CHAPTER 8

Addressing the growth of ancillary services in physicians' offices

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Chapter summary

The Ethics in Patient Referrals Act, also known as the Stark law, prohibits physicians from referring Medicare patients for "designated health services" (DHS)—such as imaging, radiation therapy, home health, durable medical equipment, clinical laboratory tests, and physical therapy—to entities with which they have a financial relationship, unless the relationship fits within an exception. The in-office ancillary services (IOAS) exception allows physicians to provide most DHS to patients in their offices under certain conditions.

Many physicians have expanded their practices in recent years to provide diagnostic imaging, clinical laboratory testing, physical therapy, and radiation therapy. These services—particularly diagnostic imaging—account for a significant share of Part B revenue for certain specialties. Many ancillary services have experienced rapid volume growth over the last five years, which contributes to Medicare's growing financial burden on taxpayers and beneficiaries. Rapid volume growth, along with the diffusion of new technologies, also raises questions about the equity and accuracy of physician payments. Moreover, there is evidence that some diagnostic imaging and physical therapy services ordered by physicians are not clinically appropriate (Hendel et al. 2010, Office of Inspector General 2006, Pham et al. 2009).

In the proposed rule for the 2008 physician fee schedule, CMS noted the migration of expensive imaging equipment, pathology services, and therapy

In this chapter

services to physicians' offices and asked for comment on whether the IOAS exception should be changed (Centers for Medicare & Medicaid Services 2007a). Specifically, CMS asked whether certain services should continue to qualify for the exception, such as services that are not needed at the time of the office visit to help the physician with a diagnosis or plan of treatment.

Proponents of the IOAS exception argue that it enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations. On the other hand, there is evidence that physician investment in ancillary services leads to higher volume through greater overall capacity and financial incentives for physicians to order additional services (Baker 2008, Gazelle et al. 2007, Medicare Payment Advisory Commission 2009a, Mitchell and Sass 1995). In addition, there are concerns that physician ownership could skew clinical decisions.

We used Medicare claims data to examine the frequency with which certain services covered by the IOAS exception are provided on the same day as an office visit. We found that outpatient therapy (such as physical and occupational therapy) is rarely provided on the same day as a related office visit. In addition, fewer than half of advanced imaging, ultrasound, and clinical laboratory and pathology services are performed on the same day as an office visit, and about half of standard imaging studies (such as X-rays) are performed on the same day as an office visit. The finding that many ancillary services are not usually provided during an office visit raises questions about a key rationale for the IOAS exception—that it enables physicians to provide ancillary services during a patient's visit.

Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current fee-for-service payment systems, which reward higher volume. However, under a model in which providers receive a fixed payment in advance for a group of beneficiaries (capitation) or an episode of care (bundling), they would not be able to generate additional revenue by ordering more services. Therefore, the preferred approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Integrated delivery systems that are able to coordinate care and manage resource use are likely to perform better under such a payment model than unaffiliated individual providers. Because it will take several years to establish new payment models and delivery systems, policymakers may wish to consider interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. Such strategies should be careful to not limit the development of accountable care organizations that could generate savings for Medicare and

improve quality. Interim policies could include restricting the ability of practices to self-refer for ancillary services, improving payment accuracy, and ensuring the appropriate use of ancillary services. This chapter does not make recommendations but explores several options in more detail:

- excluding therapeutic services such as physical therapy and radiation therapy from the IOAS exception,
- limiting the exception to physician practices that are clinically integrated,
- excluding diagnostic tests that are not usually provided during an office visit from the exception,
- reducing payment rates for diagnostic tests performed under the exception,
- improving payment accuracy and expanding payment rates to include multiple related services, and
- adopting a carefully targeted prior authorization program for advanced imaging services.

In future work, the Commission plans to further examine these strategies with the goal of crafting policy recommendations. ■

Background

The Ethics in Patient Referrals Act, also known as the Stark law, prohibits physicians from referring Medicare patients for "designated health services" (DHS)—such as imaging, hospital services, radiation therapy, home health, durable medical equipment (DME), and physical therapy—to entities with which they have a financial relationship, unless the relationship fits within an exception. For example, physicians are prohibited from referring patients to an imaging center or clinical lab that they own. However, a provision in the law—called the in-office ancillary services (IOAS) exception—allows physicians and group practices to provide most DHS in their own offices as long as certain requirements are met (42 CFR § 411.355(b)) (see text box, pp. 218–219).[1]

According to a summary of the bill that became the Stark law, the IOAS exception was expected to apply mostly to in-office laboratory tests or X-rays, based on the need for a quick turnaround time on crucial tests (*Congressional Record* 1989). However, the exception applies to almost all DHS, including therapeutic services and services that are delivered on a different day from the patient's office visit. The exception may also cover certain arrangements in which physicians share testing equipment with or lease equipment from other providers (see text box, pp. 218–219).

In the proposed rule for the 2008 physician fee schedule, CMS noted the migration of expensive imaging equipment, pathology services, and therapy services to physicians' offices and asked for comment on whether the IOAS exception should be changed (Centers for Medicare & Medicaid Services 2007a). Specifically, CMS asked whether certain services should continue to qualify for the exception, such as services that are not needed at the time of the office visit to help the physician with a diagnosis or plan of treatment. To date, CMS has not proposed a specific policy change.

The Commission has also noted the rapid growth of services covered by the IOAS exception and evidence that these services are sometimes furnished inappropriately. Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current fee-for-service (FFS) payment systems, which reward higher volume. However, under a model in which providers receive a fixed payment in advance for a group of beneficiaries (capitation) or an episode of care (bundling), they would not be able to generate additional revenue by ordering more services. Therefore, the preferred approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Under such a payment model, integrated delivery systems that are able to coordinate care and manage resource use are likely to perform better than unaffiliated individual providers. Because it will take several years to establish new payment models and delivery systems, policymakers may wish to consider interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. Such strategies should be careful to not limit the development of accountable care organizations that could generate savings for Medicare and improve quality.

This chapter explores several options, including limiting the ability of physician practices to self-refer for ancillary services, improving payment accuracy, and ensuring the appropriate use of imaging services, but does not make recommendations. These strategies could be considered individually or in combination. In future work, the Commission plans to further examine these options with the goal of crafting policy recommendations.

In the sections that follow, we

- describe the increased investment by physicians in services covered by the IOAS exception and the potential benefits and risks of physician self-referral,
- discuss the volume growth of these services and questions about clinical appropriateness,
- present results of our analysis of how frequently diagnostic tests and outpatient therapy services are provided on the same day as an office visit, and
- map out several policy options.

Physicians have increased the provision of ancillary services in their offices

Many physicians have expanded their practices in recent years to provide diagnostic imaging, clinical laboratory testing, physical therapy, and radiation therapy (Anscher et al. 2010, Centers for Medicare & Medicaid Services 2007a, Medicare Payment Advisory Commission 2006a, Pham et al. 2004, Pham and Ginsburg 2007, Saul 2006).[2] According to a survey sponsored by the Commission in 2006, about 27 percent of physicians reported that they expanded in-office testing and lab services in the past year and almost 20 percent reported that they increased their use of in-office imaging (Medicare Payment Advisory Commission 2007a). An analysis by the Government

The in-office ancillary services exception

The in-office ancillary services (IOAS) exception to the Stark self-referral law has three key criteria known as the supervision, building (or location), and billing requirements: (1) The designated health services (DHS)—such as imaging or outpatient therapy—must be personally supervised by the referring physician, a physician who is a member of the group practice, or an individual who is supervised by the referring physician or another physician in the group (the supervision requirement). (2) The services must be furnished in the same building where the referring physician provides services that are not DHS; alternatively, groups may furnish services in a centralized facility that the group uses for ancillary services (the building requirement). (3) The services must be billed by the physician performing or supervising the service, the group practice, an entity that is wholly owned by the performing or supervising physician or by that physician's group practice, or a third-party billing company acting as an agent of the physician or group (the billing requirement) (42 CFR § 411.355 (b)).

The definition of a group practice is important because it allows physicians greater flexibility to provide ancillary services in their offices. Physicians who are in a group may order services that are furnished or supervised by other physicians in the group, and groups may also provide services in a centralized facility. The Stark law defines a group practice as one in which "substantially all" of the services provided by members of the group are furnished through the group and billed by the group. The Stark regulations interpreted "substantially all" as requiring that at least 75 percent of the patient care services provided by members of the group be provided and billed by the group (42 CFR § 411.352 (d)). Members include owners and employees of the group. The 75 percent rule applies to all the services collectively provided by physicians who are group members; individual members do not have to meet the 75 percent threshold. Nevertheless, this rule can make it difficult for groups to qualify as a group practice under the Stark law if they have many part-time physician members who also work for other groups. However, the Stark regulations created a new category called "physicians in the group" that applies to physicians who independently contract with the group. These physicians are not counted toward the 75 percent rule. Thus, groups can contract with physicians

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Accountability Office found that physicians' offices accounted for 64 percent of spending on imaging under the physician fee schedule in 2006, compared with 58 percent in 2000 (Government Accountability Office 2008).

