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Linkages Between Utilization of Prostate Surgical Pathology Services and Physician Self-Referral

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Objective: Federal law prohibits a physician from referring Medicare patients for procedures or services to health care entities in which the physician has a financial relationship. This law has exceptions which enable physicians to self-refer under certain conditions. This study evaluates the effects of self-referral on use rates of surgical pathology services performed in conjunction with prostate biopsies and whether such changes are linked to urologist self-referral arrangements.

Data and Sample: A targeted market area case study design was employed to identify the sample from Medicare claims data. The sample included male beneficiaries who resided in geographically dispersed counties; were continuously enrolled in Medicare fee-for-service (FFS) during 2005-2007; and who met the criteria to be a potential candidate to undergo a prostate biopsy.

Outcomes: Prostate biopsy procedures per 1000 male Medicare beneficiaries in each county; counts of surgical pathology specimens (jars) associated with prostate biopsy procedures per 1000 male Medicare beneficiaries in each county.

Findings: Regression analysis shows the self-referral share (percentage) of total utilization was associated with significant increases in the use rate of prostate surgical pathology specimens ($p < .01$). The use rate of prostate surgical pathology specimens (jars) would be 41.5 units higher in a county where the self-referral share of total utilization was 50% compared to a county with no self-referral (share equals 0%).

Conclusions: The findings show that urologist self-referral of prostate surgical pathology services results in increased utilization and higher Medicare spending. The results suggest that exceptions in federal and state self-referral prohibitions need to be reevaluated.

Keywords: Prostate Biopsies, Surgical Pathology Services, Urologist Self-Referral

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Introduction

Self-referral describes arrangements in which physicians refer patients to health care entities in which they have a financial stake. During the early 1990s, the federal government enacted a law that restricted the practice of self-referral for Medicare and Medicaid patients (MedPAC, 2010). Nearly half the states followed and implemented self-referral prohibitions that apply to all patients regardless of insurance coverage. For several years, these laws curbed the increased utilization that characterized self-referral arrangements (Hillman & Goldsmith, 2010). Nevertheless, exceptions in the prohibitions have enabled the practice of self-referral to persist and proliferate (Mitchell, 2007; Carreyrou & Tammen, 2010; Hillman & Goldsmith, 2010). One noteworthy exception in the federal law relates to in-office ancillary services (IOAS); this provision allows physicians and group practices to provide “designated health services,” such as physical therapy, diagnostic imaging, clinical laboratory tests, and anatomic pathology within their offices under certain conditions (MedPAC, 2010; Hillman & Goldsmith, 2010). The primary justification for the IOAS exception was patient convenience, thereby, enabling physicians to provide ancillary services (e.g., simple x-rays or clinical lab tests) as part of the office visit. Furthermore, the group practice component of the exception was intended to exclude large multispecialty groups, such as the Cleveland Clinic, where physician members are paid a salary. The presumption was that referring physicians who belong to large multispecialty group practices would not derive financial benefit from making internal referrals to other physicians within the group (MedPAC, 2010). During the last decade, an increasing number of physicians have established self-referral arrangements by incorporating various types of ancillary services into their practices (Mitchell, 2007; MedPAC, 2010; Reschovsky, Cassil, & Pham, 2010).

Considerable recent research on self-referral has focused on use of advanced imaging procedures (Hughes, Bhargavan, & Sunshine, 2010; Baker, 2010; MedPAC, 2009; Gazelle, Halpern, Ryan, & Tramontano, 2007). The consensus is that self-referral arrangements result in increased use of advanced imaging and higher costs per episode of care in comparison to situations where patients are referred to independent radiologists. While patient convenience is often cited as one justification for self-referral, recent evidence refutes this contention. Nearly all advanced imaging procedures are not performed on the same day as the related office visit (Sunshine & Bhargavan, 2010; MedPAC, 2010). This is also the case for anatomic pathology services; surgical pathology typically does not occur on the same day as the biopsy procedure (MedPAC, 2010).

Some evidence suggests that self-referral exists throughout the health care system (MedPAC, 2010). Yet, recent research has concentrated on advanced imaging self-referral and physician ownership of either specialty hospitals or ambulatory surgery centers. Little attention has focused on self-referral’s impact on use of other services. One ancillary service of particular

interest is anatomic pathology. *Laboratory Economics*, a trade industry newsletter, reports that self-referral arrangements for anatomic pathology services involving urologists, gastroenterologists, or dermatologists have proliferated in recent years (Klipp, 2010a, 2011a, 2011b). This “insourcing” of anatomic pathology services by referring physicians is permissible under exceptions in existing federal law. This study investigates this anecdotal evidence by examining trends in use of surgical pathology services associated with prostate biopsy procedures and whether changes in use can be linked to self-referral arrangements involving urologists. This issue merits investigation for at least two more reasons. First, prostate cancer is the second leading cause of cancer deaths among American men, accounting for one in four newly diagnosed cancers found (American Cancer Society, 2010). Second, surgical pathology, which falls under the genre of anatomic pathology, ranked seventh (by charges) among all Medicare Part B services in 2008; allowed payments exceeded \$1.17 billion, accounting for 52% of Medicare spending on anatomic pathology services (Klipp, 2010b).

