ALSTON&BIRD LLP

The Atlantic Building
950 F Street, NW
Washington, DC 20004-1404

202-239-3300
Fax: 202-654-4834
www.alston.com

Peter Kazon **Direct Dial: 202-239-3334** **Email: peter.kazon@alston.com**

June 1, 2012

Jonathan D. Blum
Centers for Medicare & Medicaid Services
Director, Center for Medicare Management
Mail Stop 314G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Jon:

Thank you very much for meeting with representatives of the College of American Pathologists and ACLA last week. We thought it was a very useful meeting and appreciated the opportunity to discuss pathology self-referral issues, particularly in light of the recent publication of Dr. Jean Mitchell's study in *Health Affairs.* As we discussed, this study demonstrates the increased utilization and the reduced cancer detection rate in urology practices that engaged in self-referral of pathology services.. In follow-up to our discussion, we wanted to emphasize several points.

As we mentioned at our meeting, Dr. Mitchell's study is just one in a long line demonstrating the impact of self-referral on overutilization. We are attaching a summary that we compiled of recent articles from *Health Affairs* alone, which highlights the problems of self-referral generally across several specialties and settings, including its effect on utilization and costs. Numerous other studies and government reports have also come up with similar findings.

Second, we wanted to reemphasize that self-referral limitations would not affect the convenience of the patient. Self-referral limitations would not affect the urologist's ability to perform the biopsy—the one part of the process where the patient's convenience is a factor. The physician will continue to be able to perform the biopsy, either in his office or in an ASC just as he does today, although without a financial interest the number of biopsies he chooses to perform would likely go down.

Self-referral limitations only affect where the specimen is sent for processing and interpretation after the biopsy. However, whether the laboratory is on-site or off-site does not affect the convenience of the patient in any way. A tissue sample taken during a biopsy procedure must be fixed in a preservative, processed, and sectioned, before it can be read by the pathologist. These preparatory steps and pathologist interpretation typically take a minimum of 24 hours to complete (and may take longer depending on the complexity of the diagnosis); thus

the pathology service cannot be completed at the same time as procurement of the tissue during biopsy or while the patient waits in the physician's office or at the ASC following biopsy.

In fact, when a physician engages in self-referral, the patient is usually adversely affected. Independent laboratories typically process the tissue as soon as it received, and have a pathologist interpret the slides within one working day. On the other hand, an in-house laboratory that depends on self-referral usually has longer turnaround time because, as we shared at our meeting, in-house labs often have fewer histotechnologists to prepare the slides, which means the tissue may not be processed right away. In addition, if the self-referring practice also bills for the professional component, the pathologist who provides that service on-site may only be at that office once or twice a week. Both of these factors mean that it may take longer for patients to find out the results of their biopsies, a more problematic—and far less convenient—experience for the patient.

In addition to patient convenience, as you heard, the quality of pathology at in-house laboratories may also present concerns. The economic model for these self-referring arrangements hinges on their keeping overhead as low as possible, which often limits the number of personnel available to prepare the slides. And, when they are prepared, the slides often do not include as many "levels" for each specimen. These limitations on resources may be particularly significant when the pathologist requests that additional slides be prepared from the paraffin block to further evaluate the specimen following review of the initial slides. The experience of our members is that such additional slides are difficult, if not impossible, to obtain when the slides are prepared by a histotechnologist who works for an in-house laboratory. In addition, at an independent laboratory a community of pathologists is readily available to consult together on difficult cases. Where necessary, the pathologists can also go back to the tissue "block" to obtain tissue for additional studies if questions arise during the pathologists' interpretation. Neither of these advantages is possible in the in-office situation. Thus, the quality of the pathology results being reported is more consistent and reliable at the independent laboratory.

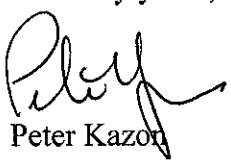
We wanted to re-emphasize that self-referral results in physicians making decisions based on financial incentives rather than solely on what is in the best interest of the patient. If a physician does not have a financial interest in processing the biopsy, the decision as to where to send the biopsy for processing will be based solely on medical grounds and the best interest of the patient. Financial self-interest leads to physicians taking more biopsies in cases of marginal utility. It also increases the number of specimens taken and specimen "jars" billed. As we noted at the meeting, the correct question is not whether the appropriate number of biopsy cores obtained is 12 or 10 or 6. The question is: Should decisions related to whether or not to perform a biopsy and, if so, how many specimens are taken, be driven by a physician's personal financial interest, rather than concerns about what is best for the patient?

We also wish to emphasize that although Dr. Mitchell's study focused on questions of prostate biopsies, the question of self-referral in anatomic pathology is much broader and involves not only urologists, but also gastroenterologists and dermatologists. A solution that focuses merely on one particular subspecialty, therefore, will not truly address the problem.