Ancillary services—particularly diagnostic imaging—account for a significant share of Part B revenue for certain specialties (Figure 8-1, p. 220).[3] Imaging accounted for 38 percent of cardiology's Part B revenue in 2008, up from 35 percent in 2003, and it represented 23 percent of vascular surgery's Part B payments in 2008, compared with 20 percent in 2003. In 2008, imaging, clinical lab tests, pathology services, outpatient therapy, and radiation therapy collectively accounted for 12 percent of Part B revenue for orthopedic surgery (no change from 2003), 11 percent for urology (up from 5 percent in 2003), and 10 percent for internal medicine (no change from 2003).

Potential benefits and risks of physician investment in ancillary services

Although physician investment in imaging equipment and other ancillary services may improve access and convenience for patients, it may also lead to higher volume through additional capacity and financial incentives for physicians to order more services (Casalino 2008, Kouri et al. 2002). Proponents argue that allowing physicians to provide tests and other ancillary services in their offices enables them to better supervise quality of care, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations. According to CMS, a key rationale for the IOAS exception was to permit physicians to provide ancillary services in their offices during patient visits to enhance patients' convenience (Centers for Medicare & Medicaid Services 2001). The ability to provide tests and

The in-office ancillary services exception

on a part-time basis to provide or supervise ancillary services without affecting their ability to comply with the 75 percent rule.

The IOAS exception prohibits group practices from compensating their physicians in a manner that directly or indirectly reflects their referrals for DHS (42 CFR § 411.352 (g)). However, the Stark regulations allow practices to allocate profits from DHS to physicians in the practice using certain indirect methods, such as on a per capita basis or based on the practice's distribution of revenue from services that are not DHS.[4]

In addition to group practices that provide imaging in their own offices, arrangements exist in which a practice shares a facility with another practice or leases a block of time from a separate imaging provider. Under a block-of-time lease arrangement, a physician practice sends its patients to another provider for imaging and bills Medicare for the services, profiting from the difference between Medicare's payment rate and the fee paid by the practice to the provider that performs the services. According to data from a California health plan, more than 60 percent of the physicians who billed the plan for MRI or computed tomography (CT) scans engaged in a block lease or similar arrangement (Mitchell 2007). Shared facility or block lease arrangements may comply with the IOAS exception as long as the supervision, building, and billing requirements are met (e.g., the imaging study is performed in the same building where the referring physician furnishes services that are not DHS).[5] Under a CMS rule, however, imaging providers that are enrolled in Medicare as fixed-site independent diagnostic testing facilities (IDTFs) may not lease their operations to or share testing equipment with other organizations (42 CFR § 410.33). This rule does not apply to mobile IDTFs. Although this rule prohibits leasing arrangements between group practices and IDTFs, physician groups may still engage in block-of-time leases with each other.

The Patient Protection and Affordable Care Act of 2010 requires physicians who provide MRI, CT, or positron emission tomography services under the IOAS exception to inform their patients that they may obtain these services from another provider and to provide patients with a list of alternative providers in their area. ■

other services during an office visit may help physicians initiate treatment more quickly.

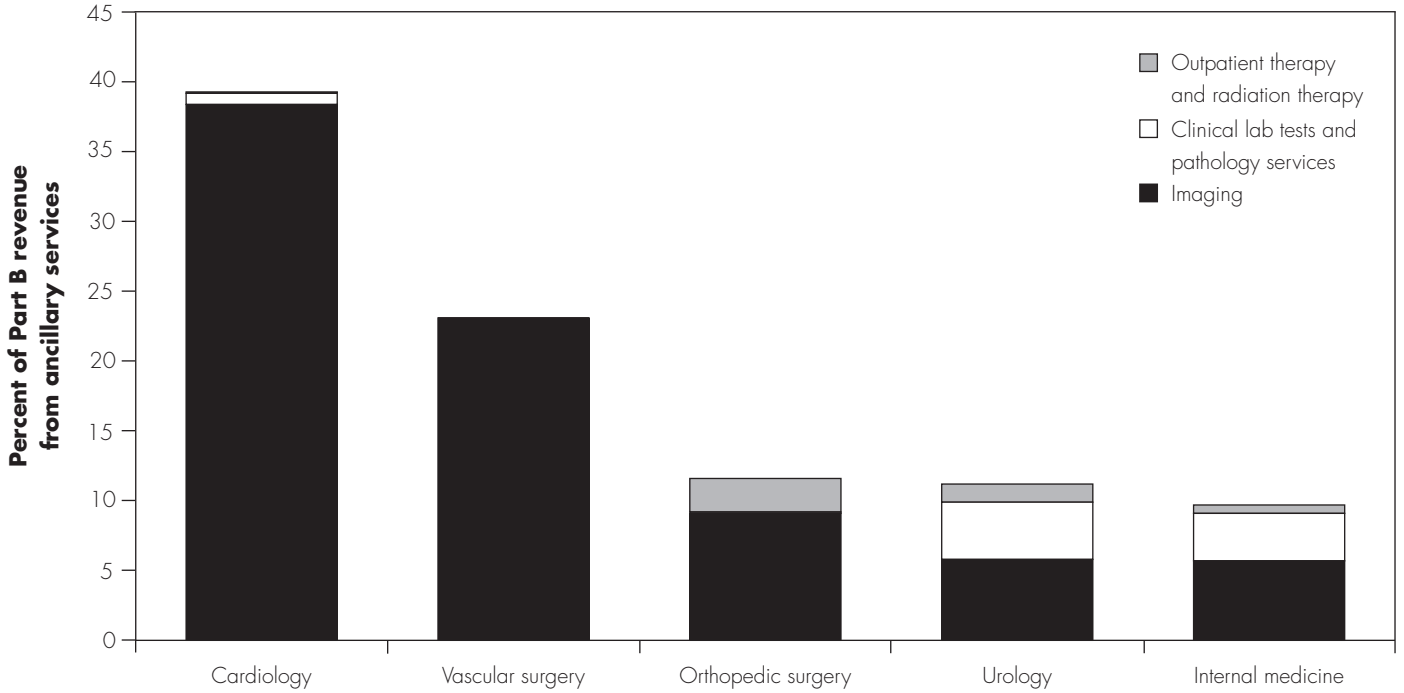
On the other hand, physician investment in ancillary services could lead to higher volume through greater overall capacity and financial incentives for physicians to order additional services. A study by Baker and colleagues estimated that each additional MRI scanner in a market is associated with 733 additional MRI scans among Medicare beneficiaries, and each additional computed tomography (CT) machine is associated with 2,224 additional CT scans (Baker et al. 2008). It is unclear whether the growth in scans is driven by changes in demand for medically necessary care or changes in the supply of machines. Several studies—including recent research conducted by the Commission—have found that physicians who furnish imaging services in their offices refer patients for more imaging than other physicians (Baker 2008, Gazelle et al. 2007, Government Accountability Office 1994, Hillman et al. 1990, Hillman et al. 1992, Kouri et al. 2002, Litt et al. 2005, Medicare Payment Advisory Commission 2009a). Researchers also found that physicians with a financial interest in physical therapy initiated therapy for patients with musculoskeletal injuries more frequently than other physicians and that physical therapy clinics with physician ownership provided more visits per patient than non-physician-owned clinics (Mitchell and Sass 1995, Swedlow et al. 1992).

Volume of ancillary services has grown rapidly

Many services covered under the IOAS exception experienced rapid volume growth under the physician fee schedule from 2003 to 2008.[6] The volume of diagnostic imaging services increased by 7.2 percent per beneficiary per year during this period. Also during this period, the

FIGURE 8–1

Percent of Part B revenue derived from imaging and other services, for selected specialties, 2008



Note: The services in this figure are considered designated health services under the Stark self-referral law. Outpatient therapy includes physical therapy, occupational therapy, and speech–language pathology services. The figure only includes outpatient therapy services that were furnished "incident to" a physician's service; it does not include therapy services furnished by therapists employed by physician groups who bill Medicare independently. Clinical lab tests are paid under the clinical lab fee schedule and pathology services are paid under the physician fee schedule. Part B spending does not include Part B drugs. The specialties in the figure are those with the highest share of Part B payments derived from ancillary services, excluding specialties and facilities that predominantly perform imaging or radiation therapy, such as radiology, radiation oncology, and independent diagnostic testing facilities.

