comments and Our Evaluation

We provided a draft of this report to HHS for comment. HHS provided written comments, which are reprinted in appendix VI. We also obtained oral comments from representatives of three professional associations selected because they represent stakeholders with specific involvement in prostate cancer–related IMRT services.

The three associations were the American Society for Radiation Oncology (ASTRO), which represents radiation oncologists; the American Urological Association (AUA), which represents urologists; and the Large Urology Group Practice Association (LUGPA), which represents large urology group practices. We summarize and respond to comments from HHS and representatives from the three professional associations in the following sections.

HHS Comments

In its comments, which are reprinted in appendix VI, HHS stated that it did not concur with our recommendation. HHS did not comment on the matter for congressional consideration or the main finding of the report—that self-referring providers, particularly those belonging to limited-specialty groups, referred a substantially higher percentage of their prostate cancer patients for IMRT.

HHS did not concur with our recommendation that CMS insert a self-referral flag on its Medicare Part B claims form, require providers to indicate whether the IMRT service for which a provider bills Medicare is self-referred, and monitor the effects that self-referral has on costs and beneficiary treatment selection. HHS stated that flagging self-referred services and tracking their effects would not address overutilization that occurs as a result of self-referral, would be complex to administer, and may have unintended consequences, which HHS did not delineate. In addition, HHS stated that the President's fiscal year 2014 budget proposal includes a provision to exclude certain services from the in-office ancillary services (IOAS) exception. To the extent that self-referral for IMRT services continues to be permitted, we believe that including an indicator or flag on the claims would be an effective way to identify and track self-referral and would give CMS the ability to analyze the effects of self-referral on utilization patterns. Furthermore, we do not believe an indicator or flag on the claims would be complex to administer, as CMS requires providers to use similar indicators to provide additional information about certain other services.

On the basis of HHS's written response to our report, we are concerned that HHS does not appear to recognize the effects IMRT self-referral can have on beneficiaries and the Medicare program. HHS did not comment on our matter for congressional consideration or our key finding that self-referring providers, particularly those belonging to limited specialty groups, referred a substantially higher percentage of their prostate cancer patients for IMRT. Given the magnitude of these findings, we continue to believe that CMS should take steps to monitor the impact that IMRT self-referral has on costs and treatment selection.

HHS also provided technical comments that we incorporated as appropriate.

Professional Association Comments

American Society for Radiation Oncology

ASTRO representatives generally agreed with our findings but thought our recommendation and matter for congressional consideration should be stronger. They said we should recommend that Congress close the IOAS exception because the findings from the report, in combination with previous self-referral research we and others have published, indicate the necessity for such an action. An examination of the IOAS was beyond the scope of our work. To the extent that IMRT self-referral is still permissible, ASTRO representatives also said that inserting a self-referral flag would not be an effective way to identify self-referral. Instead, they suggested implementing reporting requirements similar to the financial transparency requirements for physician-owned specialty hospitals under PPACA and requiring self-referring providers to indicate on their Medicare provider enrollment forms their financial interest in referrals. Further, ASTRO representatives said that self-referring providers should be required to notify patients that they may receive IMRT at alternative locations and that other treatment options are available. We continue to believe that inserting a self-referral flag on Medicare Part B claims would be an effective way to track and monitor self-referral and that beneficiary awareness of their providers' financial interests is important. However, to the extent that other strategies exist that would allow CMS to increase beneficiary awareness and monitor self-referral, such efforts would be consistent with the intent of our recommendation and matter for congressional consideration.

American Urological Association

AUA representatives said we did not have sufficient evidence to link financial incentives to the increase in IMRT use among self-referring providers and disagreed with our conclusion that financial incentives for self-referring providers belonging to limited specialty groups were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT. Specifically, AUA representatives said the flat trend in the utilization of prostate cancer-related IMRT services from 2007 through 2010 indicates utilization has simply shifted from hospital outpatient departments to physician offices and that this trend undermines our conclusion that financial incentives increase IMRT use. As explained in our report, the trend in the percentage of patients newly diagnosed with prostate cancer referred for IMRT was not flat; instead, it increased over the study period. This increase occurred while the utilization of IMRT services remained about the same in part because the annual number of Medicare FFS beneficiaries who were diagnosed with prostate cancer declined by about 20 percent over our study period. In addition, we found that self-referring providers, which were predominantly from limited-specialty groups, referred a higher percentage of their Medicare FFS patients for IMRT than did other providers and that their higher IMRT referral rate could not be explained by differences in age, geographic location, or beneficiary health. As a result, we continue to believe that financial incentives were likely a major factor driving the higher IMRT referral rate of self-referring providers from limited-specialty groups.

AUA representatives had several other critiques of our report. Specifically, they indicated that we did not put enough emphasis on the patient's role in choosing a treatment and expressed concern that we did not include more clinical information on patients' prostate cancer, such as information on cancer stage and grade, or include Medicare Advantage beneficiaries in our study population. We address two of these critiques in the report. Specifically, we note that patient preference is one of many factors that affect a beneficiary's treatment decision, and we include clinical information on patients' prostate cancer for a subset of beneficiaries from New York.[34] However, we did not include Medicare

[34]We used clinical information from the New York State Cancer Registry because such information is not available on Medicare claims, and we determined that the geographic areas included in another common source of such information—Surveillance Epidemiology and End Results (SEER) data—did not sufficiently overlap with areas in which IMRT self-referral was prevalent during our study period.

Advantage beneficiaries in our study population because Medicare Advantage plans are not required to submit claims to CMS, and, thus, we do not have detailed information on the services Medicare Advantage beneficiaries receive or the providers who refer and perform those services.