As indicated above, Dr. Mitchell's study is just one of many examining the negative effects of self-referral on utilization and Medicare costs. For this reason and all those indicated above, we urge CMS to consider a solution that removes the perverse incentive created by self-referral by limiting the In Office Ancillary Services exception in the Stark law. As we discussed, we believe that other proposed solutions, such as reducing or bundling payment, will only result in greater utilization of pathology services and an increase in the number of related services, such as special stains. In addition, bundling could also result in patients in need of biopsies not receiving them because the bundled payment encourages the underutilization of services.

Thank you again for taking the time to meet with us. If you have any questions, please do not hesitate to contact me.

Sincerely yours,



Peter Kazon

cc: Troy Barsky

Enclosure
LEGAL02/33331290v1

Health Affairs coverage of the perverse financial incentives of Physician Self-Referral

Abstract 1

Urologists' Self-Referral For Pathology Of Biopsy Specimens Linked To Increased Use And Lower Prostate Cancer Detection
Jean M. Mitchell
Health Aff April 2012 31:4741-749; doi:10.1377/hlthaff.2011.1372

Urologists' Self-Referral For Pathology Of Biopsy Specimens Linked To Increased Use And Lower Prostate Cancer Detection

Federal law allows physicians in some circumstances to refer patients for additional services to a facility in which the physician has a financial interest. The practice of physician self-referral for imaging and pathology services has been criticized because it can lead to increased use and escalating health care expenditures, with little or no benefit to patients. This study examined Medicare claims for men in a set of geographically dispersed counties to determine how the "in-office ancillary services" exception affected the use of surgical pathology services and cancer detection rates associated with prostate biopsies. I found that self-referring urologists billed Medicare for 4.3 more specimens per prostate biopsy than the adjusted mean of 6 specimens per biopsy that non-self-referring urologists sent to independent pathology providers, a difference of almost 72 percent. Additionally, the regression-adjusted cancer detection rate in 2007 was twelve percentage points higher for men treated by urologists who did not self-refer. This suggests that financial incentives prompt self-referring urologists to perform prostate biopsies on men who are unlikely to have prostate cancer. These results support closing the loophole that permits self-referral to "in-office" pathology laboratories.

Full Text

Abstract 2

Imaging Self-Referral Associated With Higher Costs And Limited Impact On Duration Of Illness
Danny R. Hughes, Mythreyi Bhargavan, and Jonathan H. Sunshine
Health Aff December 2010 29:122244-2251; doi:10.1377/hlthaff.2010.0413

Imaging Self-Referral Associated With Higher Costs And Limited Impact On Duration Of Illness

Self-referral for imaging services occurs when a physician sends patients to receive an imaging procedure from a device that the physician owns or leases. Advocates argue that this shortens the duration of illness and lowers costs. For twenty common combinations of medical conditions and types of imaging, we evaluated the association between self-referral, duration of illness episode, and three measures of cost. Self-referral was associated with significantly and substantially higher episode costs for most of the combinations of medical conditions and imaging that we studied. There was no decrease in the length of illness, except when doctors self-referred patients to receive x-rays for a few common conditions. These findings indicate that except for x-rays, constraining the self-referral of imaging may be appropriate.

Full Text

Abstract 3

Imaging: The Self-Referral Boom And The Ongoing Search For Effective Policies To Contain It
Bruce J. Hillman and Jeff Goldsmith
Health Aff December 2010 29:122231-2236; doi:10.1377/hlthaff.2010.1019

The Self-Referral Boom And The Ongoing Search For Effective Policies To Contain It

When a physician who isn't a radiologist holds an ownership interest in an advanced imaging machine and refers patients for diagnostic procedures on that machine, this act of self-referral presents a conflict of interest. Numerous studies demonstrate greater use of high-tech imaging when physicians can financially benefit from such referrals. This overview summarizes the issues surrounding imaging self-referral and reviews the history of attempts to control it, as well as options for limiting its impact on spending. Recent payment reductions by Medicare limited the rewards for imaging self-referral, and the Affordable Care Act mandated disclosure of physicians' ownership interests. However, the rewards for imaging self-referral remain strong. Policy makers continue to search for the right mechanisms for containing the practice and for assuring that Medicare beneficiaries receive only medically necessary imaging studies, regardless of who owns or operates the equipment.

Full Text

Abstract 4

The Practice Of Imaging Self-Referral Doesn't Produce Much One-Stop Service
Jonathan Sunshine and Mythreyi Bhargavan
Health Aff December 2010 29:122237-2243; doi:10.1377/hlthaff.2009.1081

The Practice Of Imaging Self-Referral Doesn't Produce Much One-Stop Service

Imaging as a result of self-referral—when a physician refers patients for imaging tests at a facility owned or leased by the same physician—is widespread. The practice has come under much scrutiny because it is associated with higher volumes of imaging services. Proponents of such self-referral argue that the practice offers patients convenient same-day, one-stop service and allows treatment to start sooner. Our analysis of 2006 and 2007 Medicare data showed that self-referral provided same-day imaging for 74 percent of straightforward x-rays, but for only 15 percent of more-advanced procedures such as computed tomography and magnetic resonance imaging. Policy makers attempting to make the use of imaging more responsible should consider narrowing Medicare's special provision allowing referrals to a physician's own practice so that the provision covers x-rays only.

