United States Government Accountability Office

Report to Congressional Requesters

June 2013

# MEDICARE

# Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer

GAO Highlights

Highlights of GAO-13-445, a report to congressional requesters

## 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 providers refer patients to entities in which they or their family members have a financial interest. Services that can be self-referred under certain circumstances include anatomic pathology—the preparation and examination of tissue samples to diagnose disease. GAO was asked to examine the prevalence of anatomic pathology self-referral and its effect on Medicare spending. This report examines (1) trends in the number of and expenditures for self-referred and non-self-referred anatomic pathology services, (2) how provision of these services may differ on the basis of whether providers self-refer, and (3) implications of self-referral for Medicare spending. GAO analyzed Medicare Part B claims data from 2004 through 2010 and interviewed officials from the Centers for Medicare & Medicaid Services (CMS) and other stakeholders. GAO developed a claims-based approach to identify self-referred services because Medicare claims lack such an indicator.

## What GAO Recommends

CMS should identify self-referred anatomic pathology services and address their higher use. The Department of Health and Human Services, which oversees CMS, agreed with GAO's recommendation that CMS address higher use of self-referral through a payment approach, but disagreed with GAO's other two recommendations to identify self-referred services and address their higher use. GAO believes the recommended actions could result in Medicare savings.

View GAO-13-445. For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

June 2013

# MEDICARE

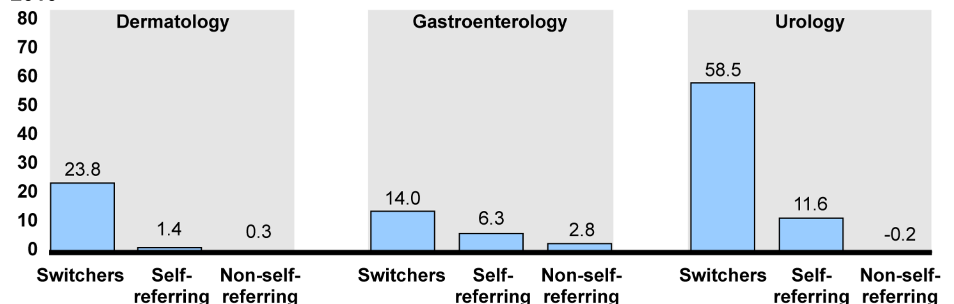
# Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer

## What GAO Found

Self-referred anatomic pathology services increased at a faster rate than non-self-referred services from 2004 to 2010. During this period, the number of self-referred anatomic pathology services more than doubled, growing from 1.06 million services to about 2.26 million services, while non-self-referred services grew about 38 percent, from about 5.64 million services to about 7.77 million services. Similarly, the growth rate of expenditures for self-referred anatomic pathology services was higher than for non-self-referred services. Three provider specialties—dermatology, gastroenterology, and urology—accounted for 90 percent of referrals for self-referred anatomic pathology services in 2010.

Referrals for anatomic pathology services by dermatologists, gastroenterologists, and urologists substantially increased the year after they began to self-refer. Providers that began self-referring in 2009—referred to as switchers—had increases in anatomic pathology services that ranged on average from 14.0 percent to 58.5 percent in 2010 compared to 2008, the year before they began self-referring, across these provider specialties. In comparison, increases in anatomic pathology referrals for providers who continued to self-refer or never self-referred services during this period were much lower. Thus, the increase in anatomic pathology referrals for switchers was not due to a general increase in use of these services among all providers. GAO's examination of all providers that referred an anatomic pathology service in 2010 showed that self-referring providers of the specialties we examined referred more services on average than non-self referring providers. Differences in referral for these services generally persisted after accounting for geography and patient characteristics such as health status and diagnosis. These analyses suggest that financial incentives for self-referring providers were likely a major factor driving the increase in referrals.

**Percentage Change in Medicare Anatomic Pathology Services by Provider Specialty, 2008 to 2010**




Source: GAO analysis of CMS data.

Note: Switchers are providers that did not self-refer in 2007 or 2008, but did self-refer in 2009 and 2010.

GAO estimates that in 2010, self-referring providers likely referred over 918,000 more anatomic pathology services than if they had performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers. These additional referrals for anatomic pathology services cost Medicare about $69 million. To the extent that these additional referrals were unnecessary, avoiding them could result in savings to Medicare and beneficiaries, as they share in the cost of services.

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## Abbreviations

| | |
|---|---|
| AADA | American Academy of Dermatology Association |
| AGA | American Gastroenterological Association |
| AUA | American Urological Association |
| CAP | College of American Pathologists |
| CMS | Centers for Medicare & Medicaid Services |
| HHS | Department of Health and Human Services |
| FFS | fee-for-service |
| HCPCS | Healthcare Common Procedure Coding System |
| ICD-9-CM | International Classification of Diseases, Ninth Revision, Clinical Modification |
| NPI | national provider identifier |
| OIG | Office of Inspector General |
| PC | professional component |
| TC | technical component |
| TIN | taxpayer identification number |

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

June 24, 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 time period. Some policymakers have raised questions about the growth in Part B spending, including the extent to which this growth may be attributable to financial incentives that exist for physicians to self-refer certain services. Self-referral occurs when providers refer their patients for services delivered by entities—such as themselves or a group practice—with which the providers or an immediate family member has a financial relationship. While federal law generally prohibits self-referral under Medicare, there are exceptions for certain services and arrangements.[1]

Among the Medicare diagnostic and therapeutic services that may be self-referred under one of these exceptions are anatomic pathology services, in which physicians trained as pathologists prepare and examine tissue samples and other specimens to diagnose disease and guide patient care.[2] Providers from an array of physician specialties, including dermatology, urology, and gastroenterology, may self-refer the preparation of a patient's tissue for examination, the examination of this tissue to make a diagnosis, or both. Proponents of self-referral contend that arrangements in which physicians have laboratories in their offices

[1]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).

[2]Anatomic pathology includes multiple subspecialties, such as surgical pathology—the macroscopic and microscopic examination of surgical specimens; cytopathology—the examination of cells from fluids or smears; and hematology—the examination of cells from bone marrow aspirations or biopsies. For the purposes of this report "anatomic pathology" services refer to those services with a Healthcare Common Procedure Coding System (HCPCS) code of 88305.

allow providers to make rapid diagnoses and improve coordination of care. In 2010, expenditures for anatomic pathology services under the Medicare physician fee schedule—the payment system used to determine fees for physician-billed services in Medicare fee-for-service (FFS)—totaled $1.94 billon.

While we and other federal agencies have reported on physician self-referral, only a series of studies by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) has focused explicitly on how self-referral may affect the provision of anatomic pathology services.[3] Specifically, in 2007, HHS OIG issued three studies that examined self-referral of anatomic pathology services among three urology practices. The HHS OIG found that, for all three practices, utilization of anatomic pathology services increased after the practice began to self-refer.

You asked us to examine the prevalence of self-referral of anatomic pathology services and Medicare spending for these services.[4] In this report, we examine (1) trends in the number of and expenditures for self-referred and non-self-referred anatomic pathology services from 2004 through 2010, (2) how the provision of anatomic pathology services may differ for providers who self-refer when compared with other providers, and (3) the implications of self-referral for Medicare spending on anatomic pathology services.

[3]For studies by GAO and other agencies on physician self-referral, see, for example, GAO, *Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions,* GAO-12-966 (Washington, D.C.: Sept. 28, 2012) and Medicare Payment Advisory Commission, *Report to the Congress: Improving Incentives in the Medicare Program* (Washington, D.C.: June 2009). For studies by HHS OIG on physician self-referral of anatomic pathology services, see Department of Health and Human Services, Office of the Inspector General, *Audit of Pathology Laboratory Services Claimed by Florida Urology Physicians, P.A. for the Period September through December 2004* (Washington, D.C.: June 2007); *Review of Pathology Services Claimed by Urology Tyler, P.A. Tyler, Texas from May Through December 2004* (Washington, D.C.: June 2007); and *Audit of Pathology Laboratory Services Claimed by Atlantic Urological Associates, P.A. for Calendar Year 2004* (Washington, D.C., June 2007).

[4]In addition to this report on anatomic pathology services, we have ongoing work related to the self-referral of intensity-modulated radiation therapy services and physical therapy services.

To identify trends in the number of and expenditures for self-referred and non-self-referred anatomic pathology services, we analyzed claims from the Medicare Part B Carrier File for 2004 through 2010. Because there is no indicator or “flag” on Medicare claims that identifies whether or not services were self-referred, we developed a claims-based methodology to identify services as either self-referred or non-self-referred.[5] Specifically, we classified services as self-referred if the provider that referred the beneficiary for an anatomic pathology service and the provider that performed the anatomic pathology service were identical or had a financial relationship with the same entity.[6] We focused our review of anatomic pathology services and service components to services with a Healthcare Common Procedure Coding System (HCPCS) code 88305, which is the code for anatomic pathology services related to the examination of tissue samples taken through biopsy procedures.[7] About 66 percent of the $1.94 billion in expenditures for anatomic pathology services in 2010 were associated with HCPCS code 88305. (We also reviewed services with HCPCS codes 88312, 88313, and 88342—special stains—which are used in conjunction with anatomic pathology services to assist providers in making a diagnosis. See app. I for our analysis related to special stains.) We limited the universe for this portion of our analysis to those anatomic pathology services performed in a provider’s office or in an independent clinical laboratory.[8] We focused on these settings because the financial incentive for providers to self-refer is most direct when the service is performed in a physician office. Further, we limited our analysis to self-referral of the preparation of these services, because we could determine that the services were performed in a

[5]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. For example, if a provider is only billing for the technical component of an anatomic pathology service, the provider would use a modifier to alert CMS that the claim does not cover the professional component of the service.

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

[7]We use the term “biopsy procedure” to refer to the process of extracting tissue samples for analysis. Multiple tissue samples (sometimes also referred to as biopsies) can be extracted from a single biopsy procedure.

[8]Providers can also provide anatomic pathology services in settings other than physician offices or clinical laboratories, such as hospitals.

physician's office or independent laboratory.[9] We used the claims to identify trends in the number and proportion of self-referred and non-self-referred anatomic pathology services performed from 2004 through 2010, the expenditures for these services from 2004 through 2010, and the proportion of self-referred and non-self-referred anatomic pathology services by provider specialty for 2004 and 2010. To determine expenditures, we used the allowed charges variable from the Medicare Part B Carrier File, which includes the amounts paid by Medicare and the beneficiary.

To determine how the provision of anatomic pathology services may differ for providers who self-refer when compared with other providers, we performed two separate analyses. First, we compared the provision—that is, the number of referrals made—of anatomic pathology services by self-referring providers and non-self-referring providers in 2010, disaggregated by provider size (i.e., the number of Medicare beneficiaries seen by the provider), provider specialty, geography (i.e., urban or rural) and patient characteristics.[10] Second, we determined the extent to which the number of anatomic pathology referrals made by providers changed after the providers began to self-refer. Specifically, we identified a group of providers who began to self-refer anatomic pathology services in 2009 and calculated the change in the number of anatomic pathology referrals the providers made from 2008 (i.e., the year before they began self-referring) through 2010 (i.e., the year after they began self-referring).[11] We then compared this change to the change made by (1) providers who self-referred anatomic pathology services over this time period and (2) providers who did not self-refer services over the time period.

To determine the implications of self-referral for Medicare spending on anatomic pathology services, we summed the number of and expenditures for all anatomic pathology services performed in 2010

[9]We did not analyze the self-referral related to the interpretation of these services because we could not reliably determine whether they were performed in a physician's office or independent laboratory using Medicare Part B Carrier File data.

[10]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 in population; all other settings are considered rural.

[11]We used 4 years of experience (2007 through 2010) to categorize providers even though we compared referrals in 2008 to 2010 because we wanted to ensure that providers that began self-referring in 2009 did not self-refer for at least the 2 prior years.

across the three provider specialties—dermatology, gastroenterology, and urology—we reviewed. We then calculated the number of and expenditures for anatomic pathology services if self-referring providers performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers of the same provider size and specialty. We repeated this analysis incorporating an approximation of the payment reduction for anatomic pathology services that became effective in 2013.[12]

We took several steps to ensure that the data used to produce this report were sufficiently reliable. Specifically, we assessed the reliability of the data we used from the Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare—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 reliable for the purposes of our study. For further information on the scope and methodology for this report, see appendix II.

We conducted this performance audit from January 2012 through June 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

Anatomic pathology services aid in the diagnosis and treatment of diseases such as cancers and gastroenteritis—a condition that causes irritation and inflammation of the stomach and intestines. Medicare pays providers for performing the services and subsequently interpreting the results. Payment for the performance of the services can be made through different payment systems, depending on where the anatomic pathology service is performed. In 2010, Medicare paid about $1.28 billion under the physician fee schedule for anatomic pathology

[12]See *Medicare Program; Revision of Payment Policies Under the Physician Fee Schedule for CY 2013*, 77 Fed. Reg. 68,892 (Nov. 16, 2012).