Finally, AUA representatives stated that the declining percentage of self-referring providers' patients referred for brachytherapy from 2007 to 2009 could reflect a change in practice standards, as they said brachytherapy is no longer recommended as a sole treatment for intermediate- and high-risk prostate cancer. While we note that brachytherapy use has declined even among providers who do not self-refer, we do not believe that changing guidelines or the possibility of differences in guideline adherence between non-self-referring and self-referring providers could explain in totality why self-referring providers refer a smaller percentage of their patients for brachytherapy. First, self-referring providers referred a substantially lower percentage of their patients for brachytherapy, even after accounting for the decline in brachytherapy use for both non-self-referring and self-referring providers from 2007 to 2009. Second, among those patients for whom we had clinical data, the biggest differences in IMRT and brachytherapy use between self-referring and non-self-referring providers were for patients with low-risk cancer, which would not be affected by the change in practice guidelines for intermediate- and high-risk prostate cancer the AUA representatives referenced.

Large Urology Group Practice Association

LUGPA representatives disagreed with our conclusion that financial incentives for self-referring providers—specifically those in limited-specialty groups—were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT. Instead, they said patient preference and an increase in the number of self-referring providers explain the increase in IMRT utilization by self-referring providers. While we did not perform our trend analysis at the provider level, we do note in the report that the number of self-referring groups increased substantially over our study period. This corresponds with a shift in the location where patients received IMRT, from hospital outpatient departments to physician offices. However, these trends that we note do not negate our analysis of the referral patterns of self-referring providers. Specifically, self-referring providers who belonged to a limited-specialty group referred a higher percentage of their newly diagnosed prostate cancer patients for IMRT, and, thus, the increased number of

self-referring providers has also resulted in a higher percentage of patients receiving IMRT. Also, LUPGA representatives said the increase in the percentage of self-referring providers' patients referred for IMRT could be due to such patients more frequently consulting with radiation oncologists before initiating treatment, which one study indicated leads to higher utilization of radiation therapy, defined as EBRT or brachytherapy.[35] We believe it is unlikely that access to a radiation oncologist drove the differences in IMRT referrals between self-referring and non-self-referring providers because self-referring providers who belonged to a multispecialty group referred a substantially lower percentage of their patients for IMRT compared to self-referring providers who belonged to a limited-specialty group, despite the likelihood that patients in both instances had access to a radiation oncologist within the group practice.

LUGPA raised several other points of concern about our review. First, LUGPA representatives said our assertion that IMRT, brachytherapy, and a prostatectomy are clinically equivalent treatments is inappropriate. We disagree with LUGPA's characterization of our discussion of IMRT, brachytherapy, and a prostatectomy as treatment options. We recognize that these treatments are not equally appropriate for all men diagnosed with prostate cancer and do not assert that in our report. Rather, we say that these treatments are often—not always—considered equally appropriate and give an example of when they are considered equally appropriate—men with low-risk prostate cancer. We also recognize that, for any particular patient, a given treatment might not be appropriate due to considerations such as age and comorbidities. Second, LUGPA representatives said that we did not acknowledge that all sites of services have essentially identical financial incentives to perform services for which they receive compensation. They said our work showed the percentage of newly diagnosed prostate cancer patients referred for active surveillance was nearly equal between self-referring and non-self-referring providers and that this was evidence that self-referring providers treat patients based on patient choice and sound clinical decision making. We disagree with LUGPA's assertion that the percentage of newly

[35]Thomas L. Jang et al., "Physician Visits Prior to Treatment for Clinically Localized Prostate Cancer," *Archives of Internal Medicine* 172, no.5 (March 8, 2010): 440-450.

diagnosed prostate cancer patients referred for active surveillance was nearly equal between self-referring and non-self-referring providers, as self-referring providers were approximately 8 percent less likely to refer their patients for active surveillance than were non-self-referring providers. As we note in the report, IMRT is more costly than other treatments for prostate cancer, resulting in a financial incentive for self-referring providers to refer their patients for IMRT over other treatments. We found that self-referring providers referred a higher percentage of their patients for IMRT than did non-self-referring providers and that the difference in IMRT referral rates could not be explained by variations in patient age, geographic location, or patient health status. As a result, we continue to believe that self-referring providers' higher IMRT referral rates are driven by a financial incentive for these providers to refer newly diagnosed prostate cancer patients for IMRT. Third, LUGPA representatives said we should have studied the use of IMRT for conditions other than prostate cancer. The use of IMRT to treat other conditions was outside the scope of our work. Finally, LUGPA representatives indicated that our estimates of 3D-CRT utilization for newly diagnosed prostate cancer patients are too low. We believe our calculation of the percentage of patients who were newly diagnosed with prostate cancer in 2009 and referred for 3D-CRT is accurate. We solicited input from multiple physician associations, including members of LUGPA, regarding the appropriate HCPCS codes to use to track 3D-CRT and examined 100 percent of claims from the Medicare Carrier and hospital outpatient department files to identify all 3D-CRT services received by newly diagnosed prostate cancer patients.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, interested congressional committees, and others. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff has any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VII.

James C. Cosgrove
Director, Health Care

List of Requesters

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

The Honorable Chuck Grassley
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: Scope and Methods

This section describes the scope and methodology used to analyze our two objectives: (1) comparing trends in the number of and expenditures for Medicare prostate cancer–related intensity-modulated radiation therapy (IMRT) services provided by self-referring and non-self-referring groups from 2006 through 2010 and (2) examining how the percentage of Medicare prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer.

To compare trends in the number of and expenditures for prostate cancer–related IMRT services provided in physician offices or hospital outpatient departments from 2006 through 2010, we analyzed IMRT claims from the Medicare Part B Carrier and hospital outpatient files.[1] We identified IMRT services on the basis of Healthcare Common Procedure Coding System (HCPCS) codes associated with the delivery of IMRT—77418 and 0073T.[2] We classified IMRT services as related to prostate cancer if the principal diagnosis code was 185 or 233.4—malignant neoplasm of the prostate or carcinoma in situ of prostate, respectively—or if one of these codes was billed on an IMRT claim and no other diagnosis code related to another cancer was billed on the same claim.