Source: MedPAC analysis of 100 percent physician supplier procedure summary file from CMS, 2008.

volume of outpatient therapy services (which includes physical therapy, occupational therapy, and speech–language pathology services) rose by an average of 11.4 percent per beneficiary per year, and radiation therapy services increased by 7.8 percent per year. By comparison, all physician services grew by 4.6 percent per year.

Although the volume growth of all imaging services slowed to 3.3 percent per beneficiary from 2007 to 2008, some types of imaging grew more rapidly. For example, the volume of echocardiography and CT scans of parts of the body other than the head increased by 4.6 percent, and CT scans of the head rose by 4.4 percent. Moreover, as described below, there are reasons to be concerned that some of the increased use of imaging in recent years may not be appropriate.

Rapid volume growth contributes to Medicare's rising financial burden on taxpayers and beneficiaries. Many factors appear to be driving the growth of imaging, outpatient therapy, and radiation therapy, including:

- technological innovation and new clinical applications,
- changes in the population and disease prevalence,
- incentives in Medicare's FFS payment systems to increase volume,
- potential mispricing of services,
- defensive medicine,
- consumer demand, and
- the expansion of services offered in physicians' offices (Baicker et al. 2007, Iglehart 2009, Medicare Payment Advisory Commission 2009a, Medicare Payment Advisory Commission 2009b).

In addition, collaborative relationships between hospitals and physicians—such as joint ventures and hospital employment of physicians—have become increasingly common and contribute to volume growth of profitable admissions and outpatient services. This issue is discussed in a prior Commission report (Medicare Payment Advisory Commission 2008).

In this chapter, we focus on two factors driving volume growth: the expansion of services offered in physicians' offices and the potential mispricing of services in the physician fee schedule.

Questions about the clinical appropriateness of some ancillary services

There is evidence that some diagnostic imaging and physical therapy services ordered by physicians are not clinically appropriate. A pilot study conducted by the American College of Cardiology Foundation (ACCF) and United Healthcare of six practices that perform nuclear cardiology procedures found that 14 percent of the procedures performed at these sites were inappropriate, based on criteria developed by the ACCF and the American Society of Nuclear Cardiology (Hendel et al. 2010). Another study examined the appropriateness of cardiac imaging stress tests conducted at the Mayo Clinic and found that between 14 percent and 18 percent of the tests were inappropriate (Gibbons et al. 2008). A significant proportion of noncardiac imaging studies may also be inappropriate. For example, one study found that nearly 30 percent of Medicare beneficiaries with uncomplicated low back pain received an imaging service within 28 days, even though imaging is rarely indicated for this condition in the absence of specific complications or comorbidities (Pham et al. 2009). A recent analysis reviewed imaging orders from primary care physicians at a large urban hospital and found that 26 percent did not meet appropriateness criteria developed by a radiology benefit management program (Lehnert and Bree 2010). Inappropriate orders included CT for chronic headache, spine MRI for acute back pain, and knee or shoulder MRI for osteoarthritis. It is important to point out that inappropriate use is not limited to imaging services provided in physicians' offices; it also occurs in hospitals. Therefore, policy approaches to address this problem may need to consider multiple settings.

Questions have also been raised about the medical necessity of physical therapy services (Medicare Payment Advisory Commission 2006a). An Office of Inspector General (OIG) investigation estimated that 26 percent of physical therapy services billed by physicians that were provided during the first half of 2002 were not medically necessary (Office of Inspector General 2006).

The growth of imaging has also sparked concerns about the long-term impact of radiation exposure. Certain types of imaging expose beneficiaries to ionizing radiation, which is associated with an increased risk of developing cancer (Brenner and Hall 2007, Center for Devices and Radiological Health 2010, Smith-Bindman et al. 2009). A recent report estimates that the United States population's per capita dose of radiation from medical imaging increased almost 600 percent from the early 1980s to 2006, primarily due to higher use of CT and nuclear medicine studies (National Council on Radiation Protection and Measurements 2009). Although an individual's risk of developing cancer from a single test is small, these risks are applied to a growing number of patients. A recent study projected that approximately 29,000 future cancers could be related to CT scans performed in the United States in 2007 (Berrington de Gonzalez et al. 2009).

Most diagnostic tests and outpatient therapy services are not usually provided on the same day as an office visit

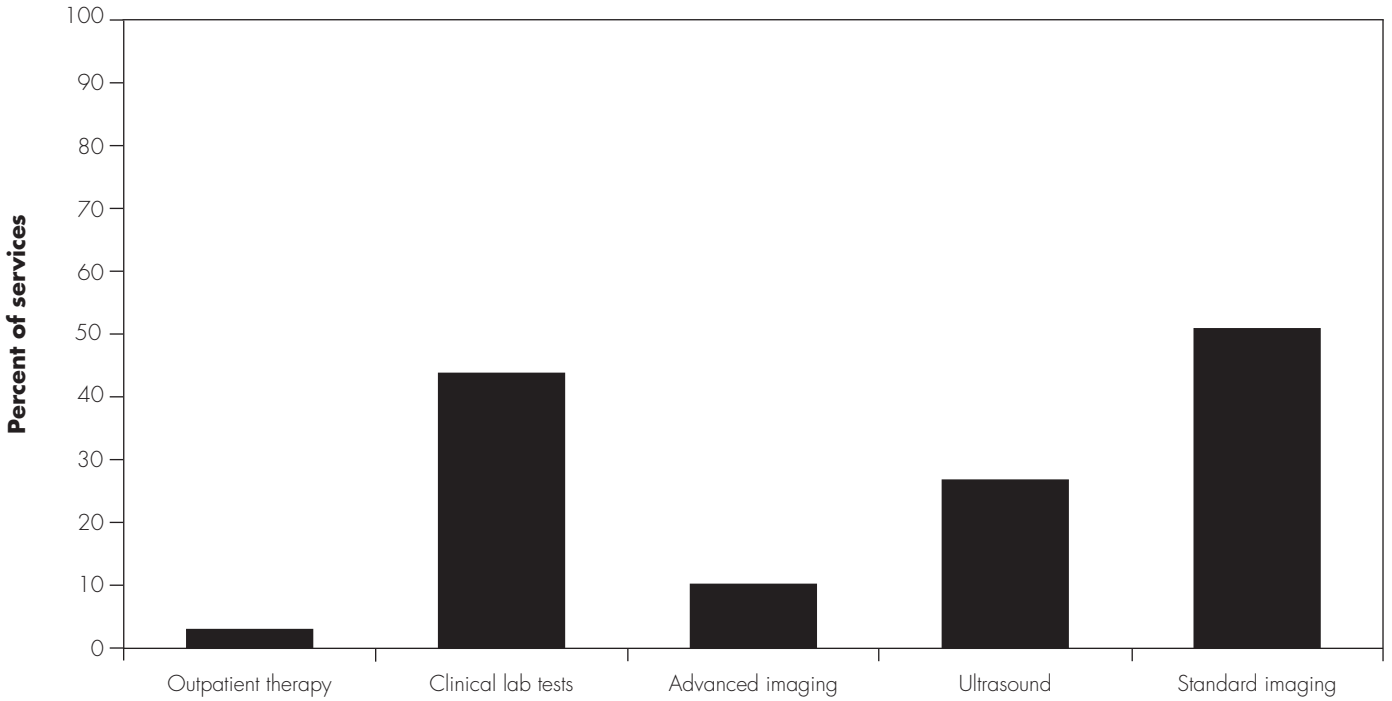
A key—but not the only—rationale for the IOAS exception is that patients should be able to receive ancillary services during their office visits (Centers for Medicare & Medicaid Services 2001). We explored this rationale by examining the share of ancillary services received by patients on the same day as a visit. Our analysis of Medicare claims data indicates that several types of ancillary services are infrequently provided on the same day as a patient's visit. Specifically, we found that outpatient therapy is rarely provided on the same day as a related evaluation and management (E&M) or consultation office visit; fewer than half of advanced imaging, ultrasound, and clinical lab tests are performed on the same day as an office visit; and about half of standard imaging studies are performed on the same day as an office visit. These findings raise questions about one of the primary rationales for the IOAS exception.