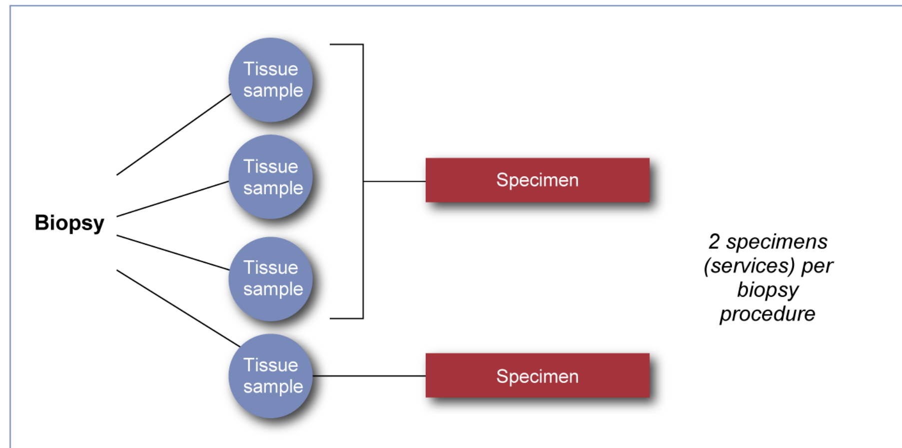
services across all settings, of which about $945 million was for services performed in physician offices and independent laboratories.

## Anatomic Pathology Services

Anatomic pathology services involve the examination of tissues and other specimens to diagnose diseases, such as cancers and gastroenteritis, and guide patient care. The services may be performed after a biopsy procedure used to obtain tissue samples. For example, after removing tissue samples during a biopsy procedure on a patient's prostate, a urologist may refer the patient's tissue sample for examination to determine whether, on the basis of an analysis of the tissue sample or samples, the patient has prostate cancer. After collecting these tissue samples, a non-self-referring provider may send them to an independent diagnostic laboratory, a hospital laboratory, or pathology physician group for further preparation and analysis. In contrast, self-referring providers may prepare specimens or evaluate specimens or both at their practices, rather than involving an external diagnostic laboratory or pathology physician group. For example, the ordering provider's group practice may have a technician who prepares specimens into slides or include a pathologist who interprets these specimens, or both.

Providers have discretion in determining the number and type of tissue samples that become a specimen. For example, a provider referring anatomic pathology services may include more than one tissue sample in a specimen if the samples are from the same areas of abnormal tissue (see fig. 1). Alternatively, a provider may choose to create multiple specimens, each containing a single tissue sample. Providers differ on whether or to what extent tissue samples can be combined in creating a specimen or if each tissue sample must become a specimen. For example, urologists differ on whether it is clinically appropriate to combine tissue samples obtained through a prostate biopsy procedure or whether each tissue sample must became a specimen. The resultant number of specimens has implications for payment as each specimen submitted for analysis can be billed to Medicare separately as an anatomic pathology service. CMS policy states that specimens submitted for individual examination should be medically reasonable and necessary for diagnosis. Finally, a pathologist—a specialty provider trained to interpret specimens—examines the specimen with and without a microscope and prepares written results of this examination for the referring provider.

**Figure 1: Preparation of Specimens from Tissue Samples**




Source: GAO.

Note: Two specimens—anatomic pathology services—are prepared from four tissue samples in fig. 1. Providers have the discretion to determine the number of samples that become specimens, so alternatively, four specimens could have been prepared from these four tissue samples. The resultant number of specimens has implications for payment as each specimen submitted for analysis can be billed to Medicare separately as an anatomic pathology service.

Depending on the level of complexity, biopsy procedures can involve risks for patients. For example, biopsies of the skin to detect cancer are generally considered safe, but complications such as bleeding, bruising, or infection can occur.[13] Additional complications, such as difficulty urinating and infections resulting in hospitalization, can occur from other biopsy procedures.

## Medicare Payment and Billing Policies for Anatomic Pathology Services

Medicare's payments for anatomic pathology services are separated into two components—the technical component (TC) and the professional component (PC). The TC payment is intended to cover the cost of preparing a specimen for analysis, including the costs for equipment, supplies, and nonphysician staff. The PC payment is intended to cover the provider's time examining the specimen and writing a report on the findings. The PC and TC can be billed together, on what is called a global

[13]Key types of skin biopsy procedures include (1) shave (use of a tool to remove a small section of the top layers of the skin), (2) punch (use of a circular tool to remove a small section of the skin), and (3) excisional (use of a scalpel to remove an entire area of abnormal skin).

claim, or alternatively the components can be billed separately. For instance, a global claim could be billed if the same provider prepares and examines the specimen, whereas the TC and PC could be billed separately if the performing and interpreting providers are different.

Medicare reimburses providers through different payment systems depending on where the anatomic pathology service is performed. When an anatomic pathology service is performed in a provider's office or independent clinical laboratory, both the PC and TC are reimbursed under the Medicare physician fee schedule. Alternatively when the service is performed in an institutional setting such as a hospital inpatient department, the provider is reimbursed under the Medicare physician fee schedule for the PC, while the TC is reimbursed under a different Medicare payment system. For instance, the TC of an anatomic pathology service performed in a hospital inpatient setting is reimbursed through a facility payment made under Medicare Part A.

## Certain Policies Implemented by CMS Regarding Anatomic Pathology Services

In response to concerns about potential overutilization of anatomic pathology services due to physician self-referral, CMS established rules limiting the reimbursements allowed under certain self-referral arrangements. Specifically, in 2008 CMS imposed an "anti-markup rule" that prohibits providers from billing Medicare for anatomic pathology services for amounts that exceed what the providers themselves pay to subcontract the services from other providers or pathology laboratories.[14] However, in the 2009 physician fee schedule final rule, CMS identified an exception to the anti-markup rule: a service may be marked up when performed by a physician who shares a practice with the billing provider.[15] Since then, arrangements in which a provider group practice includes a

[14]Specifically, billing providers under these arrangements are limited in the amount they can charge Medicare for the cost of leasing equipment and contracting with staff to perform the service when the services are purchased from other providers or performed at a site other than where the full range of physician services is provided. See *Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008.* 72 Fed. Reg. 66,222. (Nov. 27, 2007) (amending 42 C.F.R. § 414.50).

[15]*Medicare Program; Payment Policies Under the Physician Fee Schedule for CY 2009*, 73 Fed. Reg. 69,726 (Nov. 19, 2008) (amending 42 C.F.R. § 414.50). Under this rule, a shared practice exists if either (1) the performing physician furnishes at least 75 percent of his or her services through the billing provider, or (2) the physician performs or conducts and supervises a diagnostic test in the office of the billing provider.

pathologist in the practice's office space have become a common self-referral arrangement.

In the 2009 physician fee schedule, CMS also introduced a payment change for anatomic pathology services related to a specific biopsy procedure due to concern of overpayment. Specifically, CMS began paying for multiple anatomic pathology services from prostate saturation biopsy procedures through a single payment, rather than paying for each specimen individually. This specific biopsy procedure involves taking numerous tissue samples—typically 30 to 60—to increase the likelihood of detecting prostate cancer in a subgroup of high-risk individuals in whom previous conventional prostate biopsies had been negative. As a result, CMS introduced four new HCPCS codes to pay for these specimens, which were previously paid through HCPCS 88305.[16] The four HCPCS codes noted are payment for 1 to 20 specimens (G0416), 21 to 40 specimens (G0417), 41 to 60 specimens (G0418), and more than 60 specimens (G0419).[17] The payment change resulted in a substantial decrease in payment for anatomic pathology services resulting from prostate saturation biopsy procedures.[18]

CMS reduced its payment for anatomic pathology services in 2013 as part of its efforts to examine the payment for certain high-volume services. Specifically, CMS reduced its payment of anatomic pathology services in 2013 because it determined that fewer resources—equipment, supplies, and nonphysician staff—were required to prepare anatomic pathology services, which in turn reduced payment for the TC. Effective January 1, 2013, CMS reduced Medicare's reimbursement for anatomic pathology services under the physician fee schedule by lowering

[16]73 Fed. Reg. 69,726, 69,751 (Nov. 19, 2008). CMS made this change after concluding that anatomic pathology services resulting from prostate saturation biopsies did not require the same amount of provider work in terms of evaluation, interpretation, and reporting as other anatomic pathology services.

[17]In the 2013 physician fee schedule, CMS revised HCPCS G4016 to payment for 10 to 20 specimens. See *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule,* 77 Fed. Reg. 68,892 (Nov. 16, 2012).

[18]For example, on the basis of 2009 payment rates, a provider that performed both the TC and PC for 30 anatomic pathology services resulting from a prostate saturation biopsy procedure was paid about $1,233 under G0417. However, if a provider was paid at the 2009 payment rate for HCPCS code 88305 for each of the 30 services, he or she would have received about $3,116.

reimbursement for the TC by approximately half. With this change, a payment for a global claim for an anatomic pathology service was reduced by approximately 30 percent.[19]

### 2010 Anatomic Pathology Services Utilization and Expenditures

In 2010, there were about 16.2 million anatomic pathology services performed in all settings, including physician offices and hospitals. In 2010, expenditures for anatomic pathology services paid under the physician fee schedule totaled about $1.28 billion across all settings. About $945 million of the $1.28 billion—74 percent—in expenditures for anatomic pathology services in 2010 were for services performed in physician offices and independent laboratories.

## Self-referred Anatomic Pathology Services and Expenditures Grew Faster Than Non-self-referred Services and Expenditures

The number of self-referred anatomic pathology services increased at a faster rate than non-self-referred anatomic pathology services from 2004 through 2010. Similarly, expenditures for self-referred anatomic pathology services increased at a faster rate than expenditures for non-self-referred services. The share of anatomic pathology services that were self-referred increased overall during the period we reviewed.

### Number of Self-referred Anatomic Pathology Services Increased at a Faster Rate Than Non-self-referred Services

While both the number of self-referred and non-self-referred anatomic pathology services grew overall from 2004 through 2010, self-referred services increased at a faster rate than non-self-referred services. Specifically, the number of self-referred anatomic pathology services more than doubled over the period we reviewed, growing from about 1.06 million services in 2004 to about 2.26 million services in 2010 (see fig. 2).[20] In contrast, the number of non-self-referred anatomic pathology

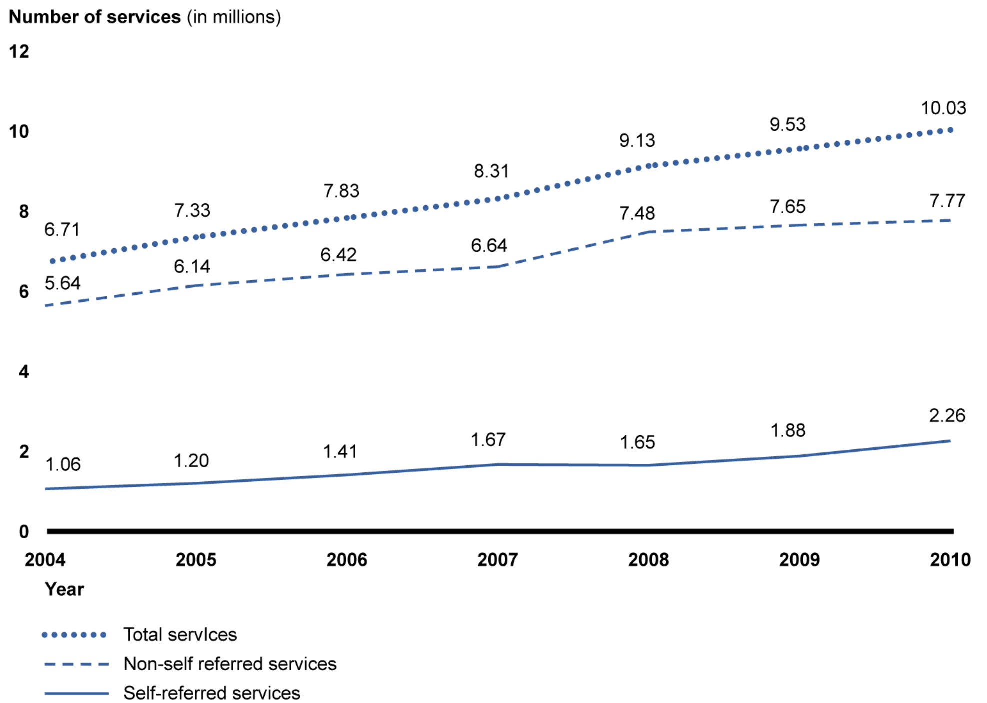
[19]See *Medicare Program; Revision of Payment Policies under the Physician Fee Schedule for CY 2013*, 77 Fed. Reg. 68,892 (Nov. 16, 2012). This estimate of the 2013 payment reduction does not include payment reductions that may result from implementation of the Budget Control Act of 2011, Pub. L. No. 112-25, 125 Stat. 240, as amended by the American Taxpayer Relief Act of 2012 (Pub. L. No. 112-240, 126 Stat. 2313) (2013).