To determine whether prostate cancer–related IMRT services from 2006 through 2010 were performed by self-referring or non-self-referring provider groups, we first limited our analysis to only those IMRT services in the Medicare Part B Carrier file.[3] Because there is no indicator or "flag" on the claim that identifies whether services are self-referred or non-self-referred and the Centers for Medicare & Medicaid Services (CMS), the

[1]We also used the Part B National Summary Data Files to track the total number of prostate biopsies from 2006 through 2010. The Medicare Part B Carrier File contains final action Medicare Part B claims for noninstitutional providers, such as physicians. The Medicare hospital outpatient file contains final action, fee-for-service claims data submitted by institutional outpatient providers, such as hospital outpatient departments.

[2]Medicare expenditure amounts for these codes include beneficiary cost sharing throughout this report. IMRT delivery codes represent individual treatment sessions during which patients receive radiation. In addition to receiving radiation, patients receive several different types of services during a course of IMRT.

[3]Our analysis of self-referred prostate cancer–related IMRT services is limited to those services performed in physician offices. We focused on this setting because our work showed rapid growth in this setting compared to hospital outpatient departments and because the financial incentive for providers to self-refer is most direct when the service is performed in a physician office. We refer to services billed through the Carrier file as services performed in physician offices.

agency that administers Medicare, has no other method for identifying whether a service was self-referred, we developed a claims-based methodology for identifying provider group practices as self-referring or non-self-referring.[4] We classified groups, identified by taxpayer identification numbers (TIN)—an identification number used by the Internal Revenue Service—as self-referring in a given year if: (1) we could identify a prostate biopsy for at least 50 percent of the prostate cancer–related IMRT episodes provided by groups,[5] (2) at least 50 percent of these episodes were self-referred, and (3) a group had a minimum number of 10 self-referred IMRT episodes.[6] The remaining groups were considered non-self-referring.[7] To ensure that how we defined our criteria were reliable, we tested alternative thresholds for defining self-referring groups and found that, regardless of specification, the rapid growth of services performed by self-referring groups persisted and that the growth was due to limited-specialty groups. A patient's episode of prostate cancer–related IMRT was considered self-referred if the provider who performed his prostate biopsy and the performing provider(s) on the IMRT claim(s) billed to the same TIN in the year(s) the IMRT services were performed, the year the biopsy was performed, or the year between, if applicable.[8] To find prostate biopsies for beneficiaries, we searched through 2 years of their claims history to find the prostate biopsy nearest to, but not after, the date of their first IMRT service. If a beneficiary received multiple episodes of IMRT from 2006 through 2010,

[4]An indicator or "flag" could be, for example, a modifier that a provider lists on a claim to indicate that a service is self-referred. Providers currently use modifiers to provide additional information about a service to CMS.

[5]From 2006 through 2010, beneficiaries could receive multiple episodes of prostate cancer–related IMRT. We defined an episode of IMRT as a contiguous group of IMRT services not separated by more than 7 days. If a beneficiary had more than one prostate-cancer related IMRT episode over the course of our study, we classified each episode as self-referred or non-self-referred separately.

[6]Respectively, these restrictions were made to ensure that we (1) did not classify groups as self-referring on the basis of a small percentage of the IMRT episodes they provided, (2) classified groups on the basis of the predominant way in which the group practiced, and (3) had an adequate number of IMRT episodes to accurately categorize groups.

[7]Services performed by non-self-referring groups in the physician office setting could include services provided in places such as freestanding cancer centers.

[8]Self-referral occurs when providers refer their patients to entities—such as themselves or a group practice—in which they or a member of their families has a financial relationship. We used TINs to identify financial relationships between the provider who performed the prostate biopsy and the provider(s) who administered IMRT.

we searched back 2 years from the date of the first IMRT service for each episode. We further defined self-referring provider groups as either limited-specialty or multispecialty groups. We defined groups as limited specialty if more than 75 percent of its office visits in a given year were performed by urologists, nonphysician practitioners, or physicians whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists. The remaining self-referring groups were comprised of providers from a large number of different specialties and were considered multispecialty groups.

To examine how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer, we first identified a list of Medicare beneficiaries who were newly diagnosed with prostate cancer in 2007 or 2009. We used a Medicare claims-derived date from the Chronic Condition Data Warehouse (CCDW), a CMS database, that indicates the first occurrence of prostate cancer as a proxy for the date on which a beneficiary was diagnosed with prostate cancer. We further narrowed the list of prostate cancer patients we studied to those who (1) were at least 66 years of age on their date of diagnosis, (2) were continuously enrolled in Medicare Parts A and B in the year of, before, and after they were diagnosed,[9] and (3) received a prostate biopsy on the same day as or within 1 year prior to their diagnosis.[10] We then analyzed prostate cancer–related claims from the Medicare Part B Carrier and hospital outpatient files to determine what types of treatments these beneficiaries received from their diagnosis date through 1 year after that date.[11] We used the provider who performed a beneficiary's prostate biopsy that was nearest to his date of diagnosis as a proxy for the provider who referred the beneficiary for treatment. We classified referring

[9]This requirement includes not being enrolled in Medicare Advantage in the year of, before, or after a beneficiary's prostate cancer diagnosis.

[10]These restrictions removed beneficiaries for whom the diagnosis date could have been unrelated to when they were actually diagnosed with prostate cancer. For instance, a 65-year-old beneficiary could have been diagnosed with prostate cancer before aging onto Medicare, and, therefore, the claims-based diagnosis date could have represented when the beneficiary became eligible for Medicare rather than when he was first diagnosed.