Methodology

We used Medicare claims from 2007 and 2008 to examine outpatient therapy (which includes physical therapy, occupational therapy, and speech–language pathology

FIGURE 8–2

Percent of ancillary services performed on the same day as a related office visit varies by type of service, 2008



Note: The services in this figure are considered designated health services under the Stark self-referral law. This figure excludes services performed in hospitals and the professional component of imaging services. Outpatient therapy includes physical therapy, occupational therapy, and speech–language pathology services. Clinical lab tests include pathology services paid under the physician fee schedule and tests paid under the clinical lab fee schedule. Advanced imaging includes MRI, computed tomography, and nuclear medicine. Ultrasound includes echocardiography and other echography. Standard imaging includes chest, breast, musculoskeletal, and other X-rays. Office visits include evaluation and management and consultation services provided in physicians' offices.

Source: MedPAC analysis of 5 percent carrier Standard Analytic File from CMS, 2008.

services), clinical lab tests, anatomic pathology tests, and diagnostic imaging. We focused on these services because they are covered by the IOAS exception and are frequently provided in physicians' offices or other nonhospital settings.[7] For the purposes of the Stark law, CMS includes anatomic pathology tests—in which a tissue sample is acquired through a biopsy or other procedure—in the category of clinical lab tests. Although radiation therapy is also covered by the IOAS exception, we excluded it from our analysis because radiation oncologists do not bill for E&M services during an episode of radiation treatment. Instead, they bill for a radiation treatment management code that covers patient management related to a week's worth of treatment sessions (Centers for Medicare & Medicaid Services 2009c).[8]

Because the goal of our analysis was to focus on office-based services, we excluded ancillary services provided in inpatient or outpatient hospital settings. For imaging services, we included both global and technical component (TC) claims for tests that were performed in a physician's office or an independent diagnostic testing facility (IDTF) but excluded professional component claims for interpreting the studies to avoid double-counting the number of examinations. A global or TC claim indicates that the study was conducted in a physician's office or IDTF.

We determined whether each claim for outpatient therapy, a clinical lab test, or diagnostic imaging could be linked to an E&M or consultation visit in a physician's office for the same beneficiary.[9] Next, we examined whether the ancillary service was performed on the same date as the visit, within 7 days after the visit, or within 14 days after the visit.

A visit was assumed to be related to an imaging or clinical lab service if:

- the office visit appeared on the same claim as the imaging or clinical lab service, or

- the same physician who provided the office visit also ordered the test.

We used a different algorithm for outpatient therapy services because claims for these services do not indicate which physician ordered the service. An office visit was assumed to be related to an outpatient therapy service if:

- the office visit appeared on the same claim as the outpatient therapy service, or
- the office visit shared the same diagnosis category as the outpatient therapy service.

We used Clinical Classifications Software from the Agency for Healthcare Research and Quality to group the diagnosis codes from the International Classification of Diseases, Ninth Revision, into broader diagnosis categories.

We examined ancillary services provided in both self-referral and non-self-referral situations, because we wanted to assess how frequently these services were performed on the same day as an office visit, regardless of whether the service was provided by a self-referring physician. In addition, it is difficult to identify whether an outpatient therapy service was performed by a therapist employed by a physician group (see pp. 225–226). In addition to analyzing imaging across all specialties, we performed the analysis separately for radiologists and IDTFs, which are generally not permitted by Medicare to order diagnostic imaging, and for other specialties, which are permitted by Medicare to order and perform imaging studies.[10]

Results

Outpatient therapy services are not generally associated with a related office visit. In 2008, only 3 percent of outpatient therapy services were provided on the same day as an office visit, 9 percent within 7 days after a visit, and 14 percent within 14 days after a visit (Figure 8-2). These results are not surprising; under Medicare's coverage rules, a beneficiary does not need to receive an office visit with each outpatient therapy service. Instead, a physician must certify the initial plan of care within 30 days of the initial therapy service and must recertify the plan of care every 90 days (Centers for Medicare & Medicaid Services 2007b). In addition, patients tend to receive multiple sessions of therapy within an episode of care (Ciolek and Hwang 2004).

Slightly fewer than half of clinical lab tests and anatomic pathology services were performed on the same day as a related office visit.[11] The share of these services linked to an office visit increased from 44 percent to 52 percent when we expanded the time window to 14 days. Our analysis may overstate the proportion of these services performed on the same day or within 14 days of a visit, because Medicare rules require that the date of service on a claim reflect the date on which the specimen was collected from the patient, not the date when the test was actually performed (42 CFR § 414.510). In other words, if the specimen for a clinical lab or pathology test was collected on the same day as an office visit but the test was performed the following day, this test would be counted as having been performed on the same day as the visit.

Advanced imaging services—MRI, CT, and nuclear medicine—were less commonly provided on the same day as an office visit than ultrasound and standard imaging, such as chest, musculoskeletal, and other X-rays (Figure 8-2). Only 10 percent of advanced imaging services were performed on the same day as a related office visit. This proportion increased to 33 percent of services within 7 days after a visit, and 41 percent within 14 days after a visit. Slightly more than one-quarter of ultrasound studies (which include echocardiography and other ultrasound) were performed on the same day as an office visit, 40 percent within 7 days after a visit, and 46 percent within 14 days after a visit. Just over half of standard imaging services were performed on the same day as an office visit; this share increased to 59 percent when we expanded the time window to 14 days. The lower rate at which advanced imaging studies were performed on the same day as an office visit may reflect the need to schedule certain imaging procedures in advance. For example, patients may need to fast for several hours before receiving CT studies with contrast material (Mayo Foundation for Medical Education and Research 2008, Radiological Society of North America 2009).

Within the category of advanced imaging, there was variation in how frequently different modalities were furnished on the same day as an office visit, ranging from 8.2 percent of studies in the category of "MRI: other" to 23.8 percent of "CT: head" studies (Table 8-1, p. 224). Also worth noting is that the proportion of all imaging studies performed on the same day as an office visit declined by 1.6 percentage points (4.2 percent) from 2007 to 2008, even though the total volume of imaging increased by 3.3 percent per beneficiary. For example, from 2007 to 2008, the rate of nuclear medicine studies furnished on the same day as a visit fell from 9.7 percent to 8.5 percent and the rate of "MRI: brain" studies declined from 9.7 percent to 8.4 percent.

TABLE 8–1 **Wide variation in how frequently different types of imaging services were performed on same day as a related office visit, 2008**

Type of imaging	Proportion of services performed on same day as office visit
Advanced imaging	
MRI: brain	8.4%
MRI: other	8.2
CT: head	23.8
CT: other	13.1
Nuclear medicine	8.5
Echocardiography	25.9
Other echography	28.4
Standard imaging	50.9
All imaging	35.4

Note: CT (computed tomography). All imaging services in the table are considered designated health services under the Stark self-referral law. Table excludes the professional component of imaging services (unless it is part of a global service) and imaging performed in hospitals. Office visits include evaluation and management and consultation services provided in physicians' offices.

Source: MedPAC analysis of 5 percent carrier Standard Analytic File from CMS, 2008.

When we separately examined imaging studies by specialty, we found that imaging services were more likely to be provided on the same day as a visit when they were performed by a nonradiologist than by a radiologist or an IDTF.[12]

Options to address concerns about the growth of ancillary services

We examine three types of options to address concerns about the growth of ancillary services:

- limiting the types of services or physician groups covered by the IOAS exception,
- developing payment tools to mitigate incentives to increase volume, and
- adopting a targeted prior authorization program for advanced diagnostic imaging services.

Limiting the types of services or physician groups covered by the in-office ancillary services exception

We describe three ways in which the types of services or physician groups covered by the IOAS exception could be limited:

- exclude outpatient therapy and radiation therapy from the exception,
- limit the exception to physician practices that are clinically integrated, and
- exclude diagnostic tests that are not usually provided during an office visit from the exception.

In prior work, the Commission has examined various aspects of the Stark regulations and recommended ways to strengthen them but has not recommended changes to the IOAS exception (Medicare Payment Advisory Commission 2005b). To address concerns about rapid volume growth, we recommended that CMS add nuclear medicine services to the list of DHS, which CMS subsequently did (Centers for Medicare & Medicaid Services 2005, Medicare Payment Advisory Commission 2005b). The Commission also recommended that CMS expand the definition of physician ownership to include investments in an entity that derives a substantial proportion of its revenue from another provider, such as physician ownership of imaging equipment that is leased to a hospital (Medicare Payment Advisory Commission 2005b).

In response to this recommendation, CMS expanded the definition of an "entity" under the Stark law to include an entity that performs DHS in addition to an entity that bills Medicare for DHS (Centers for Medicare & Medicaid Services 2008a). This change prohibited physicians from referring Medicare patients to an entity that performs DHS if they are owners or investors in that entity. CMS also prohibited "per click" leasing arrangements in which physicians lease equipment or office space to or from a DHS provider on a per service basis (Centers for Medicare & Medicaid Services 2008a).