[20]Payment for these services include expenditures beneficiaries paid as part of cost-sharing paid under Medicare.

services increased about 38 percent, growing from about 5.64 million services to about 7.77 million services. Because of the faster growth in self-referred anatomic pathology services, the proportion of anatomic pathology services that were self-referred grew from about 15.9 percent in 2004 to about 22.5 percent in 2010. Notably, the number of self-referred anatomic pathology services increased from 2004 through 2010, even after accounting for the decrease in the number of Medicare FFS beneficiaries.[21] Specifically, the number of self-referred anatomic pathology services per 1,000 Medicare FFS beneficiaries grew from about 30 to about 64, an increase of about 113 percent.

[21]While the total number of Medicare beneficiaries increased during our study period, the number of beneficiaries enrolled in Medicare FFS decreased. This was due to increased enrollment in the Medicare Advantage program, an alternative to the original Medicare FFS program in which private health plans offer health care coverage to Medicare beneficiaries.

**Figure 2: Number of Self-referred and Non-self-referred Medicare Anatomic Pathology Services, 2004–2010**




Source: GAO analysis of CMS data.

Note: Results include services performed in a physician's office or diagnostic laboratory for services with a Healthcare Common Procedure Coding System (HCPCS) code of 88305. Services performed in other settings, such as hospital outpatient departments, are not included.

Although both self-referred and non-self-referred anatomic pathology services increased over the period of our study, the number of self-referred anatomic pathology services decreased slightly from about 1.67 million in 2007 to about 1.65 million in 2008 before increasing about 14 percent to 1.88 million services in 2009.[22] This decrease in 2008 corresponds to the implementation of CMS's anti-markup rule that limits reimbursement for anatomic pathology services in certain self-referral arrangements. In contrast, the number of non-self-referred anatomic

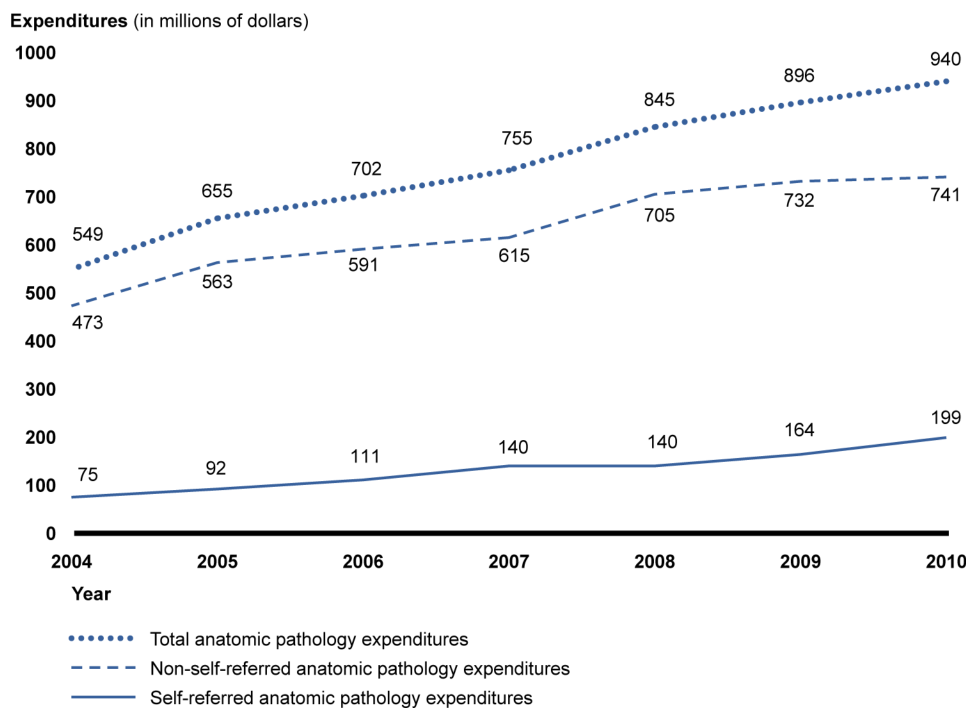
[22]This increase in 2009 corresponds to CMS's identification of an exception to the anti-markup rule implemented in 2008. *See Medicare Program; Payment Policies Under the Physician Fee Schedule for CY 2009*, 73 Fed. Reg. 69,726 (Nov. 19, 2008) (amending 42 C.F.R. § 414.50).

pathology services increased every year during the period we studied, with the largest annual increase (about 13 percent) in 2008.

## Medicare's Expenditures for Self-referred Anatomic Pathology Services Grew Faster Than Expenditures for Non-self-referred Services

While Medicare expenditures for self-referred and non-self-referred anatomic pathology services grew from 2004 through 2010, expenditures for the self-referred services increased at a faster rate. Specifically, expenditures for self-referred anatomic pathology services grew about 164 percent from 2004 to 2010, increasing from about $75 million in 2004 to $199 million in 2010 (see fig. 3). In contrast, non-self-referred anatomic pathology expenditures increased about 57 percent, from $473 million to about $741 million.

**Figure 3: Expenditures for Self-referred and Non-self-referred Medicare Anatomic Pathology Services, 2004–2010**




Source: GAO analysis of CMS data.

Note: Results include expenditures for anatomic pathology services performed in a physician's office or diagnostic laboratory for Healthcare Common Procedure Coding System (HCPCS) code 88305. Services performed in other settings, such as hospital outpatient departments, are not included.

## Share of Self-referred Anatomic Pathology Services Increased across Provider Specialties Referring Most Anatomic Pathology Services

Consistent with the overall trend, the proportion of anatomic pathology services that were self-referred increased for the three provider specialties—dermatology, gastroenterology, and urology—that accounted for over 90 percent of self-referred anatomic pathology services in 2010 (see table 1). For example, the proportion of anatomic pathology services self-referred by dermatologists increased from 24 percent in 2004 to about 29 percent in 2010.

**Table 1: Change in Self-referral Rates for Medicare Anatomic Pathology Services from 2004 to 2010 for Select Provider Specialties**

| Provider specialty | Percentage of anatomic pathology services self-referred in 2004 | Percentage of anatomic pathology services self-referred in 2010 | Percentage of self-referred services referred by specialty in 2010 |
|---|---|---|---|
| Dermatology | 24.0% | 29.3% | 58.9% |
| Urology | 13.9 | 32.5 | 16.4 |
| Gastroenterology | 6.6 | 20.9 | 14.9 |
| **Total** | **N/A** | **N/A** | **90.2%** |

Source: GAO analysis of CMS data.

Note: No other provider specialty referred more than 2 percent of self-referred anatomic pathology services in both 2004 and 2010.

## Self-referring Providers Generally Referred More Anatomic Pathology Services on Average Than Non-self-referring Providers

Self-referring providers in 2010 generally referred more anatomic pathology services on average than those providers who did not self-refer these services, even after accounting for differences in specialty, number of Medicare FFS beneficiaries seen, patient characteristics, or geography. Providers' referrals for anatomic pathology services substantially increased the year after they began to self-refer.

## Self-referring Providers Generally Referred More Anatomic Pathology Services Than Other Providers Regardless of Practice or Patient Characteristics

Across the three provider specialties—dermatology, gastroenterology, and urology—that refer the majority of anatomic pathology services, we found that in 2010, self-referring providers referred more anatomic pathology services, on average, than other providers, regardless of number of Medicare FFS beneficiaries seen. Specifically, we found this pattern for dermatologists, gastroenterologists, and urologists treating small, medium, and large numbers of Medicare beneficiaries (see table 2). Notably, for all provider specialties, providers who treated a large number of Medicare FFS beneficiaries—more than 500—had the highest relative rate within each specialty.

**Table 2: Average Number of Medicare Anatomic Pathology Services Referred by Self-referring and Non-self-referring Providers for Select Provider Specialties in 2010**

| Provider specialty and number of unique Medicare FFS beneficiaries[a] | Average number of anatomic pathology services referred: Self-referring providers | Average number of anatomic pathology services referred: Non-self-referring providers | Relative rate of self-referring providers[b] |
|---|---|---|---|
| Dermatology | | | |
| 1 to 250 | 169 | 143 | 1.18 |
| 251 to 500 | 541 | 451 | 1.20 |
| >500 | 1,583 | 1,013 | 1.56 |
| Gastroenterology | | | |
| 1 to 250 | 171 | 140 | 1.22 |
| 251 to 500 | 417 | 350 | 1.19 |
| >500 | 813 | 645 | 1.26 |
| Urology | | | |
| 1 to 250 | 100 | 75 | 1.33 |
| 251 to 500 | 248 | 174 | 1.43 |
| >500 | 465 | 303 | 1.53 |

Source: GAO analysis of CMS data.

Notes: We use the term anatomic pathology services to refer specifically to those services with a Healthcare Common Procedure Coding System (HCPCS) code of 88305, the examination of specimens from tissue samples taken through biopsy procedures. Provider specialties above represent 29,870 providers who referred about 64 percent of anatomic pathology services across all settings during 2010. Providers were considered to be self-referring if they self-referred anatomic pathology services for at least one biopsy procedure. Of the 29,870 providers represented above that referred at least one beneficiary for an anatomic pathology service in 2010, 7,177 were self-referring and 22,693 were non-self-referring. Of the 7,177 self-referring providers, 3,364 were dermatologists, 1,769 were gastroenterologists, and 2,044 were urologists. Of the non-self-referring providers, 6,656 were dermatologists, 9,566 were gastroenterologists, and 6,471 were urologists.

[a]The number of unique Medicare fee-for-service (FFS) beneficiaries refers to the number of unique beneficiaries that received at least one service from a provider.

[b]The relative rate of self-referring providers refers to the factor by which the average number of anatomic pathology services referred by self-referring providers is greater or less than the average number of anatomic pathology services referred by non-self-referring providers. For example, if the relative rate of self-referring providers is equal to 2, it would mean that, on average, self-referring providers referred twice as many anatomic pathology services as non-self-referring providers.

Self-referring providers generally referred more anatomic pathology services on average than non-self-referring providers due to referring more services—specimens to be examined—per biopsy procedures and, in certain cases, performing a greater number of biopsy procedures. Across the three specialties we reviewed, self-referring providers referred more services per biopsy procedure, on average, than non-self-referring providers, regardless of the number of Medicare FFS beneficiaries seen. Specifically, self-referring providers referred from 7 percent to 52 percent more services per biopsy procedure for the provider specialty and size category combinations we examined. Further, we observed a greater number of biopsy procedures performed by self-referring providers in certain cases. Specifically, self-referring dermatologists treating medium and large numbers of Medicare FFS beneficiaries performed about 8 and 38 percent more biopsy procedures on average, respectively, than non-self-referring dermatologists treating similar numbers of Medicare beneficiaries.[23] In the remaining provider specialty and size category combinations, the rate of biopsy procedures performed by self-referring providers was similar to that for non-self-referring providers.

The higher number of referrals for anatomic pathology services among self-referring providers relative to other providers of the same size and specialty cannot, in general, be explained by differences in patient diagnoses, patient health status, other patient characteristics, or geography.

### Patient Diagnoses

Differences in referrals for anatomic pathology services between self-referring and non-self-referring providers of the same specialty treating a similar number of Medicare FFS beneficiaries could not be explained by differences in their patients' diagnoses. Generally, we found that the types and proportions of patient diagnoses were similar for self-referring and non-self-referring providers of the same specialty. However, we

[23]We classified anatomic pathology services as being from the same biopsy procedure if they were referred by the same provider, for the same beneficiary, on the same day.

found that self-referring providers referred more anatomic pathology services per biopsy procedure for nearly all—53 of 54—primary diagnoses for which beneficiaries were referred for anatomic pathology services.[24] This pattern is particularly evident for those diagnoses that accounted for a large proportion of anatomic pathology services referred within each specialty (see table 3).For example, self-referring urology providers referred on average about 12.5 anatomic pathology services per biopsy procedure for diagnosis of elevated prostate specific antigen (790.93) while non-self-referring urology providers referred about 8.5 anatomic pathology services per biopsy procedure for this diagnosis. For further information on the average number of anatomic pathology services referred per biopsy procedure by beneficiary primary diagnosis, see appendix III.