[11]We did not determine whether treatments were curative or palliative. We also did not differentiate on the basis of the order of different treatment combinations or the duration of treatments. A prostate cancer patient was considered to have undergone active surveillance if he—in addition to meeting the general inclusion criteria—did not receive a service indicating that he received any other prostate cancer treatment within one year of diagnosis.

providers as self-referring if they were the performing provider on a claim that was paid to a self-referring provider group in the year of, before, or after a beneficiary's prostate cancer diagnosis. All other providers were considered non-self-referring. Similarly, we classified providers as belonging to a limited-specialty group if they were the performing provider on a claim that was paid to a limited-specialty provider group in the year of, before, or after a beneficiary's prostate cancer diagnosis. If a provider did not belong to a limited-specialty group, we considered the provider to belong to a multispecialty group.

To assess the possibility that beneficiary characteristics affected the types of treatments for which self-referring and non-self-referring providers referred their prostate cancer patients, we examined beneficiaries' (1) age at the time they were diagnosed with prostate cancer, (2) geographic location (i.e., urban or rural), and (3) health, including clinical characteristics of prostate cancers for a subset of beneficiaries who lived in New York. We determined a beneficiary's age at diagnosis using a beneficiary's date of birth and the date on which he was diagnosed with prostate cancer. We defined urban settings as metropolitan statistical areas, a geographic entity defined by the Office of Management and Budget as a core urban area of 50,000 or more population. We used rural-urban commuting area codes—a Census tract–based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work-commuting information to characterize all of the nation's Census tracts regarding their rural and urban status—to identify beneficiaries as living in metropolitan statistical areas.[12] We considered all other settings to be rural. We used CMS's risk score file to identify average risk score, which serves as a proxy for beneficiary health status. For a subset of beneficiaries who lived in New York, we obtained clinical information on the beneficiaries' prostate cancer—including information used to determine whether the localized cancer was low, intermediate, or high risk—from the New York State Cancer Registry.[13] To establish whether a prostate cancer was low, intermediate, or high risk, we used a beneficiary's Gleason score, prostate-specific antigen (PSA), and tumor

[12]We considered a location with a rural-urban commuting area code of 1.0, 1.1, 2.0, 2.1, or 3.0 to be a metropolitan statistical area.

[13]This analysis includes beneficiaries who were diagnosed with prostate cancer in either 2007 or 2009.

stage from the New York State Cancer Registry.[14] The results of the New York analysis are not generalizable to the entire Medicare population.

We also determined whether the percentage of a provider's prostate cancer patients referred for IMRT changed after providers began to self-refer. Specifically, we identified a group of providers, which we called "switchers," that did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. We then calculated the change in the percentage of switchers' patients referred for IMRT and other treatments among those diagnosed with prostate cancer in 2007 and 2009. We then compared the change among switchers to the change experienced by providers that did not change whether or not they self-referred IMRT services from 2007 to 2009. Specifically, we compared the change in the percentage of switchers' prostate cancer patients they referred for IMRT to the percentage of patients referred for IMRT by (1) self-referring providers—providers that self-referred in 2007, 2008, and 2009 and either self-referred or did not bill Medicare in 2006 and 2010 and (2) non-self-referring providers—providers that did not self-refer in 2007, 2008, and 2009 and either did not self-refer or did not bill Medicare in 2006 and 2010.[15]

We took several steps to ensure that the data used to produce this report were sufficiently reliable. Specifically, we assessed the reliability of the CMS data we used by interviewing officials responsible for overseeing these data sources, including CMS and Medicare contractor officials. We also reviewed relevant documentation and examined the data for obvious errors, such as missing values and values outside of expected ranges. We determined that the data were sufficiently reliable for the purposes of our study.

[14]Such information is not available on Medicare claims. Researchers commonly use the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) data to obtain clinical information about Medicare patients who were diagnosed with cancer. We did not use SEER data because we examined treatments received by men diagnosed with prostate cancer in 2007 and 2009, and, in 2007, IMRT self-referral was concentrated in states not included in SEER data. Respectively, low-, intermediate-, and high-risk prostate cancers were defined as follows: T1-T2a, Gleason score 2-6, and PSA < 10 ng/ml; T2b-T2c, Gleason score 7, or PSA 10-20 ng/ml; and T3a, Gleason score 8-10, or PSA > 20 ng/ml.

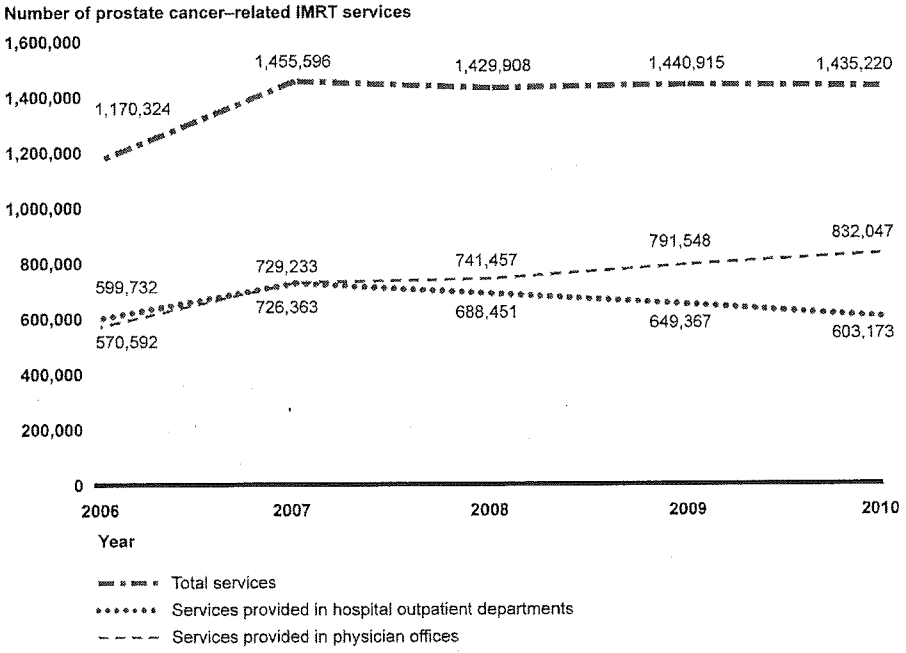
[15]For this analysis and our analysis of all providers who referred a Medicare beneficiary in our study who was diagnosed with prostate cancer in 2007 or 2009, we counted IMRT and other treatments regardless of the setting in which they were performed.