Excluding outpatient therapy and radiation therapy from the in-office ancillary services exception

Under this option, outpatient therapy (physical therapy, occupational therapy, and speech–language pathology services) and radiation therapy would be excluded from the IOAS exception. They are the primary therapeutic services covered by the exception that are provided in

physicians' offices.[13] Physician investment in therapeutic services may differ from investment in diagnostic services because of its potential to skew clinical decisions about the treatment of patients. For example, some have suggested that financial incentives may influence how cancer patients are treated. One study found that physicians who were paid more generously than the national average for chemotherapy drugs prescribed more costly chemotherapy regimens for certain types of cancer patients (Jacobson et al. 2006). In addition, therapeutic services are not typically ancillary to a patient's office visit. Outpatient therapy and radiation therapy generally involve multiple sessions and are rarely initiated on the same day as an office visit.[14]

Changes in self-referral of radiation therapy The IOAS exception applies to radiation therapy services when a physician who is not a radiation oncologist refers a patient for radiation therapy that is performed in his or her office. According to the Stark law, it is not considered a self-referral when a radiation oncologist orders radiation therapy for a patient as long as the consultation was initiated by another physician and the radiation oncologist supervises the treatment.

In 2008, specialties other than radiation oncology and radiology (such as urology, general surgery, and medical oncology) received $104 million in Medicare payments for radiation therapy, an 84 percent increase from 2003.[15] Because of the rapid overall growth in spending on radiation therapy, however, these specialties accounted for about the same share of total physician fee schedule payments for radiation therapy in 2008 (5.1 percent) as in 2003 (4.7 percent). However, the actual share of spending on radiation therapy delivered under self-referral arrangements may be higher than 5 percent because some of the services billed by radiation oncologists may be provided in a self-referral situation. For example, a physician group may employ a radiation oncologist and refer patients to him or her for radiation therapy. In these cases, the radiation oncologist may bill Medicare directly and reassign payments to the physician group that employs him or her. Unfortunately, Medicare claims data do not indicate whether the payment was reassigned to another provider.

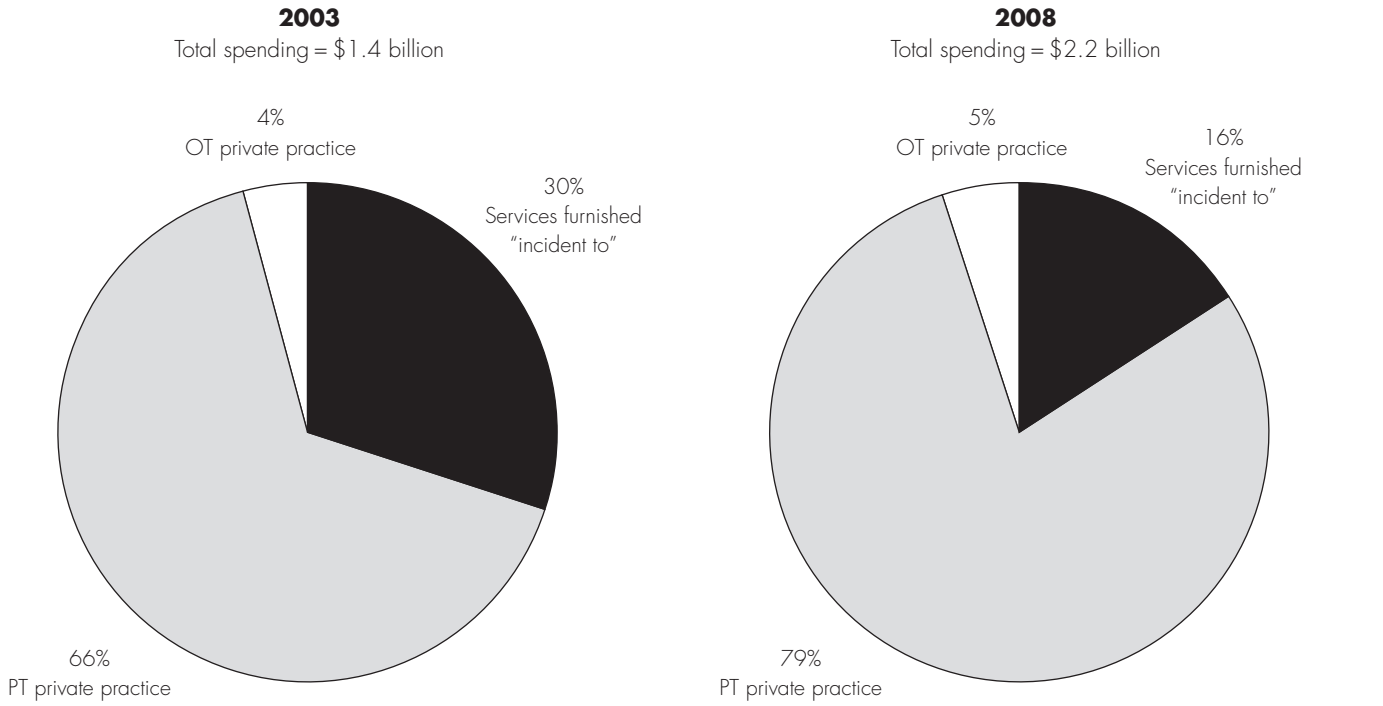
Changes in self-referral of outpatient therapy The IOAS exception applies to outpatient therapy when a physician orders therapy for a patient and the services are provided by therapists who are employed by the physician's practice. Therapists who work in a physician's office may provide services as "incident to" a physician service or may bill Medicare independently under their own billing number and reassign the payments to the physician group. "Incident to" services must meet certain requirements, including that they be supervised by a physician who is in the same office suite when the services are performed (Office of Inspector General 2006). However, therapists who bill Medicare independently (called therapists in private practice (TPP)) do not require physician supervision. Physicians who employ therapists may prefer that the therapists bill Medicare independently because a physician is not required to be in the office suite when therapy is provided. Therapists who bill independently may also work in their own offices rather than in a physician's office; the IOAS exception does not apply in these situations.

Overall, spending for outpatient therapy services paid under the physician fee schedule grew from $1.4 billion to $2.2 billion between 2003 and 2008 (Figure 8-3, p. 226). These figures exclude outpatient therapy provided in hospital outpatient departments, outpatient rehabilitation facilities (ORFs), comprehensive outpatient rehabilitation facilities (CORFs), and skilled nursing facilities (SNFs). The share of spending for therapy services that were provided incident to a physician's service declined by nearly half between 2003 and 2008, from 30 percent to 16 percent. "Incident to" services are provided by therapists employed by a physician's practice. Meanwhile, the share of payments for therapy services delivered by physical or occupational TPP, who bill Medicare independently, grew from 70 percent to 84 percent. Several factors help explain the growth of services provided by TPP:

- In 1999, CMS allowed licensed employee therapists to begin billing Medicare independently; previously, owners of therapy practices had to be on site and do all the billing for services furnished by employed therapists.
- Also in 1999, CMS eliminated payment disparities between settings for therapy services; as a result, many therapists changed their practice from an ORF to an independent practice to avoid the survey and certification requirements of institutional settings.
- CMS clarified in 2003 that therapists could be employees of physicians' practices but still be considered in independent practice, which allowed physicians to employ therapists without being responsible for supervising their work (Medicare Payment Advisory Commission 2006a).

FIGURE 8–3

Physician fee schedule spending for outpatient therapy services shifted to therapists in private practice, 2003–2008



Note: PT (physical therapy), OT (occupational therapy). Outpatient therapy includes physical therapy, occupational therapy, and speech–language pathology services. "Incident to" therapy services must meet certain requirements, including that they be supervised by a physician who is in the same office suite when the services are performed. Physical and occupational therapists in private practice bill Medicare independently and do not require physician supervision. Medicare claims data do not indicate if therapists in private practice are employed by a physician group or work in their own offices. These numbers exclude outpatient therapy provided in hospital outpatient departments, outpatient rehabilitation facilities, comprehensive outpatient rehabilitation facilities, and skilled nursing facilities.

Source: MedPAC analysis of 5 percent carrier file from CMS, 2003–2008.

We are unable to estimate the proportion of the payments for TPP that was related to self-referral because Medicare claims do not indicate whether TPP are employed by a physician group or work in their own offices (Medicare Payment Advisory Commission 2006a).

Concerns about excluding outpatient therapy and radiation therapy from the in-office ancillary services exception There may be a concern that excluding outpatient therapy and radiation therapy from the IOAS exception would inconvenience patients by forcing them to receive care at hospitals. However, physical and occupational therapists can deliver therapy in private practices that are separate from physician groups. Patients can also receive therapy in ORFs, CORFs, and SNFs. In addition, patients may receive radiation therapy from radiation oncologists who practice outside hospitals. According to data from IMV, a market research firm, 30 percent of radiation therapy sites were outside of hospitals in 2004 (IMV Medical Information Division 2005).