**Table 3: Average Number of Medicare Anatomic Pathology Services per Biopsy Procedure for Most Common Diagnoses Referred by Self-referring and Non-self-referring Providers, Select Provider Specialties in 2010**

| Provider specialty and most common diagnoses, including International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code | Average number of anatomic pathology services per biopsy procedure | | |
|---|---|---|---|
| | Self-referring providers | Non-self-referring providers | Percentage difference |
| Dermatology | | | |
| Neoplasm of uncertain behavior of skin (238.2) | 1.8 | 1.6 | 13% |
| Other malignant neoplasm of skin of other and unspecified parts of face (173.3) | 1.6 | 1.4 | 14 |
| Actinic keratosis (702.0) | 1.7 | 1.5 | 13 |
| Gastroenterology | | | |
| Benign neoplasm of colon (211.3) | 2.2 | 1.9 | 16 |
| Atrophic gastritis, without mention of hemorrhage (535.10) | 2.2 | 1.9 | 16 |
| Unspecified gastritis and gastroduodenitis, without mention of hemorrhage (535.50) | 2.7 | 2.0 | 35 |
| Urology | | | |
| Elevated prostate specific antigen (790.93) | 12.5 | 8.5 | 47 |

[24]We examined the number of services referred per biopsy procedure for each diagnosis that comprised at least 1 percent of the diagnoses listed on the claims referred by self-referring providers for each of the three provider specialties. The one primary diagnosis for which self-referring providers did not refer more services per biopsy procedure on average than non-self-referring providers was unspecified disorder of skin and subcutaneous tissue (709.9). This diagnosis accounted for approximately 1.6 percent of the diagnoses listed on claims for self-referring dermatologists.

| Provider specialty and most common diagnoses, including International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code | Average number of anatomic pathology services per biopsy procedure | | |
|---|---|---|---|
| | Self-referring providers | Non-self-referring providers | Percentage difference |
| Malignant neoplasm of prostate (185) | 8.5 | 6.1 | 39 |
| Malignant neoplasm of bladder, part unspecified (188.9) | 1.8 | 1.7 | 6 |

Source: GAO analysis of CMS data.

Note: Proportion of all diagnoses referred for anatomic pathology services represented by the three most common codes varies by specialty. Specifically, the three most common diagnoses account for 36.3 percent and 30.2 percent of biopsy procedures performed by self-referring and non-self-referring dermatologists, 43.2 percent and 44.7 percent of biopsy procedures performed by self-referring and non-self-referring gastroenterologists, and 50.3 percent and 46.6 percent of biopsy procedures performed by self-referring and non-self-referring urologists, respectively.

## Patient Health Status

Differences in the number of referrals for anatomic pathology services between self-referring and non-self-referring providers of the same specialty treating similar numbers of Medicare FFS beneficiaries could generally not be explained by differences in patient health status. Specifically, for all three provider specialties we reviewed, the beneficiaries seen by self-referring providers treating a small, medium, or large number of Medicare FFS beneficiaries were of similar health status as patients seen by non-self-referring providers of the same specialty and size category (see table 4), as indicated by having similar average risk scores.[25] If self-referring providers saw relatively sicker beneficiaries, it could have explained why these providers referred more anatomic pathology services on average than other providers of the same provider specialty and size categories.

[25] A risk score is a relative measure of a beneficiary's expected health care costs and serves as a proxy for a beneficiary's health status.

**Table 4: Average Health Status of Medicare Beneficiaries for Select Provider Specialties by Practice Size in 2010**

| Provider specialty and number of unique Medicare fee-for-service (FFS) beneficiaries[a] | Average risk score of beneficiaries[b] | |
|---|---|---|
| | Self-referring providers | Non-self-referring providers |
| Dermatology | | |
| 1 to 250 | 1.20 | 1.18 |
| 251 to 500 | 1.15 | 1.15 |
| > 500 | 1.12 | 1.13 |
| Gastroenterology | | |
| 1 to 250 | 1.40 | 1.49 |
| 251 to 500 | 1.36 | 1.40 |
| > 500 | 1.34 | 1.38 |
| Urology | | |
| 1 to 250 | 1.37 | 1.40 |
| 251 to 500 | 1.37 | 1.36 |
| > 500 | 1.35 | 1.33 |

Source: GAO analysis of CMS data.

[a]The number of unique Medicare FFS beneficiaries refers to the number of unique beneficiaries that received at least one service from a provider.

[b]A beneficiary's risk score is a proxy for health status and is equivalent to the ratio of expected health care expenditures for that 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. The risk scores presented are normalized using the FFS normalization factor of 1.041 that CMS used to normalize risk scores in 2010. Normalization keeps the average Medicare FFS risk score constant at 1.0 over time.

## Other Patient Characteristics

Differences in the number of anatomic pathology service referrals between self-referring and non-self-referring providers of the same specialty treating similar numbers of Medicare FFS beneficiaries could not be explained by differences in the age and sex of beneficiaries. In particular, the age and sex of Medicare FFS beneficiaries were generally consistent between those beneficiaries seen by self-referring providers and those seen by non-self-referring providers for all provider specialties and size categories we examined. For further information on the average age and sex of beneficiaries seen by self-referring and non-self-referring providers of the provider specialties we examined, see appendix IV.

## Geography

Differences in the number of anatomic pathology service referrals between self-referring and non-self-referring providers could not generally be explained by whether a provider practiced in an urban or rural area.

Self-referring providers of the same specialty treating a similar number of Medicare beneficiaries generally referred more anatomic pathology services on average than non-self-referring providers, regardless of whether the provider practiced in an urban or rural area. For example, self-referring dermatologists and urologists treating a similar number of Medicare FFS beneficiaries had higher referral rates on average for anatomic pathology services, regardless of whether they practiced in an urban or rural location. Likewise, self-referring gastroenterologists treating a medium or large number of Medicare FFS beneficiaries referred a higher number of anatomic pathology services on average than non-self-referring gastroenterologists treating a similar number of Medicare beneficiaries, regardless of whether they practiced in an urban or rural location. For further information on referral of anatomic pathology services across provider specialties and size categories in urban and rural areas, see appendix V.

## Providers' Referrals for Anatomic Pathology Services Increased the Year after They Began to Self-refer

Our analysis shows that, across the three provider specialties we reviewed, providers' referrals for anatomic pathology services substantially increased the year after they began to self-refer. In our analysis we examined the number of anatomic pathology referrals made by "switchers"—those providers that did not self-refer in 2007 or 2008 but began to self-refer in 2009 and continued to do so in 2010—and compared these referrals to the number made by providers that did not begin to self-refer during this period. Providers could self-refer by setting up an in-office laboratory, contracting for laboratory services, or joining a group practice that already self-referred. We found that the switchers saw large increases in the number of anatomic referrals they made from 2008 to 2010 when compared with other providers (see table 5). Specifically, across the three provider specialties we reviewed, the switcher group of providers increased the number of anatomic pathology referrals they made from 2008 to 2010 by at least 14.0 percent and by as much as 58.5 percent. In contrast, providers that self-referred anatomic pathology services during the entire period experienced smaller changes in the number of referrals, ranging from a 1.4 percent increase to an 11.6 percent increase, depending on the provider specialty. Among providers that did not self-refer anatomic pathology services, the number of referrals the providers made for these services ranged from a decrease of 0.2 percent to an increase of 2.8 percent, depending on the provider specialty.

**Table 5: Change in Average Number of Medicare Anatomic Pathology Services Referred by Provider Specialty, 2008 and 2010**

| Primary specialty | Referral type | Number of providers | Average number of unique Medicare fee-for-service (FFS) beneficiaries, 2010 | Anatomic pathology services, 2008[a] | Anatomic pathology services, 2010[a] | Percentage change 2008 to 2010 |
|---|---|---|---|---|---|---|
| Dermatology | Switchers | 130 | 478.2 | 658.6 | 815.5 | 23.8% |
| | Self-referring | 1,353 | 573.6 | 803.9 | 815.0 | 1.4 |
| | Non-self-referring | 2,361 | 424.4 | 451.9 | 453.2 | 0.3 |
| Gastroenterology | Switchers | 195 | 335.5 | 338.7 | 386.1 | 14.0 |
| | Self-referring | 438 | 380.9 | 413.7 | 439.6 | 6.3 |
| | Non-self-referring | 4,833 | 365.1 | 340.8 | 350.4 | 2.8 |
| Urology | Switchers | 215 | 619.1 | 257.3 | 407.7 | 58.5 |
| | Self-referring | 498 | 626.8 | 289.4 | 322.9 | 11.6 |
| | Non-self-referring | 3,192 | 473.6 | 175.8 | 175.4 | -0.2 |

Source: GAO analysis of CMS data.

Notes: Anatomic pathology services refer specifically to services with Healthcare Common Procedure Coding System (HCPCS) code 88305. We define switchers as those providers that did not self-refer in 2007 or 2008, but did self-refer in 2009 and 2010.

[a]The average number of anatomic pathology services referred by self-referring providers, non-self-referring providers, and switchers are influenced in part by the average number of unique Medicare FFS beneficiaries seen by each referral type. For example, in 2008, both switchers—who did not self-refer in 2008—and non-self-referring urologists averaged approximately 0.4 anatomic pathology referrals per unique Medicare FFS beneficiary. However, switchers averaged more anatomic pathology referrals than non-self-referring providers in 2008 because they saw, on average, more unique Medicare FFS beneficiaries.

Providers in the switcher groups for the three specialties we reviewed had an increase in the number of anatomic pathology referrals they made from 2008 to 2010 due to an increase, on average, in the number of anatomic pathology services referred per biopsy procedure. Across the three specialties we reviewed, the increase in the number of specimens submitted for examination from each biopsy procedure from 2008 to 2010 ranged from 13.3 percent to 48.9 percent. For all three specialties we reviewed, the increase in the number of anatomic pathology services referred per biopsy procedure was greater for providers in the switchers group than for providers who did not self-refer from 2008 through 2010 or those providers who self-referred for all 3 years.

The increase in anatomic pathology referrals for providers that began self-referring in 2009 cannot be explained exclusively by factors such as providers joining practices with higher patient volumes, different patient populations, or different practice cultures. Specifically, providers that remained in the same practice from 2007 through 2010, but began self-

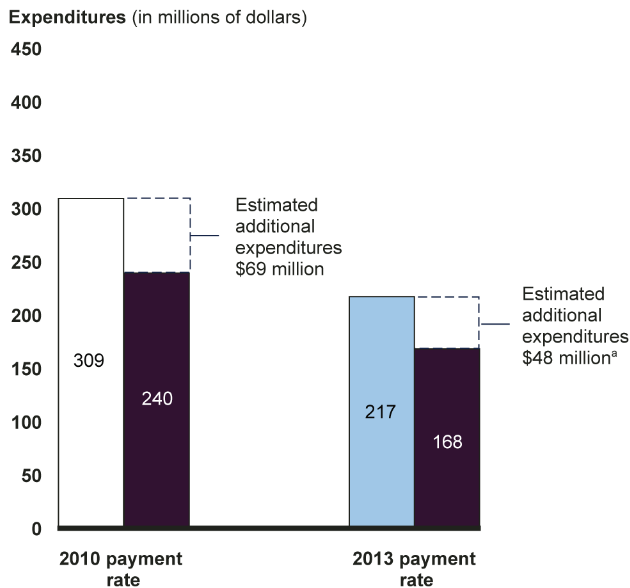
referring in 2009, also had a bigger increase in the number of anatomic pathology referrals than did providers that did not change their self-referral status. The increase in the number of anatomic pathology services referred by providers in the switcher group that met this criterion from 2008 to 2010 ranged from an increase of 6.8 percent to an increase of 38.6 percent, depending on the provider specialty.

## Higher Use of Anatomic Pathology Services by Self-Referring Providers Results in Substantial Additional Medicare Spending

We estimate that Medicare spent about $69 million more in 2010 than the program would have spent if self-referring providers performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers of the same provider size and specialty (see fig. 4).[26] This additional spending can be attributed to the fact that self-referring providers in the 3 provider specialties we examined referred about 918,000 more anatomic pathology services in 2010. In 2013, CMS reduced its payment of anatomic pathology services because it determined that fewer resources—equipment, supplies, and non-physician staff—were required to prepare anatomic pathology services. If the lower 2013 Medicare reimbursement rates for anatomic pathology services were in effect in 2010, Medicare would have spent approximately $48 million more than it would have if self-referring providers performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers of the same provider size and specialty.

[26]We limited our analysis to expenditures directly related to anatomic pathology services. There may be additional costs associated with the increased use of anatomic pathology services by self-referring providers, if these services result in inaccurate diagnoses and, in turn, additional services or procedures that are unnecessary. In contrast, increased use of anatomic pathology services may partially offset some of these direct anatomic pathology costs if increased use led to the early detection of disease and resulted in less-invasive and less-costly treatments.

**Figure 4: Estimated Additional Medicare Spending for Anatomic Pathology Services Attributed to Self-Referring Providers, 2010**




Source: GAO analysis of CMS data.