We conducted this performance audit from May 2010 through July 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Change in Prostate Cancer–Related IMRT Services and Expenditures by Setting

Medicare prostate cancer–related intensity-modulated radiation therapy (IMRT) utilization varied substantially between settings (see fig. 4). From 2006 through 2010, utilization grew at an annual rate of 10 percent in physician offices, whereas there was almost no growth in the hospital outpatient department. Moreover, while the utilization of prostate cancer–related IMRT services in the hospital outpatient department was nearly the same in 2006 as it was in 2010, utilization in this setting actually peaked in 2007 and declined thereafter.

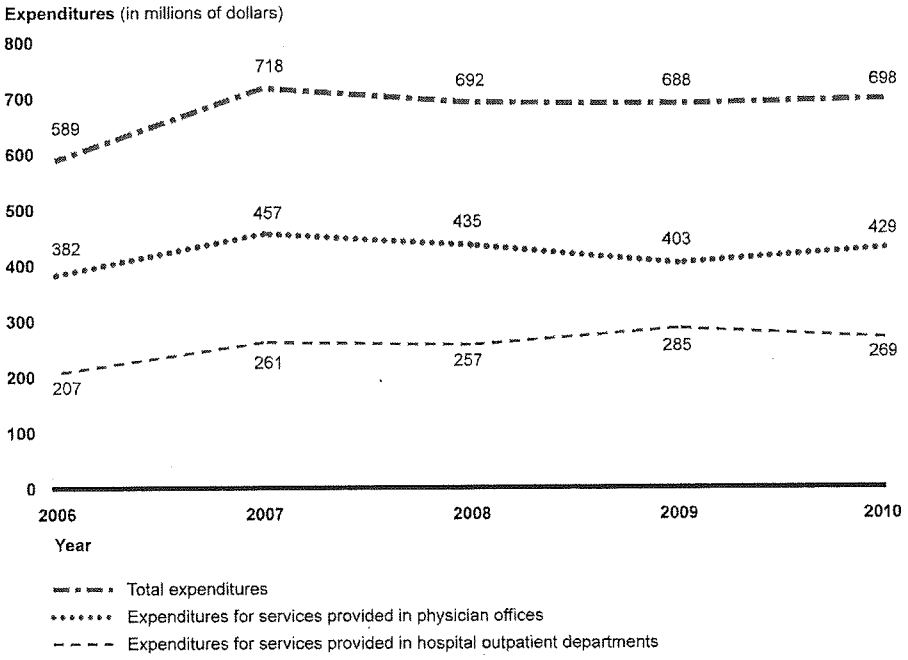
Figure 4: Number of Medicare Prostate Cancer–Related IMRT Services by Setting, 2006-2010



Source: GAO analysis of CMS data.

Total prostate cancer–related IMRT expenditures grew from $589 million to $698 million over our study period, but growth rates varied by setting (see fig. 5). In contrast to the growth in utilization, expenditures increased faster for services performed in hospital outpatient departments than those performed in physician offices—7 percent and 3 percent annual growth rates, respectively. This is due to the fact that reimbursement rates for IMRT services have been increasing for services performed in hospital outpatient departments and declining for those performed in physician offices.

Figure 5: Expenditures for Medicare Prostate Cancer–Related IMRT Services by Setting, 2006-2010



Source: GAO analysis of CMS data.

Appendix III: Discrete Prostate Cancer Treatment Categories

The higher percentage of patients that self-referring Medicare providers referred for intensity-modulated radiation therapy (IMRT) compared to non-self-referring providers was due to self-referring providers referring their patients for IMRT only and IMRT in conjunction with hormone therapy more often (see table 4). Including all combinations, self-referring and non-self-referring providers referred nearly equal percentages of their patients for a combination of treatments—27 percent and 26 percent, respectively.

Table 4: Percentage of Self-Referring and Non-Self-Referring Providers' Medicare Patients Referred for a Given Treatment or Combination of Treatments after Diagnosis of Prostate Cancer in 2009

Prostate cancer treatment	Percentage of non-self-referring providers' patients referred for a given treatment (N=48,298)	Percentage of self-referring providers' patients referred for a given treatment (N=9,991)	Percentage point difference
IMRT only	12.8%	27.0%	14.2
IMRT and radical prostatectomy	1.2	0.9	-0.3
IMRT and brachytherapy	4.7	2.6	-2.0
IMRT and hormone therapy	13.2	20.1	6.9
Active surveillance	22.9	21.0	-1.9
Radical prostatectomy only	15.5	11.5	-4.0
Radical prostatectomy and hormone therapy	1.1	0.6	-0.5
Hormone therapy only	11.4	7.7	-3.8
Brachytherapy only	6.5	3.5	-3.0
Brachytherapy and hormone therapy	2.2	0.7	-1.5
Other treatments only[a]	4.4	2.5	-2.0
Other treatments and hormone therapy	1.3	0.6	-0.7
Three-dimensional conformal radiation therapy(3D-CRT) / other external beam radiation therapy (EBRT) only	0.2	0.0	-0.1
3D-CRT / other EBRT and hormone therapy	0.3	0.1	-0.2
Other combinations[b]	2.2	1.1	-1.1

Source: GAO analysis of CMS data.