There may also be a concern that this policy change would have an impact on rural providers. However, this change would not affect rural providers who are exempt from self-referral restrictions under the rural exception to the Stark law. The rural exception covers providers who furnish at least 75 percent of their DHS to beneficiaries who live in rural areas (42 CFR § 411.356(c)). However, a concern has been raised that some rural beneficiaries may receive outpatient therapy and radiation therapy at physician practices in urban areas, which could be affected by this policy change.

Another issue is that this change would affect clinically integrated groups that care for a wide variety of cancers using a range of modalities, including radiation therapy. For example, practices that include both medical and radiation oncologists would not be able to perform radiation therapy on patients referred by a medical oncologist in the group to a radiation oncologist in the same group.

Limiting the in-office ancillary services exception to physician practices that are clinically integrated

Under this approach, the IOAS exception would be limited to physician groups that can demonstrate clinical integration. The goal of this strategy is to balance the risks of higher volume associated with self-referral with the potential benefits of clinically integrated practices, such as the capacity to provide comprehensive and coordinated care. However, under the current FFS payment system, even clinically integrated groups have a financial incentive to increase volume. Thus, Medicare should begin developing new payment models that reward providers for restraining volume growth while improving quality.

A key issue under this approach would be defining "clinical integration" in a way that could be measured. One option would be to require that each physician in the group provide a substantial share of his or her services—such as 90 percent—through the group. Such a rule would increase the likelihood that the physicians in the practice interact with each other frequently, share information about patients, and follow similar clinical pathways. Practices that employ or contract with a physician on a part-time basis to supervise or interpret diagnostic tests or to supervise radiation treatment would no longer qualify for the IOAS exception if the part-time physician also works for other groups. Arrangements with part-time physicians create a financial incentive to increase volume without the potential benefits of a clinically integrated practice.

Currently, the IOAS exception requires that physicians who are members of a group must provide at least 75 percent of their services through the group (see text box, pp. 218–219. This rule applies only to members of the group (owners and employees) and takes into account all the services provided by all members of the group. In other words, an individual group member could furnish 50 percent of his or her services through the group as long as the aggregate percentage for the entire group (based on all the members) equals or exceeds 75. In addition, physicians who independently contract with the group are not considered "members" of the group and therefore do not count toward the 75 percent rule. Thus, groups may contract with physicians on a part-time basis to provide or supervise ancillary services without affecting their ability to comply with the 75 percent rule. Under the option described above, each physician in the group—whether a member of the group or an independent contractor—would have to provide a substantial share of his or her individual services through the group.

Restricting the IOAS exception to clinically integrated groups would limit the number of practices that qualify for the exception, but the groups that qualify would still have a financial incentive to order more ancillary services under Medicare's FFS payment systems. Thus, it is important for the program to move toward payment models that reward providers for constraining volume growth while improving the quality of care. Examples include paying providers a fixed amount for a group of beneficiaries (capitation), paying providers for an episode of care (bundling), and paying bonuses to accountable care organizations that achieve both quality and cost targets (Medicare Payment Advisory Commission 2009a). Restricting the IOAS exception to clinically integrated groups could encourage the development of integrated practices, which could be well-positioned to succeed under a new payment model.

Excluding diagnostic tests that are not usually provided during an office visit from the in-office ancillary services exception

Under another approach, diagnostic tests that are generally not provided on the same day as an office visit would be excluded from the IOAS exception. The rationale for this option is that certain tests are rarely used by physicians to make a diagnosis at the time of the patient's office visit, which is a key justification for the exception. Among imaging services, there was wide variation in how frequently different modalities were furnished on the same day as an office visit in 2008, ranging from 8.2 percent of "MRI: other" studies to 50.9 percent of standard imaging tests (Table 8-1, p. 224). There was also wide variation in how frequently different high-volume clinical lab tests were furnished on the same day as an office visit in 2008, ranging from 9.6 percent for parathyroid hormone tests (Healthcare Common Procedure Coding System (HCPCS) code 83970) to 49.9 percent for natriuretic peptide tests (HCPCS 83880).

Options for defining which diagnostic tests should be covered by the IOAS exception include an empirical approach based on the frequency with which certain services are provided on the same day as an office visit or a clinical approach based on which tests do not generally require advance patient preparation. Under the empirical approach, CMS could calculate the percent of the time each test (or category of tests) is performed on the same day as an office visit and then set a threshold for services that would be covered by the IOAS exception, such as 50 percent. CMS could rebase this threshold every few years to account for changes in technology and practice. Under a clinical approach, CMS could consult with clinical experts

to determine which tests require patient preparation and are therefore scheduled in advance; these services would be excluded from the IOAS exception. For example, patients may need to fast for several hours before receiving CT studies with contrast material (Mayo Foundation for Medical Education and Research 2008, Radiological Society of North America 2009).

Excluding tests that are generally provided on a different day from an office visit would present several challenges. The rate at which services are provided on the same day as an office visit may vary by type of condition, patient severity, and other factors, which could make it difficult for CMS to apply a common rule to all providers. The empirical approach for determining which services should qualify for the IOAS exception may involve setting an arbitrary threshold. In addition, physicians may begin billing for office visits when they perform diagnostic tests in their offices to reach the threshold to qualify for the exception.

Payment tools to mitigate incentives to increase volume

Potential payment changes that could dampen incentives to increase the volume of ancillary services include:

- reducing payment rates for diagnostic tests performed by self-referring physicians, and
- improving payment accuracy for ancillary services in the physician fee schedule and eventually creating larger payment bundles that include ancillary services often furnished during the same encounter or the same episode of care.

Reducing payment rates for diagnostic tests performed by self-referring physicians

Medicare could reduce payment rates for diagnostic tests performed by self-referring physicians to offset additional Medicare spending related to self-referral, while continuing to allow physicians to provide these services in their offices. Studies by the Commission and other researchers have found that physicians who furnish imaging services in their offices refer patients for more imaging than other physicians (Baker 2008, Gazelle et al. 2007, Government Accountability Office 1994, Hillman et al. 1990, Hillman et al. 1992, Kouri et al. 2002, Litt et al. 2005, Medicare Payment Advisory Commission 2009a). Two of these studies are described further in the text box. In addition, OIG found that, on average, patients of physicians who owned clinical labs received 45 percent more lab tests than all Medicare beneficiaries (Office of Inspector General 1989). A series of OIG audits of 2004 Medicare claims from three group practices found that these groups increased their ordering of pathology services after they established their own labs (Office of Inspector General 2007a, Office of Inspector General 2007b, Office of Inspector General 2007c). For example, one practice increased the average number of tissue examinations it ordered per claim from one to nine after opening its own lab. However, these results may not be generalizable because they are based on only three practices.

Design options Reducing payment rates for diagnostic tests performed by self-referring physicians would involve several design choices. One issue is whether to apply this policy to all diagnostic tests covered by the IOAS exception or only to certain tests. Reducing payments for all diagnostic tests would be simpler to implement but would affect many more providers as well as services frequently provided in physicians' offices, such as low-cost X-rays and lab tests. Alternatively, this policy could be limited to high-cost imaging services and lab tests or those tests that are not commonly performed on the same day as an office visit (such tests may be less likely to lead to rapid diagnosis and treatment). For example, certain advanced imaging procedures—such as CT with contrast or nuclear medicine studies—are scheduled in advance because the patient needs to fast before the procedure or the provider needs to prepare radiopharmaceuticals for the study.