Notes: Anatomic pathology services refer specifically to services with Healthcare Common Procedure Coding System (HCPCS) code 88305. Our analysis included expenditures for anatomic pathology services referred by dermatologists, gastroenterologists, and urologists. Combined, these three specialties were responsible for approximately 64 percent of all referrals for anatomic pathology services and 90 percent of all self-referred anatomic pathology services in 2010. We calculated expenditures for services as if self-referring providers performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers of the same specialty and size in 2010. To estimate expenditures for 2010 as though the 2013 payment rate were in effect, we reduced expenditures for anatomic pathology services by 30 percent.

These 2013 estimated 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, as amended by the American Taxpayer Relief Act of 2012 (Pub. L. No. 112-240, 126 Stat. 2313) (2013).

[a]Estimated additional expenditures at the 2013 payment rate do not equal the difference of estimated 2010 expenditures if paid at the 2013 payment rate and the estimated expenditures if self-referring providers performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers due to rounding.

This calculation likely underestimates the total amount of additional Medicare spending that can be attributed to self-referring providers because we did not include all Medicare providers in our analysis. Specifically, we limited our analysis to anatomic pathology services

referred by dermatologists, gastroenterologists, and urologists. These specialties account for approximately 64 percent of anatomic pathology services referred across all settings and about 90 percent of all self-referred anatomic pathology services in 2010.

## Conclusions

Anatomic pathology services are vital services that help providers diagnose disease and guide treatment options for patient care. Proponents of self-referral contend that the ability of providers to self-refer anatomic pathology services has the potential benefit of more rapid diagnoses and better coordination of care. Our review indicates that across the major provider specialties that refer beneficiaries for anatomic pathology services, self-referring providers generally referred more anatomic pathology services on average than other providers of the same specialty treating similar numbers of Medicare patients. This increase is due to a greater number of specimens submitted for examination from each biopsy procedure, and in certain cases a greater number of biopsy procedures performed. This increase raises concerns, in part because biopsy procedures, although generally safe, can result in serious complications for Medicare beneficiaries. Further, our analysis shows that across these provider specialties, providers' referrals for anatomic pathology services substantially increased the year after they began to self-refer.

The relatively higher rate of anatomic pathology services among self-referring providers cannot be explained by patient diagnosis, patient health status, or geographic location. Taken together, this suggests that financial incentives for self-referring providers were likely a major factor driving the increase in anatomic pathology referrals. In 2010, providers who self-referred made an estimated 918,000 more referrals for anatomic pathology services than they likely would have if they were not self-referring. Notably, these additional referrals cost CMS about $69 million in 2010 alone. To the extent that these additional services are unnecessary, avoiding them could result in savings to Medicare and to beneficiaries.

Despite the potential safety and financial implications of unnecessary anatomic pathology services, CMS does not have policies to address the effect of how self-referral affects the utilization of and expenditures for anatomic pathology services. CMS does not currently have the ability to identify anatomic pathology services that are self-referred so that the agency can track the extent to which anatomic pathology services are self-referred and identify services that may be unnecessary. Specifically, Medicare claims do not include an indicator or "flag" that identifies

whether services are self-referred or non-self-referred. Thus, CMS does not currently have a method for easily identifying such services and cannot determine the effect of self-referral on utilization and expenditures for anatomic pathology services. Including a self-referral flag on Medicare Part B claims submitted by providers who bill for anatomic pathology services is likely the easiest and most cost-effective approach.

If CMS could readily identify self-referred anatomic pathology services, the agency may be better positioned to identify potentially inappropriate utilization of biopsy procedures. CMS could, for example, consider performing targeted audits of providers who perform a higher average number of biopsy procedures, compared to providers of the same specialty treating a similar number of Medicare beneficiaries. Given our report findings, CMS may want to initially focus its efforts on self-referring dermatologists who treated a larger number of Medicare beneficiaries.

While providers have discretion in determining the number of tissue samples that become specimens, CMS's current payment system provides a financial incentive for providers to refer a higher number of specimens—or anatomic pathology services—per biopsy procedure. Providers can double their payment for anatomic pathology services, for example, by submitting four specimens from four tissue samples instead of combining the four tissue samples into two specimens. However, providers differ on whether or to what extent tissue samples can be combined in creating a specimen or if each tissue sample must become a specimen. CMS has already implemented a payment approach for one specific biopsy procedure—prostate saturation biopsy—that pays providers through a single payment rather than paying for each specimen individually within a given range of anatomic pathology services, such as 1 to 20 specimens. However, this policy does not apply to anatomic pathology services from other biopsy procedures. CMS could expand this payment approach to other biopsy procedures and associated anatomic pathology services.

## Recommendations for Executive Action

In order to improve CMS's ability to identify self-referred anatomic pathology services and help CMS avoid unnecessary increases in these services, we recommend that the Administrator of CMS take the following three actions:

1. Insert a self-referral flag on Medicare Part B claim forms and require providers to indicate whether the anatomic pathology services for which the provider bills Medicare are self-referred or not.
2. Determine and implement an approach to ensure the appropriateness of biopsy procedures performed by self-referring providers.
3. Develop and implement a payment approach for anatomic pathology services that would limit the financial incentives associated with referring a higher number of specimens—or anatomic pathology services—per biopsy procedure.

## Agency and Third-Party Comments and Our Evaluation

We provided a draft of this report to HHS, which oversees CMS, for comment. HHS provided written comments, which are reprinted in appendix VI. We also obtained comments from representatives from four professional associations selected because they represent an array of stakeholders with specific involvement in anatomic pathology services. Three associations provided oral comments: the College of American Pathologists (CAP), which represents pathologists; the American Academy of Dermatology Association (AADA), which represents dermatologists; and the American Gastroenterological Association (AGA), which represents gastroenterologists. The American Urological Association (AUA), which represents urologists, provided written comments. We summarize and respond to comments from HHS and representatives from the four professional associations in the following sections.

### HHS Comments

HHS reviewed a draft of this report and provided written comments, which are reprinted in appendix VI. In its comments, HHS stated that it concurred with, and had addressed, one of our recommendations, but did not concur with our other two recommendations. HHS provided few comments on our findings that self-referring providers referred substantially more anatomic pathology services than non-self-referring providers.

HHS stated that it concurred with, and has already addressed, our recommendation that CMS develop and implement a payment approach for anatomic pathology services that would limit the financial incentives associated with referring a higher number of anatomic pathology services per biopsy procedure. According to HHS, the payment revaluation for anatomic pathology services in 2013 decreased payment by approximately 30 percent and significantly reduced the financial incentives associated with self-referral for these services. We are pleased that CMS examines and revalues HCPCS codes to ensure that payment for services matches the resources involved and adjusts payment to the extent needed. However, the payment revaluation that occurred in 2013 does not address the higher referral of anatomic pathology services we found associated with self-referring providers. Although no consensus exists on the number and type of tissue samples that become a specimen—an anatomic pathology service—the current payment system pays more if providers create more specimens from the same number of samples. We continue to believe that CMS should develop a payment approach that addresses the incentive to provide more services.

HHS did not concur with our recommendation that CMS insert a self-referral flag on the Medicare Part B claims form and require providers to indicate whether the anatomic pathology services for which a provider bills Medicare are self-referred or not. In its response, HHS did not provide reasons for not concurring with this recommendation, but stated that the President's fiscal year 2014 budget proposal includes a provision to exclude certain services from the in-office ancillary services exception. HHS added that anatomic pathology services may share some characteristics with the services mentioned in the proposal. To the extent that self-referral for anatomic pathology services continues to be permitted, we believe that including an indicator or flag on the claims would likely be the easiest and most cost-effective approach to improve CMS's ability to identify self-referred anatomic pathology services. Such a flag would allow CMS to monitor the behavior of self-referring providers and could be helpful to CMS in answering broader policy questions on self-referral.

HHS did not concur with our recommendation that CMS determine and implement an approach to ensure the appropriateness of biopsy procedures performed by self-referring providers. In its response, HHS noted that it would be difficult to make recommendations regarding whether services are appropriate without reviewing large numbers of claims, reporting that 918,000 instances of self-referral that we identified would need to be reviewed. Further, the agency stated that it does not

believe that this recommendation will address overutilization that occurs as a result of self-referral. We do not suggest or intend that CMS review every anatomic pathology service to determine whether it is appropriate. Self-referral, however, could be a factor CMS considers in its ongoing efforts to identify and address inappropriate use of Medicare services. As noted in the report, CMS could, for example, consider performing targeted audits of providers that perform a higher average number of biopsy procedures, compared to providers of the same specialty treating similar numbers of Medicare beneficiaries. In this regard, a flag that we also recommended to identify self-referred services would facilitate such audits.

On the basis of HHS's written response to our report, we are concerned that HHS does not appear to recognize the need to monitor the self-referral of anatomic pathology services on an ongoing basis and determine those services that may be inappropriate or unnecessary. HHS did not comment on our key finding that providers' referrals for anatomic pathology services across the three specialties we examined substantially increased the year after they began to self-refer. Nor did HHS comment on our estimate that additional referrals for anatomic pathology services from self-referring providers cost CMS about $69 million in 2010 or $48 million based on the 2013 payment rates. Given these findings, we continue to believe that CMS should take steps to monitor the utilization of anatomic pathology services and ensure that the services for which Medicare pays are appropriate. By not monitoring the appropriateness of these services, CMS is missing an opportunity to save Medicare expenditures.

## Professional Association Comments College of American Pathologists

Representatives from CAP expressed concern that our methodology to identify self-referral missed certain self-referral arrangements for anatomic pathology services and that our findings understate effects from self-referral. According to the CAP representatives, because our methodology did not identify providers who self-refer the PC only and did not include financial relationships that do not share TINs, effects from self-referral are greater than our findings suggest. As noted in the report, we excluded claims with a only a PC from our finding on utilization and expenditures trends for anatomic pathology services because we could not reliably determine that they were performed in the physician office or independent laboratory. We identified financial relationships among providers using TINs, which would identify the provider, the provider's employer, or another entity to which the provider reassigns payment. To the extent that providers self-refer only the PCs of anatomic pathology

services or self-refer to entities with which they do not share TINs, differences between self-referring and non-self-referring providers would be greater, and our estimate of the differences would be more conservative. CAP representatives also raised questions about self-referral that our report did not address, such as why the report did not examine cancer detection rates or whether anatomic pathology services should be included in the in-office ancillary services exception. These issues were outside the report's objectives. While the representatives from CAP agreed with the recommendation to include a self-referral flag on the Medicare Part B claims form, they disagreed with our other recommendations, stating that they would not sufficiently address the report findings. We believe that our recommendations incorporate actions that address the problems we identified.

## American Academy of Dermatology Association

Representatives from the AADA stated that dermatologists should continue to be allowed to prepare and review their own anatomic pathology services because they receive considerable training as part of their education and offered several possible explanations for the additional anatomic pathology services referred and biopsy procedures performed by self-referring providers. For example, they raised the possibility that the increase in anatomic pathology services referred and biopsy procedures performed by providers in the switcher group was due to increases in patient volume, providers joining a larger group practice or hiring a mid-level practitioner allowing the provider to see more patients. They also raised the possibility that providers in the switcher group became further specialized, resulting in a change in the number and type of diagnoses for their patients. Also, the AADA reported that our reliance on TINs to identify self-referral could be problematic because providers working in large, university-based practices would be flagged as self-referring, despite lacking a financial incentive to provide more services. As noted in the report, the increase in anatomic pathology referrals for providers that began self-referring in 2009 cannot be explained exclusively by factors such as providers joining practices with higher patient volumes, different patient populations, or different practice cultures. Specifically, providers that remained in the same practice from 2007 through 2010, but began self-referring in 2009, had a bigger increase in the number of anatomic pathology services referred than providers who did not change their self-referral status. Further, we found that the types and proportions of patient diagnoses were similar for self-referring and non-self-referring providers of the same specialty and that self-referring providers referred more anatomic pathology services per biopsy procedure for nearly all—53 of 54—primary diagnoses for which

beneficiaries were referred for anatomic pathology services. To the extent that providers who share a TIN, but do not have a financial incentive to refer more services, are counted as self-referring, our findings would likely underestimate differences between self-referring and non-self-referring providers and would thus provide a conservative estimate of the effects of self-referral.

The AADA agreed with our recommendation of determining an approach to ensure the appropriateness of biopsy procedures, but disagreed with our recommendation of a payment approach limiting the financial incentives associated with a higher number of services per biopsy procedure. Specifically, the AADA expressed concern about any disincentives for dermatologists to perform biopsy procedures. As noted in the report, increases in the number of anatomic pathology services per biopsy procedure were primarily responsible for the growth of anatomic pathology services referred by providers in the switcher group from 2008 to 2010 across provider specialties. We continue to believe that CMS should develop and implement a payment approach for anatomic pathology services that would limit the financial incentives associated with referring a higher number of services per biopsy procedure.