Urologist Self-Referral for Prostate Surgical Pathology Services

Urologists use a core needle biopsy to find prostate cancer (American Cancer Society, 2009). During this procedure, the urologist places a narrow needle through the wall of the rectum into the prostate gland and removes a cylinder of tissue, traditionally about one-half inch long and one-sixteenth of an inch across—defined as a tissue core. Under the Medicare Physician Fee Schedule, a single fee is paid for a core needle biopsy (HCPCS code 55700) irrespective of the number of tissue cores extracted. In 2010, the national payment rate for a prostate biopsy (professional fee) was \$237. A common practice is to extract cores from the right and left sides of the apex, mid and base regions, centrally and laterally, for a total of 12 prostate tissue cores.

The tissue extracted from the needle biopsy is then referred by the urologist for preparation in a multistep protocol that includes processing, fixation, embedding, sectioning, staining, and drying. A pathologist then examines the tissue under a microscope to determine the presence or absence of cancer. This set of services is designated as “surgical pathology” where HCPCS code 88305, level IV surgical pathology, gross and microscopic examination is used to bill for each prostate biopsy specimen. Reimbursement for each surgical pathology service has two components; the technical component (TC) is payment for slide preparation while the professional component (PC) compensates the pathologist for examination and interpretation of the prostate tissue specimens.

Unlike payment for the biopsy procedure, Medicare reimburses each provider for the number of specimens containing tissue cores that are submitted for individual examination and interpretation by a pathologist (referred to as “jars”). The number of specimens (jars) may differ from the number of tissue cores extracted because multiple cores can be combined into a single jar prior to referral for pathology services. Thus, if six jars containing twelve prostate biopsy tissue cores are submitted for a specific case, the reimbursement will be six times the Medicare global allowable payment for HCPCS code 88305, indicating that six jars or specimens are

separately and individually reviewed by a pathologist. In 2010, the Medicare national global payment amount for one surgical pathology specimen (jar) was close to \$104. Thus, if a self-referral urologist billed Medicare for twelve jars each with one prostate tissue core, the allowable reimbursement was approximately \$1,248.

In a self-referral arrangement, a urology practice either establishes an in-house lab or contracts for surgical pathology services; the urology group then bills Medicare for the biopsy procedure and related surgical pathology services. In the self-referral context there are clear incentives to increase the number of jars with prostate tissue cores referred for pathology services. Although urologists themselves do not directly perform pathology services, the self-referral urology practice may bill globally (both PC and TC) or alternatively the group may opt to only bill for either the PC or TC. Thus, the insourcing of surgical pathology services for prostate tissue cores extracted during a prostate biopsy procedure offers urologists the opportunity to significantly augment their practice revenue.

Methods

Sample Selection Criteria

To address the research question, criteria were established to identify a sample of men who displayed symptoms indicating that a prostate biopsy may be warranted, but who may or may not have prostate cancer. We obtained clinical guidance from a urologist and several pathologists to establish the selection parameters. These physicians identified a list of ICD-9 diagnosis codes that were most commonly reported on the claim for an office visit with a urologist and were likely to result in the patient undergoing a prostate biopsy. The sample of male Medicare beneficiaries who were potential candidates for a prostate biopsy had an office visit with a urologist (HCPCS codes 99201–99215, 99241–99245) that listed one of the following diagnosis codes: elevated prostate specific (790.93); malignant neoplasm of prostate (185.00); benign neoplasm–prostate (222.00); neoplasm of uncertain behavior–prostate (236.5); nodular prostate without urinary obstruction (600.10).

Recognizing that the insourcing of surgical pathology services by urology practices is an emergent market trend (Klipp, 2010a, 2011a, 2011b), a targeted market area case study design was employed to identify male Medicare beneficiaries who resided in geographically dispersed counties and who met the selection criteria prescribed by the physician consultants. There are precedents in the peer reviewed literature for adopting this type of research design when the objective is to investigate emergent market trends in the U.S. health care system. For example, this approach was used in a Center for Medicare & Medicaid Services (CMS) sponsored study that evaluated the effects of physician-owned specialty hospitals versus community hospitals on

physician referral patterns and outcomes (Greenwald et al., 2006).¹ MedPAC and the Center for Studying Health System Change frequently follow a similar research design to study nascent market trends (MedPAC, 2009; Reschovsky et al., 2010).

Laboratory Economics tracks and reports the names and location of physician groups that have insourced pathology services. We used information from this source in conjunction with data obtained from Web searches on specific urology practices, and from other sources, to identify a set of geographically dispersed counties with at least one urology group that billed Medicare for surgical pathology services. We identified the following counties where self-referral arrangements had been established prior to the end of 2007: Collier, Lee, Miami-Dade, and Orange (Florida); Chatham and Fulton (Georgia); Baltimore (Maryland); Norfolk (Massachusetts); Wayne (Michigan); Nassau and Onondaga (New York); Bexar and McLennan (Texas). Non self-referral urology practices also existed in each of these counties. We also identified a set of geographically dispersed counties where self-referral arrangements were absent. These counties included Riverside and Sacramento (California); Fairfield (Connecticut); Frederick (Maryland); Kent (Michigan); Suffolk (Massachusetts); and Nueces (Texas).