Another issue is how to determine the size of the payment reductions that would be applied to self-referred diagnostic tests. One option is to base the reduction on empirical estimates of the effects of self-referral. However, such estimates vary widely for imaging services, depending on the methodology, type of condition, and type of imaging (Medicare Payment Advisory Commission 2009a). For example, a recent study estimated that acquiring an MRI scanner led to a 22 percent increase in the probability of ordering MRI scans by orthopedic surgeons and a 28 percent increase in the probability of ordering MRI scans by neurologists (Baker 2008) (see text box). An analysis conducted by the Commission found that episodes with a self-referring physician had spending on imaging that was higher than expected given the patient's severity of illness, geographic market, and physician specialty (Medicare Payment Advisory Commission 2009a) (see text box). Conversely, episodes with no self-referring physician had lower-than-expected spending on imaging. The differences between the adjusted spending for episodes with and without a self-referring physician ranged from 5 percent

Recent studies show that physician self-referral is associated with additional use of imaging services

Two recent studies show that physician self-referral is associated with additional use of imaging services. In the first study, the Commission used 2005 Medicare claims for beneficiaries in six markets to analyze whether physician self-referral affected the use of imaging within an episode of care, adjusting for differences in patients' clinical conditions and the type of imaging (Medicare Payment Advisory Commission 2009a). Our primary definition of a self-referring physician was one who referred more than 50 percent of the imaging studies that he or she ordered to his or her practice. We examined 22 combinations of different types, or modalities, of imaging (such as computed tomography and MRI) and conditions (such as migraine headache, ischemic heart disease, and joint degeneration of the back). Our methodology allowed us to compare the observed cost of a given episode with the average cost of similar types of episodes (adjusting for severity of illness, physician specialty, and market area). There were two key results:

- Compared with episodes with no self-referring physician, a higher proportion of episodes with a self-referring physician received at least one imaging service. The magnitude of the variation ranged from 2 to 23 percentage points depending on the condition and modality; in all but one comparison, the differences were statistically significant. The magnitude of the variation was 10 percentage points or more for 14 of the 22 condition–modality pairs.

- Episodes with a self-referring physician had a higher mean ratio of observed-to-expected spending for an imaging modality than episodes with no self-referring physician. The differences between the ratios ranged from 5 percent to 104 percent, depending on the condition and modality. (For all the comparisons, the differences were statistically significant.) For example, the mean spending ratio for nuclear medicine for ischemic heart disease was twice as high for episodes with a self-referring physician as for episodes with no self-referring physician. Across all condition–modality pairs, the mean difference between ratios was 68 percent (weighted by the number of episodes in each pair).

In a study presented at a Commission meeting, Laurence Baker found that patients of neurologists and orthopedic surgeons who owned MRI machines were more likely to receive an MRI scan within seven days of an office visit than patients of neurologists and orthopedic surgeons who did not own MRI machines (Baker 2008). For example, 14.5 percent of patients who saw a neurologist who owned a machine received an MRI scan within seven days of their visit, compared with 9.3 percent of patients who saw other neurologists. This analysis used Medicare claims data from 1999 through 2005. Baker also used a regression model to examine the impact of acquiring an MRI machine on a physician's likelihood of ordering MRI studies, controlling for physician and patient characteristics. Acquiring an MRI scanner led to a 22 percent increase in the probability of ordering MRI scans by orthopedic surgeons and a 28 percent increase in the probability of ordering MRI scans by neurologists. ■

to 104 percent, depending on the condition and type of imaging (modality). Across all condition–modality pairs that we examined, spending for episodes with a self-referring physician was 68 percent higher than spending for episodes without a self-referring physician, on average, adjusted for differences in severity of illness, geographic market, and physician specialty.

Another option for determining the payment reductions for self-referred diagnostic tests would be to consider whether some of the payment for a test includes activities that have already been performed by the referring physician or his or her practice. For example, payment for the professional component of an imaging service generally includes preservice activities such as reviewing the patient's history, prior studies, medical records, and indications for the test. If the physician who supervised or interpreted the study is the same physician who ordered the service, this physician should have already obtained and reviewed much of this information during a prior E&M service. The payment for

an imaging study also includes post-service activities such as discussing the findings with the referring physician; this activity is unnecessary when the referring and interpreting physician are the same. Therefore, it may be appropriate to remove some of these preservice and postservice activities from the payment rate for imaging studies performed by self-referring physicians.

Depending on the size of the payment reduction for diagnostic tests performed by self-referring providers and physicians' behavioral responses to such a change, a reduction could offset some or all of the additional Medicare spending associated with self-referral. Physicians who already own testing equipment may respond by increasing their volume to offset the payment reduction. On the other hand, a payment reduction may discourage physicians from investing in new equipment for their offices.

Implementation issues This option could be implemented by adding a field to the Medicare claim form that records whether a diagnostic test was billed by a physician group that provided the test under the IOAS exception. If so, the payment reduction would be applied. This approach would rely on practices to accurately report whether the test was provided under the exception rather than requiring CMS to survey individual practices. Physicians would have a strong incentive to accurately report this information to avoid submitting false claims. Under the False Claims Act, the government may levy substantial penalties on those who submit a false claim to the government. To further encourage compliance, OIG could audit a random sample of practices that bill Medicare for diagnostic tests.

Improving payment accuracy and combining discrete services into larger units of payment

This section describes two related approaches: improving the accuracy of payments for discrete services in the physician fee schedule and combining discrete services into larger units of payment (packaging or bundling). The Commission has expressed concerns about the mispricing of services in the physician fee schedule and the inequity of a payment system that allows some physicians to generate volume and revenue more easily than others (Medicare Payment Advisory Commission 2010). The rapid growth of many services covered by the IOAS exception, combined with the use of newer technologies such as MRI and intensity-modulated radiotherapy equipment, suggests that payment rates for these services may need to be reexamined.

Improving payment accuracy for discrete services We have made several recommendations to address mispricing of discrete services. Some of these recommendations affect a broad range of physician services, while others focus on a specific set of services. The Commission has recommended ways to improve the process through which CMS reviews the fee schedule's relative values for accuracy (Medicare Payment Advisory Commission 2006b). Although CMS—with advice from the American Medical Association Specialty Society Relative Value Scale Update Committee—has improved the review process since our recommendations, there are still areas that should be addressed. For example, many procedures have never been reexamined to check whether the average time and intensity of effort to perform them has decreased due to advances in technology, technique, and other factors.

Other Commission recommendations relate to specific types of services. For example, we recommended that Medicare increase the equipment use rate assumption for expensive diagnostic imaging equipment from 25 to 45 hours per week, or 90 percent of the time that providers are assumed to be open for business (Medicare Payment Advisory Commission 2009b). This policy was adopted by CMS for 2010 with a four-year phase in. It reduced practice expense payments for costly imaging services and increased such payments for other physician services. The Patient Protection and Affordable Care Act of 2010 (PPACA) sets the equipment use rate assumption for expensive imaging equipment at 75 percent beginning in 2011; the savings from this policy will return to the Part B trust fund.

The Congress and CMS have made other payment changes that have affected imaging services in recent years.

- The Deficit Reduction Act of 2005 (DRA) capped physician fee schedule rates for the TC of imaging services at the level of hospital outpatient rates. This provision reduced the fee schedule amounts for many imaging services.
- In 2007, CMS made major changes to the method for calculating practice expense relative value units (RVUs) under the physician fee schedule. These changes—which were phased in over four years—shifted practice expense payments from imaging services and major procedures to E&M services and nonmajor procedures (Medicare Payment Advisory Commission 2007b).

- For 2010, CMS began using more current practice expense data from a new, privately sponsored, voluntary survey of physician and nonphysician specialties (Centers for Medicare & Medicaid Services 2009d). This change is redistributing practice expense RVUs among specialties and services over a four-year period. Several of the specialties experiencing a decline in RVUs (such as radiology, cardiology, and IDTFs) perform many imaging services.
- The PPACA reduced the TC payment for imaging services by 50 percent when providers furnish multiple studies on contiguous body parts during the same session.[16]

The Commission plans to continue addressing mispricing issues in the future. For example, we will consider the validity of estimates of the typical amount of time a physician spends furnishing physician fee schedule services (Medicare Payment Advisory Commission 2010). These time estimates explain much of the variation in payments for physician work, and questions have been raised about them. The Commission will investigate the availability of data that CMS could use to validate the time estimates.

Combining discrete services into larger units of payment

In addition to improving payment accuracy for individual services, Medicare could combine multiple services often furnished together during the same encounter or the same episode of care into a single payment rate, which could create incentives to use ancillary services more efficiently. The Commission has expressed concern that the relatively small units of payment for many physician services could give physicians a financial incentive to increase volume (Medicare Payment Advisory Commission 2005a).

Under an approach known as packaging, all the services provided during one encounter with a provider are combined into a single payment rather than each discrete service receiving a separate payment. For example, the hospital outpatient prospective payment system packages radiopharmaceuticals and certain imaging services with their associated procedures. This concept could be applied to the physician fee schedule by providing physicians a single payment for an office visit that covers the cost of the visit as well as all lab tests and X-rays provided during the visit. In its proposed rule for physician fee schedule services for 2009, CMS expressed interest in payment approaches that would account for efficiencies when services are provided together, such as packaging services into a single payment unit or discounting payments for the additional service(s) (Centers for Medicare & Medicaid Services 2008b).