Notes: Percentages do not sum to 100 percent due to rounding. Beneficiaries were sorted into "IMRT and brachytherapy" and "IMRT and radical prostatectomy" if they received IMRT plus the treatment or IMRT plus the treatment and hormone therapy. Beneficiaries sorted into "IMRT and hormone therapy" did not receive any other treatments. Men were considered to have received a combination of therapies if they received at least one service from two or more different types of treatments. We did not differentiate on the basis of the order of different treatment combinations or the duration of treatments.

[a]"Other treatments" consists of cryoablation, stereotactic body radiotherapy / stereotactic radiosurgery, and proton therapy.

[b]"Other combinations" includes any combination of treatments that does not have a separate category, such as 3D-CRT / other EBRT and brachytherapy.

Appendix IV: Distribution of Prostate Cancer Treatments by Age

While self-referring Medicare providers were more likely to refer their prostate cancer patients for intensity-modulated radiation therapy (IMRT) regardless of age, the type of treatment they were less likely to refer their patients for varied based on the age of the beneficiary (see table 5). For instance, among beneficiaries 80 years of age or older at the time they were diagnosed with prostate cancer, self-referring providers were less likely to refer their prostate cancer patients for hormone therapy only, active surveillance, and brachytherapy compared to non-self-referring providers. In contrast, among beneficiaries 66 to 69 years old, nearly the entire difference between self-referring and non-self-referring providers was due to self-referring providers referring a smaller percentage of their prostate cancer patients for a radical prostatectomy or brachytherapy.

Table 5: Percentage of Self-Referring and Non-Self-Referring Providers' Medicare Patients Referred for a Given Treatment after a Diagnosis of Prostate Cancer in 2009 by Age of Beneficiary

	Age category (in years)							
	Percentage of non-self-referring providers' patients referred for a given treatment by age category (years)				Percentage of self-referring providers' patients referred for a given treatment by age category (years)			
Prostate cancer treatment	**66-69 (N=12,988)**	**70-74 (N=16,710)**	**75-79 (N=11,025)**	**≥80 (N=7,575)**	**66-69 (N=2,636)**	**70-74 (N=3,434)**	**75-79 (N=2,340)**	**≥80 (N=1,581)**
IMRT	29.1%	36.3%	40.7%	25.7%	46.6%	54.5%	60.1%	41.8%
Active surveillance	18.1	20.7	25.9	31.4	16.1	20.1	22.4	29.0
Radical prostatectomy	35.8	20.5	5.1	0.6	28.3	14.1	3.2	0.4
Hormone therapy only	4.1	6.2	11.8	35.0	2.7	3.9	7.1	25.1
Brachytherapy	15.5	16.6	14.4	5.2	8.9	8.4	6.2	2.0
Other treatments[a]	5.2	6.7	7.4	3.9	3.2	3.3	3.6	2.7
Three-dimensional conformal radiation therapy / other external beam radiation therapy	2.2	2.7	2.9	1.8	1.0	1.1	1.3	1.0

Source: GAO analysis of CMS data.

Notes: Treatment categories do not sum to 100 percent because, with the exception of active surveillance and hormone therapy only, the categories are not mutually exclusive.

[a]"Other treatments" consists of cryoablation, stereotactic body radiotherapy/ stereotactic radiosurgery, and proton therapy.

Appendix V: Change in Prostate Cancer Treatment Patterns over Time for Different Types of Providers

The increased percentage of Medicare patients referred by switchers for intensity-modulated radiation therapy (IMRT) was accompanied by a decrease in the percentage of patients referred for several other treatments, especially brachytherapy (see table 6). Some of the changes in the percentage of patients referred by switchers for a given treatment were consistent with the patterns for other types of providers—such as in the case of three-dimensional conformal radiation therapy (3D-CRT) / other external beam radiation therapy (EBRT)—while some of the other changes were not.

Table 6: Change in the Percentage of Medicare Prostate Cancer Patients Providers Referred for a Given Treatment after a Diagnosis of Prostate Cancer in 2007 or 2009

Prostate cancer treatment	Type of provider	Percentage of providers' patients referred for a given treatment among beneficiaries diagnosed in 2007	Percentage of providers' patients referred for a given treatment among beneficiaries diagnosed in 2009	Percentage point change from 2007 to 2009	Percentage more or less likely providers were to refer patients for a given treatment in 2009 compared to 2007
IMRT	Non-self-referring	31.4%	33.1%	1.7	5.5%
	Self-referring	55.7	52.9	-2.8	-5.1
	Switcher	37.0	54.2	17.2	46.6
Active surveillance	Non-self-referring	19.3	22.6	3.3	17.3
	Self-referring	17.3	20.7	3.4	19.6
	Switcher	18.1	20.1	2.0	11.2
Brachytherapy	Non-self-referring	17.6	14.4	-3.2	-18.2
	Self-referring	4.7	2.3	-2.5	-52.4
	Switcher	20.7	9.9	-10.8	-52.2
Radical prostatectomy	Non-self-referring	16.6	18.0	1.4	8.5
	Self-referring	13.1	15.1	2.0	15.7
	Switcher	13.0	11.1	-1.9	-14.5
Hormone therapy only	Non-self-referring	14.3	11.6	-2.7	-18.6
	Self-referring	8.6	7.9	-0.7	-8.6
	Switcher	13.1	8.0	-5.1	-39.1
3D-CRT / other EBRT	Non-self-referring	5.0	2.5	-2.5	-50.4
	Self-referring	0.8	0.7	-0.1	-14.3
	Switcher	4.0	1.3	-2.7	-68.7
Other treatments[a]	Non-self-referring	5.7	6.3	0.6	10.8
	Self-referring	1.8	2.5	0.7	38.3
	Switcher	4.8	1.9	-2.8	-59.7

Source: GAO analysis of CMS data.