Data Sources

The study employed recent years (2005–2007) of claims data for samples of Medicare beneficiaries who resided in one of the counties of interest, were continuously enrolled in Medicare fee-for-service (FFS) throughout the time period, and who met the criteria to be a potential candidate to undergo a prostate biopsy. Analysis relied on five data sources: carrier standard analytical file (SAF), outpatient SAF, the beneficiary summary file, Medicare physician identification and eligibility registry (MPIER) file, and the national provider identification (NPI) file. The carrier SAF contains claims submitted by physicians and independent clinical laboratories. The outpatient SAF contains claims submitted by hospital outpatient departments. Information reported on each claim in the carrier and outpatient SAFs includes beneficiary

¹CMS contracted with RTI International to conduct a study to compare referral patterns, quality, patient satisfaction and community benefits of physician-owned specialty hospitals versus peer competitors. Both the American Hospital Association and the Physicians Hospital Association provided input regarding the market areas to be examined. The sites for the analysis were chosen based on the number and types of physician-owned specialty hospitals in operation, and the requirement that all three types of specialty hospitals permit the research team to conduct site visits as part of the investigation. Medicare claims data for a six month period in 2003 were also analyzed. The final cities included in the analysis were: Dayton, OH; Fresno, CA; Hot Spring, AR; Oklahoma City, OK; Rapid City, SD; and Tucson, AZ. Findings from the report were subsequently published in *Health Affairs*. See Greenwald et al. “Specialty Verses Community Hospitals: Referrals, Quality and Community Benefits.”

In their June 2009 report, MedPAC evaluated the effects of physician self-referral on use of imaging services within an episode. Their analysis was based on 100% of Medicare claims from 2005 for beneficiaries residing in six market areas: Boston, MA; Miami, FL; Orange County, CA; Greenville, SC; Minneapolis, MN and Phoenix, AZ.

identification numbers (IDNs), diagnosis and procedure codes, date of service, billed and paid amounts, provider IDNs and tax IDNs. The beneficiary summary file contains demographic and enrollment information about each beneficiary enrolled in Medicare during each calendar year. The MPIER and NPI files contain detailed data on each physician who participates in Medicare.

Identifying Urologists by Self-Referral Status

From Medicare claims, we identified each prostate biopsy performed and then matched each with corresponding surgical pathology services. Preliminary analysis revealed that for about one third of the biopsies, surgical pathology services were not performed on the same day as the biopsy. Thus, we constructed a window of 21 days surrounding the biopsy (7 days prior and 14 days after). Less than 0.5% had pathology services that preceded the biopsy date. This algorithm yielded a 97% match rate between the prostate biopsy and related surgical pathology services. Self-referral status was determined by examining the physician specialist that billed for surgical pathology services. Since self-referring urologists can augment their income by billing for either the PC or TC or both, it is critical to account for each type of billing arrangement.

We classified each episode as self-referring based on whether the urologist who performed the biopsy also billed Medicare for associated surgical pathology services. Contrary to prior published studies on imaging, we do not classify a physician as self-referring or not self-referring based on the proportion of imaging episodes that are self-referred. Rather, we classify each episode on a case-by-case basis. An episode was classified as self-referring if the unique physician number or national provider identification number on the pathology claims matched the corresponding number on the biopsy claim, or if the tax identification number on the pathology claim matched the tax identification number on the biopsy claim. One exception to this algorithm was if the tax identification number on the pathology claim matched the tax identification number on the biopsy claim, but the biopsy was performed at a hospital. In this situation the reason the pathology claims matched the biopsy claim was because the urologist and pathologist were members of the same physician practice plan (e.g., the Johns Hopkins physicians practice plan). This episode was classified as not self-referral. A second exception involved one urology practice that had established a separate pathology lab, which performed and subsequently billed Medicare under a different tax identification number than the one associated with the urology group; this unique case was classified as self-referral.²

²This unique situation was uncovered through preliminary examination of trends in use of surgical pathology services in each county over time. Initially we thought there was no self-referring urology practice in Chatham county Georgia. Our examination revealed the utilization rate was initially higher and rose more rapidly in Chatham county GA in comparison to Fulton county GA. This was surprising because Fulton county (Atlanta) has a large self-referring urology group. We investigated it further by identifying all the urologists who performed prostate biopsies in Chatham county Georgia and found many urologists were members of a single urology practice. The Web site for this group indicates they have a laboratory that provides pathology services. Using the NPI file we were able to identify the name and address of their lab which we discovered was located in South Carolina.