## American Gastroenterological Association

Representatives from the AGA asked for further information about the providers in our analysis (particularly gastroenterologists in the switcher group) and diagnoses of the beneficiaries referred for anatomic pathology services, and offered several possible explanations for the additional anatomic pathology services referred and biopsy procedures performed by self-referring providers. Specifically, the AGA raised the possibility that providers in the switcher group joined larger groups that perform more anatomic pathology services or changed the types of biopsy procedures they performed. Finally, the AGA also noted that an appropriate number of anatomic pathology services is not known. Specifically, they reported that larger practices, which are also more likely to self-refer, are more likely to have formal peer review, which could result in more anatomic pathology services referred. We have included an appendix with additional information on the number of services per biopsy procedure for the most common diagnoses for which beneficiaries were referred for anatomic pathology services in 2010. As noted, the types and proportions of diagnoses for which beneficiaries were referred for anatomic pathology services were similar for self-referring and non-self-referring providers. We found that self-referring providers referred more services per biopsy procedure on average than non-self-referring providers for nearly all of these diagnoses. We acknowledge that the appropriate number of

referrals for these services is not known, but the consistent pattern of self-referring providers' higher use suggests that additional scrutiny is warranted. The AGA agreed with our recommendations, but did not think the recommendation on a payment approach for anatomic pathology services limiting the financial incentives associated with referring a higher number of specimens per biopsy procedure was as applicable to providers of their specialty.

## American Urological Association

The AUA agreed with our recommendation to identify self-referred services but did not agree with our other recommendations to examine the appropriateness of biopsy procedures performed by self-referring providers or develop a payment approach that would limit the financial incentives for referring a higher number of anatomic pathology services. The AUA said that there were problems with the study's design and data gathering methodology originating from problems with identifying self-referral which resulted in their questioning the validity of the report findings. AUA did not provide further detail on their methodological concerns. We believe our methodology to identify self-referred services and classify providers as self-referring using one hundred percent of Medicare Part B claims is a reasonable and valid approach. In designing our methodology, we consulted with officials from CMS, specialty societies, and other researchers. Our approach is similar to the one used by MedPAC for its study of the effect of physician self-referral on use of imaging services.[27]

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.

[27]See Medicare Payment Advisory Commission: Report to the Congress: Improving Incentives in the Medicare Program (Washington, DC, June 2009).

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 Charles E. 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: Special Stains Used in Conjunction with Anatomic Pathology Services Paid under Medicare

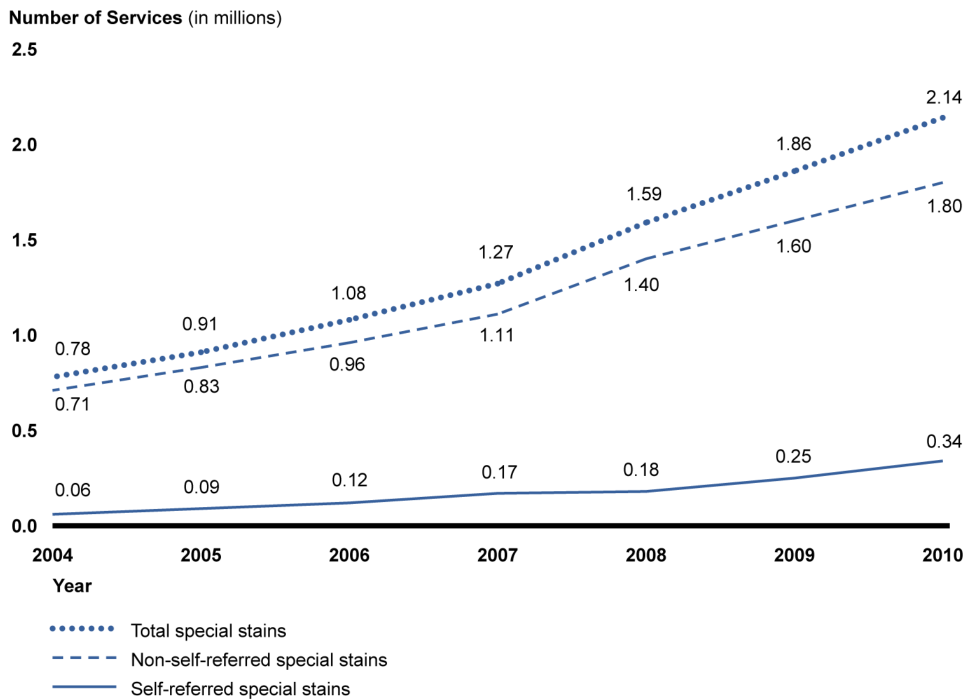
As part of our work, we also analyzed additional anatomic pathology services—known as special stains—that providers may use in conjunction with anatomic pathology services to enhance their ability in making a diagnosis. We focused our special stains analysis on services with Healthcare Common Procedure Coding System (HCPCS) codes 88312, 88313, and 88342 that were used in conjunction with the anatomic pathology service, HCPCS code 88305. We considered special stains billed on the same date, by the same provider, for the same beneficiary as those used in conjunction with anatomic pathology services. In 2010, expenditures under the physician fee schedule for these three special stain services totaled approximately $387 million. Providers may utilize special stains with a HCPCS code of 88312 on specimens to detect the presence of infectious organisms such as bacteria and fungus, special stains with a HCPCS code of 88313 to detect the presence of iron, and special stains with a HCPCS code of 88342 to identify the origin of a cancer.[1] Use of special stains is determined by the provider referring anatomic pathology services, the pathologist interpreting the anatomic pathology service, or both. We examined (1) trends in the number of and expenditures for self-referred and non-self-referred special stains, and (2) how the provision of special stains differs for providers who self-refer when compared with other providers.

## Utilization of and Expenditures for Self-referred and Non-self-referred Special Stains

Similar to anatomic pathology services, the number of both self-referred and non-self-referred special stains increased from 2004 through 2010, with self-referred special stains increasing at a faster rate than services that were not self-referred. Specifically, the number of special stains that were self-referred increased from about 60,000 in 2004 to about 340,000 in 2010, an increase of more than 400 percent (see fig. 5). Further, we found that self-referred special stains increased more than non-self-referred special stains for each of the three special stains we studied. In contrast, non-self-referred special stains grew from about 710,000 services to about 1.80 million services, an increase of about 150 percent.

[1] This special stain (88342 – immunohistochemistry) is used to evaluate diseases, including diagnosis, staging, and prognosis. For example, immunohistochemistry can be used to detect whether the specimen where cancer has been found is the primary site of that cancer or whether the cancer has spread to that location from elsewhere in the body.

**Figure 5: Number of Self-referred and Non-self-referred Medicare Special Stains, 2004–2010**

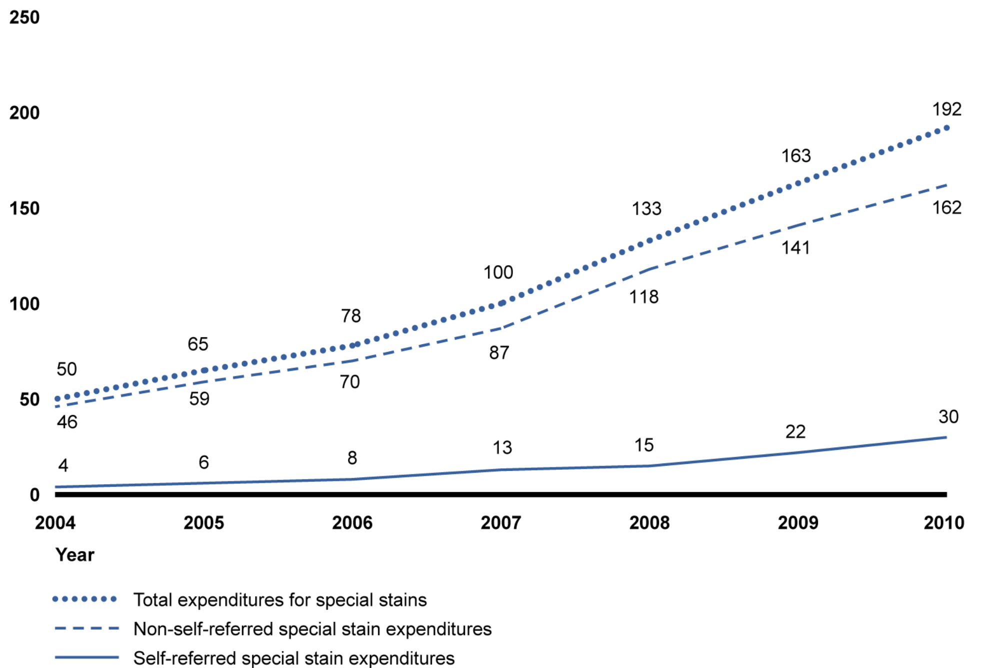



Source: GAO analysis of CMS data.

Note: Results include special stains—those services with Healthcare Common Procedure Coding System (HCPCS) codes of 88312, 88313, and 88342—that were performed in a physician's office or diagnostic laboratory and used in conjunction with the examination of tissue taken through biopsy procedures (HCPCS code 88305). Special stains performed in other settings, such as hospital outpatient departments, or performed with other anatomic pathology services are not included.

Similar to expenditures for anatomic pathology services, Medicare's expenditures for both self-referred and non-self-referred special stains used in conjunction with HCPCs code 88305 also grew rapidly during the period we studied, with the greater rate of increase among expenditures for self-referred services. Specifically, expenditures for self-referred special stains grew more than six-fold, increasing from about $4 million in 2004 to about $30 million in 2010 (see fig. 6). In comparison, expenditures for non-self-referred special stains more than tripled during these years, growing from about $46 million in 2004 to about $162 million in 2010.

**Figure 6: Expenditures for Self-referred and Non-self-referred Medicare Special Stains, 2004–2010**




Source: GAO analysis of CMS data.

Note: Results include expenditures for special stains, those services with Healthcare Common Procedure Coding System (HCPCS) codes 88312, 88313, and 88342, performed in a physician's office or diagnostic laboratory that were performed with the anatomic pathology services (HCPCS code 88305) that are a focus of our study. Special stains performed in other settings, such as hospital outpatient departments, or performed with other anatomic pathology services are not included.

## Self-referring and Non-self-referring Providers Referral for Special Stains

For two of the three specialties we examined, self-referring providers referred a higher number of special stains on average than non-self-referring providers of the same specialty treating similar numbers of Medicare fee-for-service (FFS) beneficiaries. Specifically, self-referring gastroenterologists and urologists referred more special stains on average than non-self-referring gastroenterologists and urologists treating a similar number of Medicare beneficiaries. We also found this pattern for self-referring dermatologists treating small numbers of Medicare FFS beneficiaries. Provider specialty and size category combinations we studied where self-referring providers referred more special stains on average than non-self-referring providers represented about 86 percent of special stains referred by these specialties.

**Table 6: Average Number of Medicare Special Stains Referred by Self-referring and Non-self-referring Providers for Select Provider Specialties in 2010**

| Provider specialty and number of unique Medicare FFS beneficiaries[a] | Average number of special stains referred | | Relative rate of self-referring providers[b] |
|---|---|---|---|
| | Self-referring providers | Non-self-referring providers | |
| Dermatology | | | |
| 1 to 250 | 17.6 | 15.3 | 1.15 |
| 251 to 500 | 32.8 | 36.8 | 0.89 |
| >500 | 63.3 | 67.7 | 0.94 |
| Gastroenterology | | | |
| 1 to 250 | 73.4 | 44.2 | 1.66 |
| 251 to 500 | 201.9 | 119.4 | 1.69 |
| >500 | 514.0 | 242.9 | 2.12 |
| Urology | | | |
| 1 to 250 | 17.0 | 12.6 | 1.35 |
| 251 to 500 | 36.3 | 31.8 | 1.14 |
| >500 | 79.9 | 52.9 | 1.51 |

Source: GAO Analysis of CMS data.

Notes: Results include special stain HCPCS codes 88312, 88313, or 88342 used in conjunction with the anatomic pathology services we studied.

[a]The number of unique Medicare FFS beneficiaries refers to the number of unique beneficiaries that received at least one service from a provider.

[b]The relative rate of self-referring providers refers to the factor by which the average number of special stains referred by self-referring providers is greater or less than the average number of special stains referred by non-self-referring providers. For example, if the relative rate of self-referring providers is equal to 2, it would mean that, on average, self-referring providers referred twice as many special stains as non-self-referring providers.

Our analysis shows that, for two of the three specialties we reviewed, providers' referrals for special stains substantially increased the year after they began to self-refer. Specifically, urologists and gastroenterologists that were "switchers"—those providers that did not self-refer in 2007 or 2008 but began to self-refer in 2009 and continued to do so in 2010—saw larger increases in the number of special stain referrals they made relative to other providers (see table 7). Dermatologists in the switcher group had a 17.6 percent increase in the number of special stains referred from 2008 to 2010, but this was roughly equivalent to the increase for providers in the non-self-referring group and only slightly higher than the increase for providers in the self-referring group.