Notes: Treatment categories for each type of provider do not sum to 100 percent because, with the exception of active surveillance and hormone therapy only, the categories are not mutually exclusive. In 2007, switchers, self-referring providers, and non-self-referring providers referred 4,903, 1,776, and 42,471 prostate cancer patients for treatment, respectively. In 2009, switchers, self-referring providers, and non-self-referring providers referred 4,156, 1,244, and 34,107 prostate cancer patients for treatment, respectively. Because some treatments were relatively rare, some provider type, treatment group, and year categories, such as patients referred for 3D-CRT / other EBRT by self-referring providers in 2009, have relatively few beneficiaries. However, the results of this analysis are consistent with the trends observed when referral patterns for self-referring and non-self-referring providers were studied for all beneficiaries diagnosed in 2007 and 2009.

[a]"Other treatments" consists of cryoablation, stereotactic body radiotherapy / stereotactic radiosurgery, and proton therapy.

Appendix VI: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 11 2013

James C. Cosgrove, Director
Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, entitle, "MEDICARE: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny" (GAO-13-525).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE: HIGHER USE OF COSTLY PROSTATE CANCER TREATMENT BY PROVIDERS WHO SELF-REFER WARRANTS SCRUTINY" (GAO-13-525)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

GAO recommended that the Administrator of CMS insert a self-referral flag on its Medicare Part B claims form, require providers to indicate the IMRT service for which a provider bills Medicare is self-referred, and monitor the impact self-referral has on costs and beneficiary treatment selection.

HHS Response

HHS does not concur. We do not believe this recommendation will address overutilization that occurs as a result of self-referral. We believe that adding a self-referral flag on the Medicare Part B claims form and requiring physicians to indicate whether the service is self-referred will be complex to administer and may have unintended consequences. We believe other payment reforms will better address overutilization than a new checkbox on the claim form. If a claim indicated that a service was self-referred, there would not be any information about whether such self-referral met the criteria for being an acceptable referral. For example, when a referral occurs outside the physician group or clinic context, the claim could indicate that the service was not "self-referred," but it nevertheless could be a referral that potentially violated the physician self-referral law.

Further, the President's Fiscal Year 2014 Budget proposal included a provision to exclude certain services from the in-office ancillary services exception to the physician self-referral law. The proposal notes the in-office ancillary services exception was intended to allow physicians to self-refer quick turnaround services and that some of these services, such as radiation therapy and advanced imaging, are rarely performed on the same day as the related physician office visit. The proposal is designed to encourage more appropriate use of certain services by excluding them from the in-office ancillary services exception to the prohibition against physician self-referrals, except in cases where a practice meets certain accountability standards.

1

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

James C. Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Staff Acknowledgments

In addition to the contact named above, Thomas Walke, Assistant Director; Manuel Buentello; Krister Friday; Gregory Giusto; Brian O'Donnell; Daniel Ries; and Jennifer Whitworth made key contributions to this report.

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ASTRO
TARGETING CANCER CARE

News Release
FOR IMMEDIATE REVIEW

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ASTRO applauds new GAO report on physician self-referral abuse in prostate cancer treatment and urges swift passage of "Promoting Integrity in Medicare Act of 2013"

Fairfax, Va., August 1, 2013 – ASTRO Chairman Michael L. Steinberg, MD, FASTRO, called attention to the Government Accountability Office's (GAO) striking report released today, "Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny," that details clear mistreatment of patients who trusted their physicians to care for their prostate cancer. Dr. Steinberg and radiation oncologists nationwide called on Congress to pass the "Promoting Integrity in Medicare Act of 2013" (PIMA), introduced earlier today by Rep. Jackie Speier (D-Calif.) and Rep. Jim McDermott (D-Wash.), that would address GAO's findings, result in better care for patients and save billions of dollars in Medicare that could offset the costs of repealing the Medicare physician payment formula (sustainable growth rate—SGR).

The federal "Ethics in Patient Referrals Act," also known as the self-referral law, prohibits physicians from referring a patient to a medical facility in which he or she has a financial interest in order to ensure that medical decisions are made in the best interest of the patient without consideration of any financial gain that could be realized by the treating physician. However, the law includes an exception that allows physicians to self-refer for so-called "ancillary services," including radiation therapy. Over the years, abuse of the in-office ancillary services (IOAS) exception has diluted the self-referral law and its policy objectives, making it simple for physicians to avoid the law's prohibitions by structuring arrangements that meet the technical requirements of the law,

thereby circumventing the intent of the exception. Numerous studies, including three recent GAO reports, have shown that physician self-referral leads to increased utilization of services that may not be medically necessary, poses a potential risk of harm to patients and costs the health care system millions of dollars each year.

Today's GAO report, "Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny," requested by bipartisan leaders in Congress, reviewed limited specialty [urology] groups' use of intensity modulated radiation therapy (IMRT), an effective form of advanced radiation therapy, for prostate cancer treatment. Experts, such as the National Comprehensive Cancer Network, recommend using IMRT judiciously for treating prostate cancer, and that patients should receive an unbiased presentation of all of the effective treatment options, including IMRT. In contrast, the GAO report found that from 2006-2010:

- IMRT utilization among self-referring groups increased by 356 percent. Overall increases in IMRT utilization rates and spending were due entirely to services performed by limited-specialty groups. IMRT utilization among non-self-referrers decreased by five percent.
- The number of IMRT services performed by limited specialty [urology] groups increased by 509 percent, while true multispecialty groups IMRT use decreased 3.8 percent.
- IMRT spending by self-referral groups increased by approximately $138 million, compared to a $91 million decrease in the non-self-referral group.
- Increases in IMRT utilization among self-referring practices could not be attributed to patient preferences, age, geographic location or patient's health status. Financial incentives were likely a major factor in increased referrals for IMRT among the self-referring practices. The financial incentives for self-referral groups led to patients not receiving other appropriate and less expensive treatments, including brachytherapy, prostatectomy and active surveillance.
- Self-referring centers referred 52.7 percent of men over the age of 75 for IMRT at self-referring centers. For these men, guidelines recommend active surveillance of their disease and the avoidance of aggressive treatment such as IMRT.