Outcome Measures and Analysis

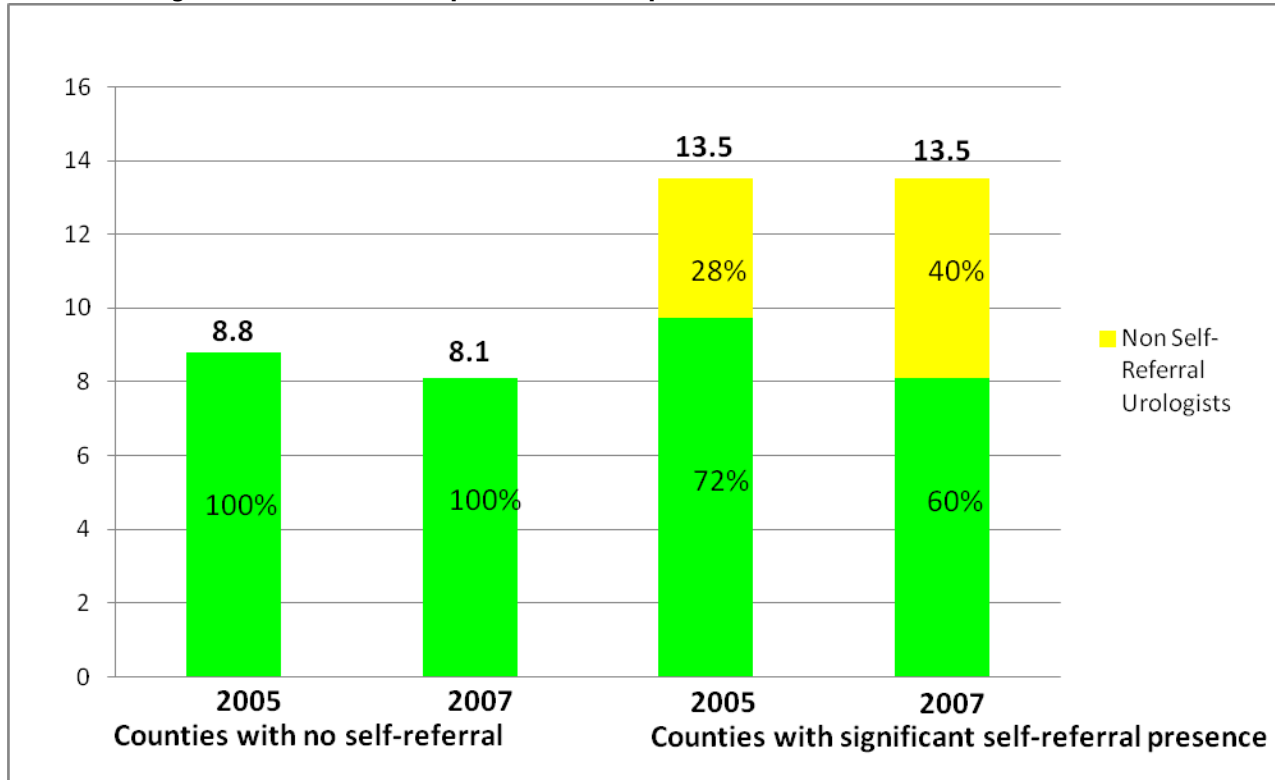
If a prostate biopsy was performed by a self-referring urologist, then all of the surgical pathology specimens (jars) associated with that prostate biopsy was earmarked as self-referral. Surgical pathology specimens (jars) that accompanied prostate biopsy procedures performed by urologists not involved in self-referral arrangements were designated as not self-referral. For each year, we counted the number of prostate biopsy procedures (HCPCS code 55700) performed on male Medicare beneficiaries residing in each county. The prostate biopsy utilization rate was computed as the total number of biopsy procedures performed per 1000 male Medicare beneficiaries who resided in each county. The self-referral share (percentage) for each year was calculated as the total number of prostate biopsies performed by self-referral urologists, relative to the total number of prostate biopsy procedures performed by all urologists (self-referral and non self-referral) on male Medicare beneficiaries in each county.

For each year, we counted the number of surgical pathology specimens or jars (HCPCS code 88305) associated with prostate biopsies performed on male Medicare beneficiaries residing in each county. The utilization rate for each year was calculated as the total number of prostate surgical pathology specimens (jars) billed to Medicare per 1000 male Medicare beneficiaries in each county. We calculated the share (percentage) that could be directly linked to self-referral providers as the ratio of the count of prostate surgical pathology specimens (jars) billed by self-referring urologists, relative to the total count of prostate surgical pathology specimens (jars) billed by all providers. We analyzed trends in use of both prostate biopsy procedures and prostate surgical pathology specimens (jars) performed in conjunction with each biopsy procedure over the time period 2005 through 2007. We also employed regression analysis to examine whether the self-referral share (percentage) had a significant impact on the prostate biopsy use rate and the prostate surgical pathology specimen (jars) use rate after controlling for county and time period fixed effects.

Results

Exhibit 1 shows that between 2005 and 2007, the prostate biopsy surgical procedure rate declined by 9% (8.9 to 8.1 per 1000) in counties where urologist self-referral arrangements were absent, whereas this rate remained stable at 13.5 per 1000 male beneficiaries in counties where such arrangements were present. The share of the total prostate biopsy utilization rate in these counties due to self-referral, however, jumped from 28% to 40%.