Full Text

Abstract 5

The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging

Jean M. Mitchell

Health Aff May 2007 26:3w415-w424; published ahead of print April 17, 2007, doi:10.1377/hlthaff.26.3.w415

The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging

Using data from a large insurer in California, we identified the self-referral status of providers who billed for advanced imaging in 2004. Nearly 33 percent of providers who submitted bills for magnetic resonance imaging (MRI) scans, 22 percent of those who submitted bills for computed tomography (CT) scans, and 17 percent of those who submitted bills for positron-emission tomography (PET) scans were classified as "self-referral." Among them, 61 percent of those who billed for MRI and 64 percent of those who billed for CT did not own the imaging equipment. Rather, they were involved in lease or payment-per-scan referral arrangements that might violate federal and state laws.

Full Text

Abstract 6

Letters: **Evidence About Imaging Self-Referral: Author Response**

Jonathan H. Sunshine, Danny R. Hughes, and Mythreyi Bhargavan
Health Aff March 2011 30:3536; doi:10.1377/hlthaff.2011.0210

Abstract 7

Letters: **A Flawed Analysis Of Self-Referral**
Elizabeth Rowe
Health Aff June 2011 30:61214; doi:10.1377/hlthaff.2011.0436

Abstract 8

Letters: **Analyzing Self-Referral: The Author Replies**
Laurence C. Baker
Health Aff June 2011 30:61214; doi:10.1377/hlthaff.2011.0427

Abstract 9

Letters: **Imaging Self-Referral: Health Affairs Responds**
Susan Dentzer
Health Aff March 2011 30:3537; doi:10.1377/hlthaff.2011.0202

Abstract 10

PERSPECTIVE: **Intolerable Risk, Irreparable Harm: The Legacy Of Physician-Owned Specialty Hospitals**
Charles N. Kahn III
Health Aff January 2006 25:1130-133; doi:10.1377/hlthaff.25.1.130

Intolerable Risk, Irreparable Harm: The Legacy Of Physician-Owned Specialty Hospitals

Issues of physician ownership and referral could cause major shifts in the structure of medical care and make the financing of U.S. hospital services problematic. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 mandated research on this matter and applied an eighteen-month moratorium against self-referral to allow policymakers to consider the issue. Research findings thus far confirm that physicians' ownership and referral present conflicts of interest through medical and economic patient selection and potentially excessive utilization. The policy response must prevent these results and preserve fair competition among hospitals.

Full Text

Abstract 11

Where Do I Send Thee? Does Physician-Ownership Affect Referral Patterns To Ambulatory Surgery Centers?

Jon R. Gabel, Cheryl Fahlman, Ray Kang, Gregory Wozniak, Phil Kletke, and Joel W. Hay

Health Aff May 2008 27:3w165-w174; published ahead of print March 18, 2008, doi:10.1377/hlthaff.27.3.w165

Where Do I Send Thee? Does Physician-Ownership Affect Referral Patterns To Ambulatory Surgery Centers?

For more than three decades, Congress has struggled with potential financial conflicts of interest when physicians share in financial gain from nonprofessional services. This study asks the question: Are physicians who are leading referrers to physician-owned ambulatory surgery centers (ASCs) more likely to send Medicaid patients to hospital outpatient clinics than other patients? The comparison group is physicians who are leading referrers to non-physician-owned ASCs, using data from two metropolitan areas. Findings indicate that physicians at physician-owned facilities are more likely than other physicians to refer well-insured patients to their facilities and route Medicaid patients to hospital outpatient clinics.

Full Text

Abstract 12

Physician-Ownership Of Ambulatory Surgery Centers Linked To Higher Volume Of Surgeries

John M. Hollingsworth, Zaojun Ye, Seth A. Strope, Sarah L. Krein, Ann T. Hollenbeck, and Brent K. Hollenbeck

Health Aff April 2010 29:4683-689; doi:10.1377/hlthaff.2008.0567

Physician-Ownership Of Ambulatory Surgery Centers Linked To Higher Volume Of Surgeries

Many physicians confronting declining reimbursement from insurers have invested in ambulatory surgery centers, where they perform outpatient surgical and diagnostic procedures. An ownership stake entitles physicians to a share of the facility's profits from self-referrals. This arrangement can create a potential conflict of interest between physicians' financial incentives and patients' clinical needs. Our analysis of Florida data for five common procedures revealed a significant association between physician-ownership and higher surgical volume. Possible remedies include revising federal law to require disclosure of investment arrangements; reducing facility payments to dilute ownership incentives; and reforms (such as accountable care organizations) that discourage an excessive rate of procedures.