**Table 7: Change in Average Number of Medicare Special Stains Referred by Provider Specialty, 2008 and 2010**

| Primary specialty | Referral type | Number of providers | Average number of unique Medicare fee-for-service (FFS) beneficiaries, 2010 | Special stains[a] | | Percentage change 2008 to 2010 |
|---|---|---|---|---|---|---|
| | | | | 2008 | 2010 | |
| Dermatology | Switchers | 130 | 478.2 | 31.2 | 36.7 | 17.6% |
| | Self-referring | 1,353 | 573.6 | 31.1 | 35.9 | 15.4 |
| | Non-self-referring | 2,361 | 424.4 | 31.9 | 37.6 | 17.9 |
| Gastroenterology | Switchers | 195 | 335.5 | 125.9 | 219.3 | 74.2 |
| | Self-referring | 438 | 380.9 | 204.6 | 271.4 | 32.6 |
| | Non-self-referring | 4,833 | 365.1 | 99.3 | 119.0 | 19.8 |
| Urology | Switchers | 215 | 619.1 | 36.7 | 56.5 | 54.0 |
| | Self-referring | 498 | 626.8 | 27.5 | 38.8 | 41.1 |
| | Non-self-referring | 3,192 | 473.6 | 28.8 | 31.7 | 10.1 |

Source: GAO analysis of CMS data.

Notes: Special stains refer specifically to services with HCPCS codes 88312, 88313, or 88342. We define switchers as those providers that did not self-refer in 2007 or 2008, but did self-refer in 2009 and 2010.

[a]The average number of special stains referred by self-referring providers, non-self-referring providers, and switchers are influenced in part by the average number of unique Medicare FFS beneficiaries seen by each referral type. For example, in 2008, both switchers—who did not self-refer in 2008—and non-self-referring urologists averaged approximately 0.06 anatomic pathology referrals per unique Medicare FFS beneficiary. However, switchers averaged more anatomic pathology referrals than non-self-referring providers in 2008 because they saw, on average, more unique Medicare FFS beneficiaries.

# Appendix II: Scope and Methods

This section describes the scope and methodology used to analyze our three objectives: (1) trends in the number of and expenditures for self-referred and non-self-referred anatomic pathology services from 2004 through 2010, (2) how the provision of anatomic pathology services may differ for providers who self-refer when compared with other providers, and (3) the implications of self-referral for Medicare spending on anatomic pathology services.

For all three objectives, we used the Medicare Part B Carrier File, which contains final action Medicare Part B claims for noninstitutional providers, such as physicians. Claims can be for one or more services or for individual service components.[1] Each service or service component is identified on a claim by its Healthcare Common Procedure Coding System (HCPCS) code, which the Centers for Medicare & Medicaid Services (CMS) assigns to products, supplies, and services for billing purposes.

We limited our universe of services and service components for our study to certain anatomic pathology services. Specifically, we limited our universe to services with a HCPCS code of 88305, which are anatomic pathology services related to the examination of tissue taken through biopsy procedures. (We also studied services with HCPCS codes 88312, 88313, and 88342—special stains—which were used in conjunction with these anatomic pathology services.)[2] CMS considers anatomic pathology services to be "designated health services"—services for which, in the absence of an exception, a physician may not make a referral to an entity

[1]Services can have technical components (TC) and professional components (PC). The TC of a service is intended to cover the performance of a test, including the cost of equipment, supplies, and nonphysician staff. The PC of the service is intended to cover the physician's time in interpreting an anatomic pathology service and writing a report on the findings. The TC and PC of a service can be billed together on the same claim—called a global claim—or billed separately.

[2]For the purposes of this report "anatomic pathology" services refer to HCPCS 88305 services, and "special stains" refer to HCPCS 88312, 88313, and 88342 services that were used in conjunction with these anatomic pathology services.

with which he or she has a financial relationship without implicating the Stark law.[3]

Because there is no indicator or "flag" on the claim that identifies whether services were self-referred or non-self-referred, we developed a claims-based methodology to identify services as either self-referred or non-self-referred. Specifically, we classified services as self-referred if the provider that referred the beneficiary for an anatomic pathology service and the provider that performed the anatomic pathology service was identical or had a financial relationship. We used taxpayer identification number (TIN), an identification number used by the Internal Revenue Service, to determine providers' financial relationships. The TIN could be that of the provider, the provider's employer, or another entity to which the provider reassigns payment.[4] In order to identify the associated TINs for the referring and performing providers, we created a crosswalk of the performing provider's unique physician identification number or national provider identifier (NPI) to the TIN that appeared on the claim and used that to assign TINs to the referring and performing providers.[5]

[3]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).

[4]Some providers may be associated with TINs with which they do not have a direct or indirect financial relationship and thus would not have the same incentives as other self-referring providers. We anticipate that relatively few providers in our self-referring group meet this description but to the extent that they do, it may have limited the differences we found in utilization and expenditure rates between self-referring and non-self-referring providers.

[5]The final rule implementing the Health Insurance Portability and Accountability Act established the standard for a unique health identifier for health care providers for use in the health care system and announced the adoption of the NPI as that standard. *HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers*, 69 Fed. Reg. 2424 (Jan. 23, 2004) (adding a new subpart D to 45 C.F.R. part 162). Performing physicians were required to include their NPI on any claim submitted to Medicare as of May 23, 2008. Prior to implementation of the NPI, Medicare required providers to submit another type of unique provider identifier called the unique physician identification number.Our methodology for identifying self-referred services was similar to the methodology we used for our study of physician self-referral of imaging services. See GAO, *Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions*, GAO-12-966 (Washington, D.C.: Sept. 28, 2012).

We considered global services and separately-billed TCs to be self-referred if one or more of the TINs of the referring and performing provider matched. However, we did not consider separately-billed PCs to be self-referred, even if they met the same criterion. We did not count claims with PC only as self-referred because we could not reliably determine whether they corresponded to anatomic pathology services that were performed in a provider's office or laboratory. Further, we excluded claims where a HCPCS code of 88305 was billed with another anatomic pathology service and a special stain, because we could not determine which service required the use of the special stain. As part of developing this claims-based methodology to identify self-referred services, we interviewed officials from CMS, provider groups, and other researchers.

To describe the trends in the number of and expenditures for self-referred anatomic pathology services from 2004 through 2010, we used the Medicare Part B Carrier file to calculate utilization and expenditures for self-referred and non-self-referred anatomic pathology services, both in aggregate and per beneficiary. We limited this portion of our analysis to global claims or claims for a separately-billed TC for anatomic pathology services, which indicates that the performance of the anatomic pathology service was billed under the physician fee schedule. As a result, the universe for this portion of our analysis is those anatomic pathology services performed in a provider's office or in an independent clinical laboratory that both bill for the performance of an anatomic pathology service under the physician fee schedule. We focused on these settings because the financial incentive for providers to self-refer is most direct when the service is performed in a physician office. Further, we limited our analysis to self-referral of the preparation—as opposed to the interpretation—of these services, because we could determine the site of service as a physician's office or laboratory. Accordingly, we did not examine self-referral of the interpretation of these services as we could not reliably determine their site of service. Approximately two-thirds of all anatomic pathology services billed under the physician fee schedule were performed in a physician's office or clinical laboratory. To calculate the number of Medicare beneficiaries from 2004 through 2010 needed for per beneficiary calculations, we used the Denominator File, a database that contains enrollment information for all Medicare beneficiaries enrolled in a given year. We also examined the utilization for self-referred anatomic pathology services by provider specialty for 2004 and 2010.

To determine the extent to which the provision of anatomic pathology services differs for providers who self-refer when compared with other providers, we first classified providers based on the type of referrals they made. Specifically, we classified providers as self-referring if they self-referred at least one beneficiary for an anatomic pathology service.[6] We classified providers as non-self-referring if they referred a beneficiary for an anatomic pathology service, but did not self-refer any of the services. We assigned to each provider the anatomic pathology services, including those for the performance of an anatomic pathology service and those for the interpretation of the anatomic pathology service result. If the TC and PC were billed separately for the same beneficiary, we counted these two components as one referred service. As a result, we counted all services that a provider referred, regardless of whether it was performed in a provider office, independent clinical laboratory, or other setting. We classified anatomic pathology services as being from the same biopsy procedure if the services were referred by the same provider for the same beneficiary on the same day.[7] We then performed two separate analyses.

First, we compared the provision—that is, the number of referrals made—of anatomic pathology services by self-referring providers and non-self-referring providers in 2010, disaggregated by the number of Medicare beneficiaries seen by the provider, provider specialty, and geography (i.e., urban or rural) and patient characteristics. We used the number of unique Medicare fee-for-service (FFS) beneficiaries for which providers provided services in 2010 as a proxy for practice size, which we identified using 100 percent of providers' claims from the Medicare Part B Carrier file. 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 providers as practicing in metropolitan statistical

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

[7]We use the term "biopsy procedure" to refer to the process of extracting tissue for analysis. Multiple tissue samples (sometimes also referred to as biopsies) can be extracted from a single biopsy procedure.

areas.[8] We considered all other settings to be rural. We identified providers' specialties on the basis of the specialties listed on the claims. These specialty codes include physician specialties, such as dermatology and urology, and nonphysician provider types, such as nurse practitioners and physician assistants. We also examined the extent to which the characteristics of the patient populations served by self-referring and non-self-referring providers differed. We used CMS's risk score file to identify average risk score, which serves as a proxy for beneficiary health status. Information on additional patient characteristics, such as age and sex, came from the Medicare Part B Carrier file claims.

Second, we determined the extent to which the number of anatomic pathology service referrals made by providers changed after they began to self-refer. Specifically, we identified a group of providers that began to self-refer anatomic pathology services in 2009.[9] We refer to this group of providers as "switchers" because it represents providers that did not self-refer in 2007 or 2008, but did self-refer in 2009 and 2010. We then calculated the change in the number of anatomic pathology referrals made from 2008 (i.e., the year before the switchers began self-referring) to 2010 (i.e., the year after they began self-referring). We compared the change in the number of referrals made by these providers to the change in the number of referrals made over the same time period by providers who did not change whether or not they self-referred anatomic pathology services. Specifically, we compared the change in the number of referrals made by switchers to those made by (1) self-referring providers—providers that self-referred in years 2007 through 2010, and (2) non-self-referring providers—providers that did not self-refer in years 2007 through 2010. For each provider, we also identified the most common TIN to which they referred anatomic pathology services. If the TIN was the same for all 4 years, we assumed that they remained part of the same practice for all 4 years. We calculated the number of referrals in 2008 and 2010 separately for providers that met this criterion.

[8]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.

[9]We used 4 years of experience (2007 through 2010) to categorize providers even though we compared referrals in 2008 to 2010 because we wanted to ensure that providers that began self-referring in 2009 did not self-refer for at least the 2 prior years.

To determine the implications of self-referral for Medicare spending on anatomic pathology services, we summed the number of and expenditures for all anatomic pathology services performed in 2010 across the three provider specialties we reviewed. We then calculated the number of and expenditures for anatomic pathology services if self-referring providers performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers of the same provider size and specialty. We repeated this analysis incorporating an approximation of the payment reduction for anatomic pathology services that became effective in 2013.

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, as they are used by the Medicare program as a record of payments to health care providers. As such, they are subject to routine CMS scrutiny.

We conducted this performance audit from January 2012 through June 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 III: Average Number of Medicare Anatomic Pathology Services per Biopsy Procedure for Most Common Diagnoses

**Table 8: Average Number of Medicare Anatomic Pathology Services per Biopsy Procedure for Most Common Diagnoses Referred by Self-referring and Non-self-referring Dermatologists in 2010**

| Provider specialty and most common diagnoses, including International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code | Average number of anatomic pathology services per biopsy procedure | | Percentage difference |
|---|---|---|---|
| | Self-referring providers | Non-self-referring providers | |
| Neoplasm of uncertain behavior of skin (238.2) | 1.8 | 1.6 | 13% |
| Other malignant neoplasm of skin of other and unspecified parts of face (173.3) | 1.6 | 1.4 | 14 |
| Actinic keratosis (702.0) | 1.7 | 1.5 | 13 |
| Inflamed seborrheic keratosis (702.11) | 1.6 | 1.4 | 14 |
| Other malignant neoplasm of skin of upper limb, including shoulder (173.6) | 1.6 | 1.4 | 14 |
| Other seborrheic keratosis (702.19) | 1.6 | 1.4 | 14 |
| Other malignant neoplasm of skin of trunk, except scrotum (173.5) | 1.6 | 1.5 | 7 |
| Other malignant neoplasm of scalp and skin of neck (173.4) | 1.6 | 1.5 | 7 |
| Benign neoplasm of skin of trunk, except scrotum (216.5) | 1.6 | 1.4 | 14 |
| Neoplasm of unspecified nature of bone, soft tissue, and skin (239.2) | 1.8 | 1.7 | 6 |
| Scar conditions and fibrosis of skin ( 709.2) | 1.6 | 1.4 | 14 |
| Other malignant neoplasm of skin of lower limb, including hip (173.7) | 1.6 | 1.4 | 14 |
| Benign neoplasm of skin of other and unspecified parts of face (216.3) | 1.6 | 1.4 | 14 |
| Other malignant neoplasm of skin of ear and external auditory canal (173.2) | 1.6 | 1.4 | 14 |
| Contact dermatitis and other eczema unspecified cause (692.9) | 1.4 | 1.2 | 17 |
| Unspecified disorder of skin and subcutaneous tissue (709.9) | 1.6 | 1.7 | -6 |
| Other malignant neoplasm of skin, site unspecified (173.9) | 1.6 | 1.4 | 14 |
| Benign neoplasm of skin, site unspecified (216.9) | 1.6 | 1.4 | 14 |
| Carcinoma in situ of skin of other and unspecified parts of face (232.3) | 1.8 | 1.5 | 20 |
| Viral warts, unspecified (078.10) | 1.5 | 1.3 | 15 |
| Other dyschromia (709.09) | 1.6 | 1.4 | 14 |
| Carcinoma in situ of skin of upper limb, including shoulder (232.6) | 1.8 | 1.5 | 20 |

Source: GAO analysis of CMS data.