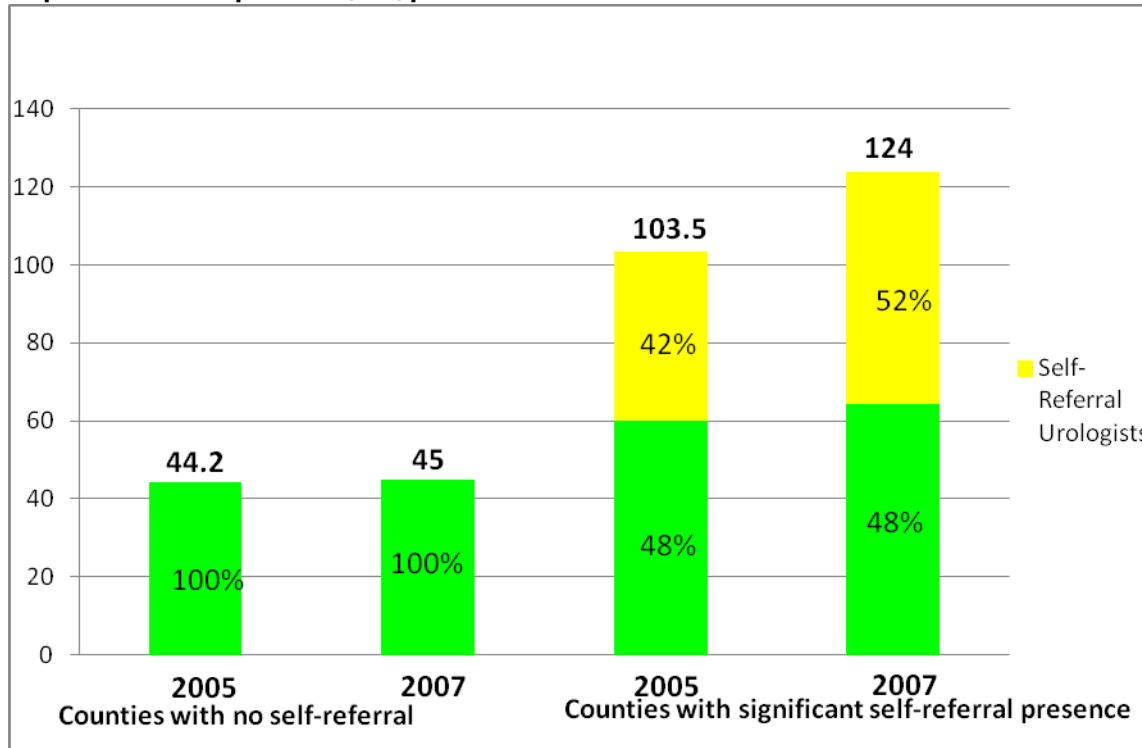
Exhibit 1: Changes in Use of Prostate Biopsies: Procedures per 1000 Male Medicare Beneficiaries



SOURCE: Author's analysis of Medicare claims files.

Exhibit 2 depicts changes in use of the count of prostate surgical pathology specimens (jars) per 1000 male Medicare beneficiaries. The overall utilization rate remained flat between 2005 and 2007 in counties where self-referring urology practices were absent. In contrast, the use rate for prostate surgical pathology specimens (jars) in counties where self-referring urology groups were present jumped by nearly 20% (103.5 to 124 per 1000) between 2005 and 2007. The overall use rate in counties where self-referral arrangements existed was 103.5 per 1000 in 2005, which was almost 134% higher than the corresponding use rate of 44.2 per 1000 male Medicare beneficiaries in counties where self-referring urology practices were absent. In 2007, the overall use rate in counties with self-referring urology practices (124 per 1000) was 175% higher than the use rate that characterized counties where self-referral was nonexistent (45 per 1000). The growth in the prostate surgical pathology specimens (jars) use rate appears to be attributed to the practice of self-referral; the share of total utilization in these counties linked to self-referral was 42% in 2005, but climbed to 52% by 2007 (Exhibit 2).

Exhibit 2: Changes in Use of Surgical Pathology Services Associated with Prostate Biopsies: Counts of Specimens (Jars) per 1000 Male Medicare Beneficiaries



SOURCE: Author's analysis of Medicare claims files.

The first two columns of Exhibit 3 report regression results for the prostate biopsy use rate, defined as the number of prostate biopsy procedures performed per 1000 male Medicare beneficiaries in each county. In the model that excludes county-fixed effects (column 1 of Exhibit 3), a 10 percentage point increase in the self-referral share (percentage) is associated with a 0.9 unit increase in the prostate biopsy use rate ($p < .01$). The self-referral effect, however, is no longer statistically significant in the specification that also controls for county-fixed effects (column 2 of Exhibit 3). Columns 3 and 4 of Exhibit 3 report the regression results for the use rate of prostate surgical pathology specimens performed in conjunction with each prostate biopsy. In the more parsimonious specification (column 3 of Exhibit 3), a 10 percentage point increase in the self-referral share (percentage) in the county is linked to a 15.6 unit increase in the use rate—count of prostate surgical pathology specimens (jars), per 1000 male Medicare beneficiaries in the county ($p < .01$). Including county fixed effects reduces the magnitude of the self-referral effect by almost one half, but it remains highly significant at the 1% level (column 4 of Exhibit 3). A 10 percentage point increase in the self-referral share in the county is associated with an 8.3 unit increase in the use rate of prostate surgical pathology specimens (jars) per 1000 male Medicare beneficiaries in the county ($p < .01$). By implication, the use rate of prostate surgical pathology specimens (jars), in a county where the self-referral share of total use is 50%, is predicted to be 41.5 units higher than the use rate in a county where urologist self-referral arrangements are absent (self-referral share equals zero).

Exhibit 3. Regression Estimates Predicting Changes in Use of Prostate Biopsy Procedures and Prostate Surgical Pathology Specimens^a (N = 60)

| Variable | Prostate Biopsy Use Rate (1) | Prostate Biopsy Use Rate (2) | Surgical Pathology Specimens Use Rate (3) | Surgical Pathology Specimens Use Rate (4) |
|----------------------------------|---------------------------------|---------------------------------|---|---|
| Self-referral Share ^b | .090*** (.024) | .032 (.026) | 1.56*** (0.23) | 0.83*** (0.24)** |
| Year 2006 | .017 (1.55) | .284 (.390) | 5.20 (17.28) | 9.29 (4.45) |
| Year 2007 | -1.32 (1.56) | -.846 (.428) | 0.72 (17.36) | 7.38 (4.77) |
| Includes county of residence. | NO | YES | NO | YES |
| Adjusted R ² | 0.17 | .95 | 0.42 | 0.96 |

Notes: ^a Coefficients and standard errors (in parentheses).