Under a concept known as bundling, all the services furnished during multiple encounters are combined into a single payment. Under the physician fee schedule's global surgical policy, for example, many surgical procedures are subject to a global payment rate that includes some preoperative care, the surgery, and postoperative visits in the hospital and office (for 10 days or 90 days after the surgery, depending on the type of surgery). Bundling may be limited to services furnished by a single provider or could include services delivered by multiple providers. For example, the Commission has recommended that CMS conduct a pilot program to test bundled payment for all services associated with a hospitalization episode (Medicare Payment Advisory Commission 2008).

Packaging and bundling are not mutually exclusive. Bundling policies may build on packaging policies as Medicare moves from a disaggregated payment system to one that is more integrated and focused on efficiency. For example, CMS may start by creating payment rates that encompass multiple services provided during a single encounter (packaging) and then develop episode-based rates that incorporate multiple encounters related to common, high-cost chronic illnesses.

The advantage of a packaging or bundling approach with respect to ancillary services is that it could encourage all physicians—whether or not they benefit financially from performing ancillary services—to use tests and other ancillary services more prudently. Further, it would not disrupt self-referral arrangements that improve convenience and care coordination for patients. However, much analytic work would need to be done to identify and price cohesive bundles of services and to address situations in which multiple providers furnish services within a bundle.

Require certain self-referring physicians to participate in a prior authorization program for advanced diagnostic imaging

Under a prior authorization approach, Medicare could require self-referring physicians who order many more advanced imaging services (MRI, CT, nuclear medicine, and positron emission tomography (PET)) than their peers to participate in a prior authorization program for these services. Such a policy could involve two steps. First, CMS would identify self-referring physicians who are outliers in terms of their use of advanced imaging for a

given set of conditions (such as use of MRI for low back pain). Second, Medicare would require these physicians to participate in a prior authorization program, in which CMS or a contractor would review their requests to use imaging services to ensure that they are clinically appropriate before they are provided. As an interim step, CMS could provide confidential feedback to outlier physicians about their use of imaging for a period of time before requiring prior authorization.

Many private plans have initiated prior authorization programs to control the growth of high-cost imaging services (such as CT, MRI, nuclear medicine, and PET) and improve the appropriate use of these studies (Congressional Budget Office 2008, Government Accountability Office 2008, Iglehart 2009). According to radiology benefit managers, the vendors who operate these programs, the programs are based on appropriateness criteria developed by specialty groups such as the American College of Radiology and American College of Cardiology, literature reviews, and clinician panels. Some plans report that these programs significantly reduce the volume growth of expensive modalities, but there are no independent studies that measure the impact of prior authorization using a control group (Government Accountability Office 2008, Levin et al. 2010, Mitchell and Lagalia 2009, Tynan et al. 2008).

In prior authorization programs, physicians who wish to order certain studies must first obtain approval from the plan. The ordering physician submits a request that includes clinical information to the plan or the plan's contractor. The plan checks whether the request is consistent with its clinical criteria and, if so, approves the test. If not, the plan may request additional clinical information or deny the test. Some plans use a variation of preauthorization called prior notification. In these programs, ordering physicians provide clinical information to plans about studies they wish to order and receive feedback on whether the studies are appropriate. If the request does not meet guidelines set by the plan, it suggests an alternative approach but does not deny payment if the physician decides to order the original study.

The main benefit of a prior authorization approach is that it would ensure the appropriate use of advanced imaging by self-referring physicians who order many more studies than their peers, rather than imposing a blanket prohibition on physicians' performing advanced imaging services in their offices. The downsides of this policy include the potentially high administrative costs of establishing and managing a prior authorization program, the administrative burden on providers who are required to submit requests for prior approval, additional waiting time for patients to receive imaging, the perceived challenges to physicians' clinical autonomy, concerns about whether the clinical guidelines are based on sound evidence, the need for a public program like Medicare to have transparent criteria, and questions about the level and sustainability of spending reductions over time. Under a demonstration program authorized by the Medicare Improvements for Patients and Providers Act of 2008, CMS is in the process of developing appropriateness criteria for imaging services in consultation with specialty societies (Centers for Medicare & Medicaid Services 2009a).[17] Although the demonstration is not testing prior authorization, these criteria could eventually become the basis for a prior authorization or prior notification program focused on self-referring physicians.

Conclusion

This chapter has described the rapid growth of services covered by the IOAS exception—such as imaging, clinical lab tests, radiation therapy, and outpatient therapy—and evidence that imaging and physical therapy services are sometimes ordered inappropriately. Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current FFS payment systems, which reward higher volume. Therefore, the preferred long-term approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Because it will take several years to establish new payment models and delivery systems, we have explored several interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. These strategies could be considered individually or in combination, and each has strengths and weaknesses and the potential for unintended consequences. In future work, the Commission plans to further examine these options with the goal of crafting policy recommendations. ■

Endnotes

1 The Congress excluded most DME and parenteral and enteral nutrients, equipment, and supplies from the IOAS exception because there was no clear justification for referring physicians to offer these services (Medicare Payment Advisory Commission 2005c). CMS determined that physicians may provide a limited number of DME items required for a patient to ambulate from the physician's office—such as canes, wheelchairs, walkers, and crutches—as well as blood glucose monitors.

2 It is difficult to estimate the magnitude of self-referral involving outpatient therapy and radiation therapy services because the ordering physician is not listed on the claims for these services. Moreover, it is difficult to identify whether an outpatient therapy service was performed by a therapist employed by a physician group or one who works independently (Medicare Payment Advisory Commission 2006a).

3 We excluded specialties from our analysis that predominantly perform imaging or radiation therapy, such as radiology, radiation oncology, and independent diagnostic testing facilities.

4 In addition, practices may create separate pools of profits from imaging and other DHS services for separate subgroups of physicians, as long as each subgroup has five or more physicians. Physician subgroups may be based on specialty, practice location, level of referrals for ancillary services, or other factors (Johnson and Keegan 2006). The pool of profits may be distributed to each physician in the subgroup on a per capita basis or by another indirect method.

5 Such arrangements would have to comply with at least two other federal requirements: (1) the anti-kickback statute, which prohibits the offer, payment, or receipt of anything of value to induce the referral of patients for services reimbursed by federal health programs; and (2) the anti-markup rules, which apply to a physician who bills Medicare for diagnostic tests that are performed (or supervised) by a physician who does not share a practice with the billing physician. In such cases, Medicare will not pay more than the performing provider's net charge to the billing physician. The anti-markup rules do not apply to tests performed or supervised by a physician in the same building where the billing physician regularly furnishes patient care (42 CFR § 414.50).

6 Volume is measured as the units of service multiplied by each service's relative weight (relative value units) from the physician fee schedule. Thus, volume growth accounts for changes in both the number of services and the complexity, or intensity, of those services.

7 We used a file from CMS to determine which Healthcare Common Procedure Coding System codes are considered DHS.

8 However, radiation oncologists bill for an initial E&M service or consultation before treatment begins to evaluate the need for radiation therapy and its likely results (American Society for Therapeutic Radiology and Oncology and American College of Radiology 2010).

9 We excluded inpatient and outpatient hospital, nursing home, and emergency room visits because these visits would be unlikely to generate office-based ancillary services on the same day as the visit. We also excluded visits to federally qualified health centers or rural health clinics because Medicare pays an all-inclusive rate for these visits that includes preventive care and services that are provided incident to a physician's service.

10 All diagnostic tests must be ordered by the physician who is treating the beneficiary, and a radiologist performing a diagnostic procedure is not considered a treating physician (Centers for Medicare & Medicaid Services 2009b). There are limited situations in which a radiologist may alter the test ordered by the treating physician, such as determining whether to use contrast material.

11 We separately examined a common pathology service, tissue exam by a pathologist (Healthcare Common Procedure Coding System code 88305), and found that it was performed 33 percent of the time on the same day as an office visit.

12 Overall, nonradiologists accounted for 69 percent of imaging services performed outside of hospitals, while radiologists and IDTFs accounted for 31 percent.

13 Although other types of therapeutic services and products are covered by the Stark law, most of them are either excluded from the IOAS exception or are not provided in physicians' offices. For example, most types of DME and supplies are specifically excluded from the exception (42 CFR § 411.355 (b)). In addition, the exception covers home health services for physicians who treat patients in their homes.

14 Before radiation treatment begins, for example, a radiation oncologist generally provides an initial E&M service or consultation to evaluate the need for radiation therapy, followed by clinical treatment planning and therapeutic radiology simulation (American Society for Therapeutic Radiology and Oncology and American College of Radiology 2010).

15 Some radiation oncologists might identify themselves as radiologists because both specialties are certified by the American Board of Radiology.

16 Under this policy, Medicare will pay the full amount for the most expensive study but reduce payment for other studies performed during the same session by 50 percent.

17 The purpose of the demonstration is to test the impact of providing feedback to physicians about their use of imaging.

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