The GAO report concluded, "... the higher use of IMRT by self-referring providers results in higher

costs for Medicare and beneficiaries. To the extent that treatment decisions are driven by providers' financial interest and not by patient preference, these increased costs are difficult to justify."

"We are extremely concerned that many older male patients are receiving such vigorous, possibly unnecessary treatment by urology groups. Clearly, these self-referring urology groups are steering patients to the most lucrative treatment they offer, depriving them of their full range of treatment choices, including potentially no treatment at all," said Dr. Steinberg. "GAO's findings also demonstrate that IMRT utilization would actually be declining if not for a small cadre of profit-motivated, self-referring urologists."

ASTRO believes that the GAO's recommendations of increased tracking and transparency are well-intentioned but insufficient to stop the costly, hazardous abuse of the IOAS exception. ASTRO concludes that the GAO's own reports and numerous independent studies overwhelmingly affirm that self-referral results in financial incentives that lead to overutilization of health care services, unnecessary spending and inappropriate care for patients.

"Patients and the Medicare program can no longer afford for self-referral abuse to continue. New regulations of tracking and reporting fall short of what is necessary to ensure unbiased patient care—closure of the self-referral loophole. We urge Congress to take swift action to close the in-office ancillary services exception for radiation therapy by passing PIMA. Radiation therapy is not an ancillary service, but rather its own distinct medical treatment, akin to surgery. This new GAO report certifies that the self-referral loophole has serious negative consequences for patients and Medicare's bottom line," said Dr. Steinberg.

Today's GAO report on self-referral in radiation therapy is the third in a groundbreaking, four-part series. The first report in November 2012 on self-referral in advanced diagnostic imaging, titled "Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions" found that "providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring"—at a cost of more than $100 million in 2010. In July 2013, the GAO report, "Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer," found that self-referring providers likely referred nearly one

million more unnecessary anatomic pathology services than non-self-referring providers, costing Medicare approximately $69 million. The final report will detail self-referral for physical therapy services.

"It is acutely obvious that the self-referral loophole must be closed to protect patients and to strengthen the Medicare program," continued Dr. Steinberg. "This loophole endangers patients and erodes their trust in us as physicians. While most urologists care deeply about high-quality patient care and consistently put patients before profits, a minority group of self-referral urology practices is endangering patients and wasting valuable, finite Medicare resources."

Contrary to the claims of limited specialty [urology] groups, GAO's report confirms that these practices are not truly integrated health care centers, but that they are moneymaking schemes intended to increase volume and achieve high profits. Effective and efficient integrated care is rendered every day by clinicians who do not take financial advantage of the IOAS. The overwhelming majority of physicians treat patients based on the best interest of the patient without engaging in self-referral schemes, while also providing coordinated care.

"Unfortunately, when you look at the numbers in this report, you start to wonder where health care stops and where profiteering begins," said Senate Finance Committee Chairman Max Baucus (D-Mont.), in a statement released today. "Enough is enough. Congress needs to close this loophole and fix the problem."

Reps. Speier's and McDermott's PIMA legislation answers the call of numerous influential bipartisan groups who have examined self-referral abuse and recommended changes to the law. In September 2012, a *New England Journal of Medicine* article, authored by leading health policy experts including former CMS administrator Donald Berwick, MD, MPP, called for closing the self-referral loophole for radiation therapy and other so-called "ancillary services." The Center for American Progress agreed with narrowing the IOAS exception, as well as several notable bipartisan groups, including the Bipartisan Policy Center, under the leadership of former Senate Majority Leaders Tom Daschle (D-S.D.) and Bill Frist (R-Tenn.), and the Moment of Truth Project, headed by Erskine Bowles and former Senator Alan Simpson (R-Wyo.). President Obama's proposed FY 2014 Budget also

recommended closing the self-referral loophole, which could save the Medicare program more than $6 billion during the standard 10-year budget window.

In addition, a November 2012 *Bloomberg News* investigative report scrutinized ordeals faced by California prostate cancer patients treated by a urology clinic that owns radiation therapy equipment and found that physician self-referral led to mistreated patients and higher health care costs. *The Wall Street Journal*, *The Washington Post* and *The Baltimore Sun* also published similar critical reports in the last three years illustrating that limited specialty [urology] groups owning radiation therapy machines have utilization rates that rise quickly and are well above national norms for radiation treatment of prostate cancer.

"ASTRO recommends removing radiation therapy services from the IOAS exception. We strongly support PIMA because it closes the self-referral loophole in a responsible, targeted way that roots out abuse while ensuring that truly integrated multispecialty groups and high-performing health systems can continue to provide high-quality and efficient care," said Dr. Steinberg. "Self-referral undermines ASTRO-supported efforts to move Medicare toward quality- and value-based payment. Closing the self-referral loophole will help to stabilize the fee-for-service system today, while we charge ahead on the long, challenging path to developing a fair, high-functioning payment system."

ASTRO is a partner in the Alliance for Integrity in Medicare (AIM), a broad coalition of medical societies committed to ending the practice of inappropriate physician self-referral and focused on improving patient care and preserving valuable Medicare resources. In addition to ASTRO, AIM partners include the American Clinical Laboratory Association, the American College of Radiology, the American Physical Therapy Association, the American Society for Clinical Pathology, the Association for Quality Imaging, the College of American Pathologists and the Radiology Business Management Association. ASTRO and AIM recommend using the Medicare savings to help offset the costs of repealing the Medicare physician payment formula this year.

ABOUT ASTRO

ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes two medical journals, International Journal of Radiation Oncology • Biology • Physics (www.redjournal.org) and Practical Radiation Oncology (www.practicalradonc.org); developed and maintains an extensive patient website, www.rtanswers.org; and created the Radiation Oncology Institute (www.roinstitute.org), a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org.

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