^b Self-referral share (percentage), measured as actual number, is defined as the share of total utilization billed by self-referral urologists.

^c Prostate biopsy use rate is defined as the number of prostate biopsy procedures per 1000 male Medicare beneficiaries in each county.

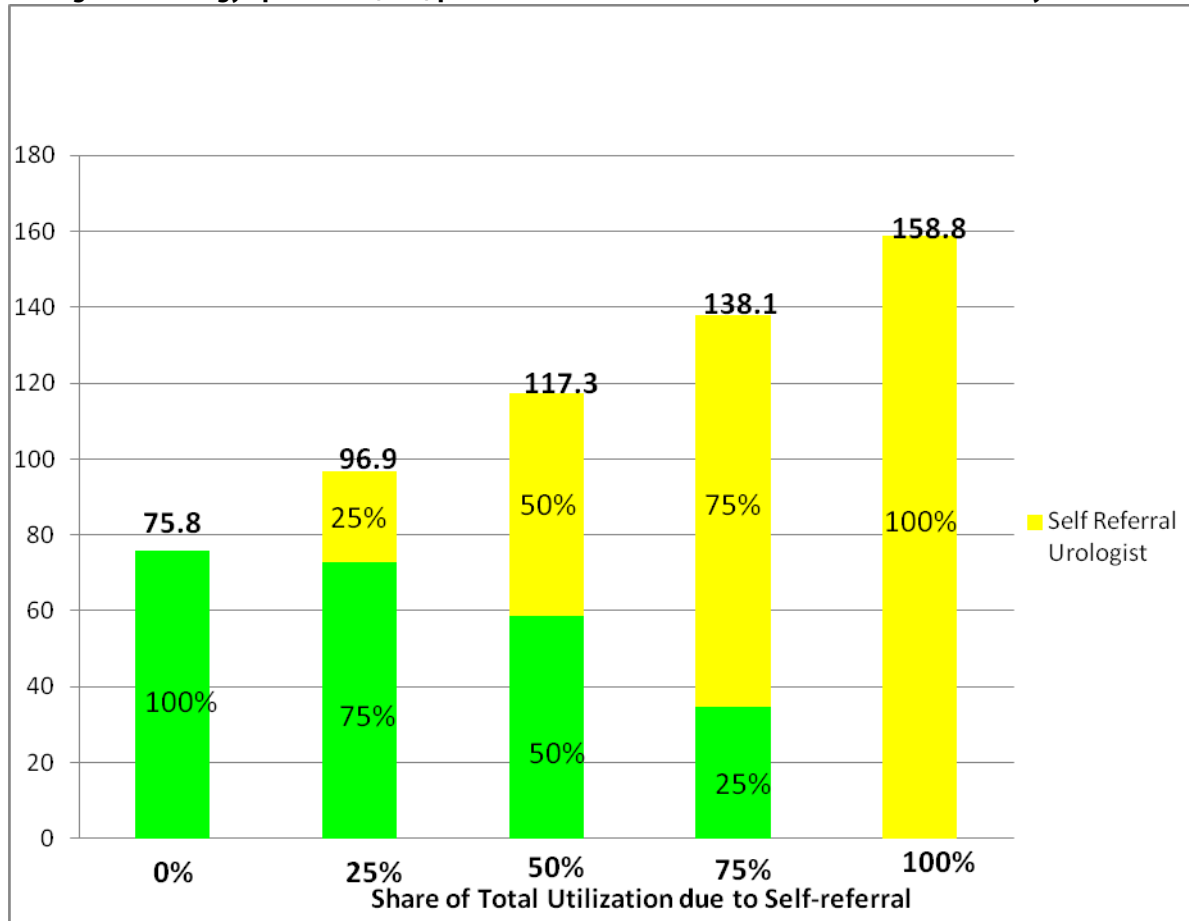
^d Surgical pathology specimens use rate is defined as the aggregate number of prostate surgical pathology specimens performed in association with prostate biopsies per 1000 male Medicare beneficiaries in each county.

***Significant at $p < .01$; **Significant at $p < .05$. Reference groups: YEAR 2005 & Sacramento, CA.

SOURCE: Author's analysis of Medicare claims files.

The parameter estimates from this regression model (column 4) can be used to predict the utilization of prostate surgical pathology specimens for varying values of the self-referral share. Exhibit 4 depicts the utilization rates from such predictions for Nassau county, NY, assuming the self-referral share is 0%, 25%, 50%, 75% and 100%. Absent urologist self-referral arrangements, the utilization of prostate surgical pathology specimens is predicted to be 75.8 per 1000 male beneficiaries. Suppose the self-referral share is 50%. Predicted utilization would be 117.3, which is 55% higher than the predicted utilization rate where self-referral is nonexistent. Next, assume the self-referral share is 75%. Under this scenario, the utilization rate would be 138.1, which is 82% higher than the corresponding rate where the self-referral share equals zero.

Exhibit 4: Predicted Effects of Urologist Self-referral on the Prostate Surgical Pathology Utilization Rate: Counts of Surgical Pathology Specimens (Jars) per 1000 Male Medicare Beneficiaries in Nassau County NY



SOURCE: Author's analysis of Medicare claims files.