Note: All diagnoses that represent at least 1 percent of the principal diagnoses listed on the claims of self-referring dermatologists are included. Diagnoses are presented in order of the most to least common.

**Table 9: Average Number of Medicare Anatomic Pathology Services per Biopsy Procedure for Most Common Diagnoses Referred by Self-referring and Non-self-referring Gastroenterologists in 2010**

| Provider specialty and most common diagnoses, including International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code | Average number of anatomic pathology services per biopsy procedure | | |
|---|---|---|---|
| | Self-referring providers | Non-self-referring providers | Percentage difference |
| Benign neoplasm of colon (211.3) | 2.2 | 1.9 | 16% |
| Atrophic gastritis, without mention of hemorrhage (535.10) | 2.2 | 1.9 | 16 |
| Unspecified gastritis and gastroduodenitis, without mention of hemorrhage (535.50) | 2.7 | 2.0 | 35 |
| Other specified gastritis, without mention of hemorrhage (535.40) | 2.3 | 1.9 | 21 |
| Barrett's esophagus (530.85) | 2.5 | 2.0 | 25 |
| Benign neoplasm of stomach (211.1) | 2.8 | 2.1 | 33 |
| Benign neoplasm of rectum and anal canal (211.4) | 1.9 | 1.6 | 19 |
| Other and unspecified noninfectious gastroenteritis and colitis (558.9) | 2.5 | 2.2 | 14 |
| Diarrhea (787.91) | 2.5 | 2.0 | 25 |
| Unspecified disorder of stomach and duodenum (537.9) | 2.3 | 2.1 | 10 |
| Esophageal reflux (530.81) | 2.6 | 2.0 | 30 |
| Reflux esophagitis (530.11) | 2.4 | 2.0 | 20 |
| Esophagitis, unspecified (530.10) | 2.0 | 1.8 | 11 |
| Acute gastritis, without mention of hemorrhage (535.00) | 2.3 | 2.0 | 15 |
| Other specified disorders of stomach and duodenum (537.89) | 2.3 | 1.9 | 21 |
| Dysphagia, unspecified (787.20) | 2.3 | 1.7 | 35 |
| Anal and rectal polyp (569.0) | 1.9 | 1.5 | 27 |
| Other specified disorders of intestine (569.89) | 2.3 | 1.8 | 28 |
| Duodenitis, without mention of hemorrhage (535.60) | 3.0 | 2.5 | 20 |

Source: GAO analysis of CMS data.

Note: All diagnoses that represent at least 1 percent of the principal diagnoses listed on the claims of self-referring gastroenterologists are included. Diagnoses are presented in order of the most to least common.

**Table 10: Average Number of Medicare Anatomic Pathology Services per Biopsy Procedure for Most Common Diagnoses Referred by Self-referring and Non-self-referring Urologists in 2010**

| Provider specialty and most common diagnoses, including International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code | Average number of anatomic pathology services per biopsy procedure | | |
|---|---|---|---|
| | Self-referring providers | Non-self-referring providers | Percentage difference |
| Elevated prostate specific antigen (790.93) | 12.5 | 8.5 | 47% |
| Malignant neoplasm of prostate (185) | 8.5 | 6.1 | 39 |
| Malignant neoplasm of bladder, part unspecified (188.9) | 1.8 | 1.7 | 6 |
| Hyperplasia of prostate, unspecified, without urinary obstruction and other lower urinary symptoms (LUTS) (600.90) | 5.0 | 3.2 | 56 |
| Other chronic cystitis (595.2) | 1.8 | 1.7 | 6 |
| Hypertrophy (benign) of prostate without urinary obstruction and other lower urinary tract symptom (LUTS) (600.00) | 5.3 | 2.6 | 104 |
| Hypertrophy (benign) of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS) (600.01) | 3.1 | 2.3 | 35 |
| Benign neoplasm of prostate (222.2) | 9.4 | 6.6 | 42 |
| Hematuria, unspecified (599.70) | 1.9 | 1.4 | 36 |
| Carcinoma in situ of prostate (233.4) | 11.5 | 7.6 | 51 |
| Nodular prostate without urinary obstruction (600.10) | 7.6 | 5.0 | 52 |
| Chronic prostatitis (601.1) | 6.1 | 4.4 | 39 |
| Cystitis, unspecified (595.9) | 1.8 | 1.6 | 13 |

Source: GAO analysis of CMS data.

Note: All diagnoses that represent at least 1 percent of the principal diagnoses listed on the claims of self-referring urologists are included. Diagnoses are listed in order of the most to least common.

# Appendix IV: Age and Sex of Medicare Beneficiaries for Select Provider Specialties by Practice Size in 2010

**Table 11: Average Age of Medicare Beneficiaries for Select Provider Specialties by Practice Size in 2010**

| Provider specialty and number of unique Medicare FFS beneficiaries[a] | Average age (in years) of beneficiaries | |
|---|---|---|
| | Self-referring providers | Non-self-referring providers |
| Dermatology | | |
| 1 to 250 | 73 | 73 |
| 251 to 500 | 74 | 74 |
| > 500 | 74 | 74 |
| Gastroenterology | | |
| 1 to 250 | 67 | 70 |
| 251 to 500 | 70 | 71 |
| > 500 | 71 | 71 |
| Urology | | |
| 1 to 250 | 70 | 71 |
| 251 to 500 | 72 | 73 |
| > 500 | 74 | 73 |

Source: GAO analysis of CMS data.

[a]The number of unique Medicare FFS beneficiaries refers to the number of unique beneficiaries that received at least one service from a provider.

**Table 12: Average Percentage of Medicare Beneficiaries Who Are Female for Select Provider Specialties by Practice Size in 2010**

| | Average percentage of beneficiaries female | |
|---|---|---|
| **Provider specialty and number of unique Medicare FFS beneficiaries[a]** | **Self-referring providers** | **Non-self-referring providers** |
| Dermatology | | |
| 1 to 250 | 51 | 53 |
| 251 to 500 | 51 | 52 |
| > 500 | 51 | 52 |
| Gastroenterology | | |
| 1 to 250 | 58 | 57 |
| 251 to 500 | 57 | 57 |
| > 500 | 57 | 58 |
| Urology | | |
| 1 to 250 | 30 | 30 |
| 251 to 500 | 28 | 28 |
| > 500 | 25 | 25 |

Source: GAO analysis of CMS data.

[a]The number of unique Medicare FFS beneficiaries refers to the number of unique beneficiaries that received at least one service from a provider.

# Appendix V: Average Number of Medicare Anatomic Pathology Referrals by Provider Self-Referral and Urban-Rural Status in 2010

| Geographic designation | Provider specialty and number of unique Medicare fee-for-service (FFS) beneficiaries[a] | Average number of anatomic pathology services | | Relative rate of self-referring providers[b] |
|---|---|---|---|---|
| | | Self-referring providers | Non-self-referring providers | |
| Urban | Dermatology | | | |
| | 1 to 250 | 168.7 | 142.5 | 1.18 |
| | 251 to 500 | 538.0 | 445.1 | 1.21 |
| | >500 | 1,532.1 | 1,019.4 | 1.50 |
| | Gastroenterology | | | |
| | 1 to 250 | 174.9 | 139.0 | 1.26 |
| | 251 to 500 | 414.9 | 344.2 | 1.21 |
| | >500 | 800.5 | 628.6 | 1.27 |
| | Urology | | | |
| | 1 to 250 | 96.9 | 74.4 | 1.30 |
| | 251 to 500 | 250.4 | 171.9 | 1.46 |
| | >500 | 472.8 | 299.3 | 1.58 |
| Rural | Dermatology | | | |
| | 1 to 250 | 183.0 | 166.2 | 1.10 |
| | 251 to 500 | 570.7 | 510.7 | 1.12 |
| | >500 | 1,863.3 | 939.0 | 1.99 |
| | Gastroenterology | | | |
| | 1 to 250 | 114.3 | 185.9 | 0.61 |
| | 251 to 500 | 478.8 | 403.1 | 1.19 |
| | >500 | 963.4 | 726.3 | 1.33 |
| | Urology | | | |
| | 1 to 250 | 142.5 | 83.5 | 1.71 |
| | 251 to 500 | 206.3 | 188.2 | 1.10 |
| | >500 | 373.9 | 316.2 | 1.18 |

Source: GAO analysis of CMS data.

Notes: Anatomic pathology services refer specifically to Healthcare Common Procedure Coding System (HCPCS) code 88305. Providers were considered to be self-referring if they self-referred anatomic pathology services for at least one biopsy procedure. Of the 29,502 providers represented above that referred at least one beneficiary for an anatomic pathology service in 2010, 7,109 were self-referring and 22,393 were non-self-referring.

[a]The number of unique Medicare FFS beneficiaries refers to the number of unique beneficiaries that received at least one service from a provider.

[b]The relative rate of self-referring providers refers to the factor by which the average number of services referred by self-referring providers is greater or less than the average number of services referred by non-self-referring providers. For example, if the relative rate of self-referring providers is equal to 2, it would mean that, on average, self-referring providers referred twice as many anatomic pathology services as non-self-referring providers.

# 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

MAY 16 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, "Medicare: Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer" (GAO-13-445).

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: ACTION NEEDED TO ADDRESS HIGHER USE OF ANATOMIC PATHOLOGY SERVICES BY PROVIDERS WHO SELF-REFER" (GAO 13-445)**

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

**GAO Recommendation 1**

GAO recommends that the Administrator of CMS insert a self-referral flag on Medicare Part B claims form and require providers to indicate whether the anatomic pathology services for which a provider bills Medicare are self-referred or not.

**HHS Response**

HHS does not concur. 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. It seems anatomic pathology services may share some characteristics with the services mentioned in the President's proposal.

**GAO Recommendation 2**

GAO recommends that the Administrator of CMS determine and implement an approach to ensure the appropriateness of biopsy procedures performed by self-referring providers.

**HHS Response**

HHS does not concur. GAO identified 918,000 instances of self-referral that would need to be reviewed to determine if the services were furnished in accordance with specific coverage and payment criteria with respect to when a particular biopsy should be taken or how many specimens should be reviewed by pathologists. Without review of large numbers of claims, we believe it is difficult to make recommendations regarding whether these services are appropriate. We encourage GAO to do additional work to determine if self-referred biopsies are more often inappropriate than biopsies that are not self-referred. In addition, we do not believe this or the above recommendation will address overutilization that occurs as a result of self-referral.

**GAO Recommendation 3**

GAO recommends that the Administrator of CMS develop and implement a payment approach for anatomic pathology services that would limit the financial incentives associated with referring a higher number of specimens - or anatomic pathology services - per biopsy procedure.

1

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE: ACTION NEEDED TO ADDRESS HIGHER USE OF ANATOMIC PATHOLOGY SERVICES BY PROVIDERS WHO SELF-REFER" (GAO 13-445)

HHS Response

HHS concurs and has already addressed this recommendation. PFS rates are determined based upon the resources involved in furnishing a service. To the extent that the payment rates are higher than the cost of resources used in furnishing the services, an incentive may exist to provide additional services. We have looked at Current Procedural Terminology code 88305 (the most commonly furnished anatomic pathology service) as a potentially misvalued code and revalued it accordingly in calendar year 2013. As we have reduced payment for this service by approximately 30 percent, we have significantly reduced the financial incentives associated with self-referral for these procedures.

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# 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; Todd D. Anderson; Manuel Buentello; Krister Friday; Gregory Giusto; Brian O'Donnell; and Daniel Ries made key contributions to this report.

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