Discussion

In recent years, an increasing number of referring physicians have integrated ancillary services into their practices (Reschovsky et al., 2010; Mitchell, 2007). These arrangements have been tailored to fit the IOAS exception in the federal law that prohibits physicians from self-referring. This study examined trends in use of surgical pathology services performed in conjunction with prostate biopsy procedures and self-referral by urologists. Little research has addressed self-referral's effect on use of pathology services.

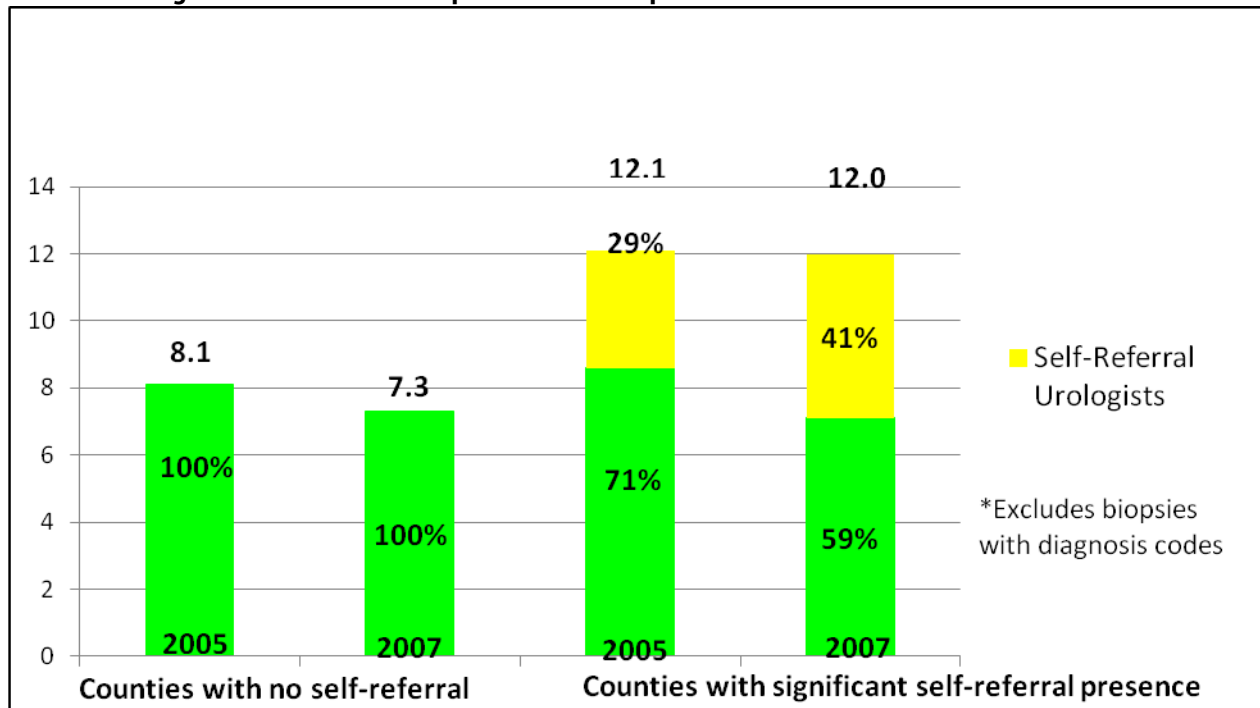
The findings show that, between 2005 and 2007, the prostate biopsy surgical procedure rate declined in counties where self-referring urology practices were absent, but held steady in counties with such arrangements. Nevertheless, in counties with a significant self-referral presence, the share of the prostate biopsy utilization rate due to self-referral rose from 28% to 40%. Notably, if one were to eliminate the 40% share due to self-referral that existed in 2007 (Exhibit 1), the prostate biopsy utilization rates in counties with and without self-referring

urology practices would be nearly identical. Regression analysis showed, however, after controlling for year and county, the self-referral share of total utilization did not significantly affect the prostate biopsy use rate.

The trend analysis further reveals that use of prostate surgical pathology specimens (jars) per 1000 male Medicare beneficiaries remained flat in counties where self-referral arrangements were nonexistent. In contrast, the use rate for prostate surgical pathology specimens (jars) in counties with self-referring urology practices jumped by almost 20% between 2005 and 2007. The share of the prostate surgical pathology specimens' utilization rate due to self-referral was 42% in 2005, but climbed to 52% in 2007. If one were to eliminate the share of utilization attributable to self-referral, the use of prostate surgical pathology specimens would have remained flat over the time period at about 60 per 1000 male Medicare beneficiaries (Exhibit 2). Regression results reveal that the self-referral effect on the use rate of prostate surgical pathology specimens was highly significant even after controlling for year and county fixed effects. For every 10 percentage point increase in the self-referral share in a county, the use rate of surgical pathology specimens (jars) per 1000 male Medicare beneficiaries increased by 8.3 units ($p < .01$). This means that the prostate surgical pathology utilization rate would be 83 units higher if all prostate surgical pathology specimens were billed by self-referring urologists compared to the case where none were self-referral (share equals 100% versus 0%).

The results in Exhibit 1 show the share of biopsies due to self-referral increased over time. This finding might be attributable to private practice urologists, who are more likely in the self-referral group, performing routine biopsies as part of active surveillance protocols. To investigate this possible explanation, we identified men with a diagnosis code of 185 (prostate cancer) or 233.4 (carcinoma in situ prostate) on the biopsy. These men had a prior diagnosis of prostate cancer and were most likely being re-biopsied as part of an active surveillance protocol to monitor pathological progression of the disease. We then excluded these cases from the sample and re-ran the analysis on the sub-sample who did not have a diagnosis code of either 185 or 233.4 on the biopsy. In the original sample, there were 45,350 prostate biopsies performed and 10.8% (4,907) had a diagnosis code of either 185 or 233.4 on the biopsy procedure. Exclusion of these cases had little impact on the biopsy use rates (Exhibit 5). In counties where self-referral arrangements were absent, the biopsy rate fell from 8.1 per 1000 male Medicare beneficiaries in 2005 to 7.3 per 1000 in 2007. In counties with a significant self-referral presence, the biopsy use rate remained flat at 12 per 1000 male Medicare beneficiaries between 2005 and 2007. Self-referral accounted for 29% of the prostate biopsy use rate in 2005 and this share grew to 41% by 2007. In the overall sample, the self-referral share of the prostate biopsy utilization rate was 28% and 40% respectively in 2005 and 2007.

Exhibit 5: Changes in Use of Prostate Biopsies: Procedures per 1000 Male Medicare Beneficiaries*



SOURCE: Author's analysis of Medicare claims files.

One possible explanation for the increased number of specimens (jars) billed by self-referring urologists is age, that is, self-referring urologists might treat disproportionately older men than their non self-referring counterparts. However, comparisons of the age composition of men who underwent a prostate biopsy show negligible differences in age by self-referral status. Mean age of men treated by both groups of urologists was 71-72.

Limitations

While the findings reported here provide new evidence documenting trends in use of prostate surgical pathology services associated with the practice of self-referral by urologists, the analysis has some limitations. One limitation relates to the targeted market area case study design employed to identify the sample of male Medicare beneficiaries who were potential candidates for a prostate biopsy. Although this study design might raise questions regarding generalizability, it is frequently adopted to evaluate nascent market trends. Others including CMS, MedPAC, and the Center for Studying Health Systems Change routinely follow similar sample selection strategies in their investigations of emergent market trends (MedPAC 2009; Greenwald et al, 2006).

This approach was adopted after carefully evaluating and subsequently ruling out other alternatives. One option was to conduct the analysis using a national sample such as the Medicare 5% sample. A national sample was deemed to be inappropriate, because it would not necessarily include a large percentage of beneficiaries who were potential candidates for a

prostate biopsy. In addition, a national sample was likely to include too few self-referring urologists to allow one to make meaningful comparisons. Another alternative was the Surveillance, Epidemiology and End Results (SEER) data merged with Medicare claims. Since the focus was on men who may or may not have prostate cancer, we concluded that the SEER data were not suitable, because the SEER only includes cases that have a positive diagnosis of cancer. A third possibility was to obtain data for all male Medicare beneficiaries who resided in a handful of states. We ruled out this option, because the cost of purchasing multiple years of this type of data file from the Centers for Medicare & Medicaid Services (CMS) was prohibitively expensive (in excess of \$200,000) and such resources were not available.

A second limitation is that the claims data only capture services rendered to FFS Medicare enrollees and thus may not be applicable to beneficiaries enrolled in Medicare Advantage plans. FFS enrollees, however, account for about 78% of all Medicare beneficiaries. Since urologists who have insourced pathology services treat patients with private insurance, one would expect to observe similar trends and increases in utilization rates for surgical pathology services among those with private insurance (including Medicare Advantage).

A third limitation stems from the absence of clinical information in Medicare claims data. Thus, we could not document grade and stage of disease for those who had a positive diagnosis of prostate cancer reported on at least one of the related surgical pathology claims. For example, grade of cancer may dictate whether future biopsies are warranted as part of active surveillance monitoring. As noted above, less than 11% of the biopsies performed had a positive diagnosis of cancer or carcinoma in situ prostate on the biopsy procedure, and their exclusion had little impact on biopsy use rates.

Conclusion

Findings from this trend analysis examining use rates of prostate surgical pathology specimens (jars) accord with three audits conducted in 2007 by the Office of the Inspector General. The OIG examined use of surgical pathology services for three urology practices before and after they began billing Medicare for pathology services. The results indicated that urologist self-referral (insourcing of pathology labs) is linked to significantly higher use of surgical pathology services (Office of Inspector General, 2007a, 2007b, 2007c). For example, Florida Urology Physicians, which has offices in the Cape Coral/ Fort Myers area, began insourcing pathology services for both Medicare and privately insured patients in September 2004. Prior to opening its own lab, Florida Urology requested an average of one pathology tissue specimen (jar) per prostate biopsy performed. During the four month period after the urology group began billing Medicare for surgical pathology services, the practice requested an average of nine tissue specimens (jars) per prostate biopsy. Other pathology providers in Florida billed Medicare for 5.5 tissue specimens (jars) per prostate biopsy performed (Office of Inspector General, 2007a).

In conclusion, the findings reported here show that urologist self-referral results in significant increases in the use rate of prostate surgical pathology specimens (jars) for Medicare beneficiaries. The findings imply that exceptions in federal and state prohibitions on self-referral that relate to pathology services need to be reevaluated. Eliminating the exception that permits urologists to self-refer for surgical pathology services has the potential to yield significant savings for the Medicare program.

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