Health care costs are higher in the United States than in any other country in the world, and imaging services have been growing much more rapidly than other services. Studies have shown a tendency for increased utilization of services, including imaging services, when referring physicians have ownership interest in the services. In recent years, the CMS has taken some action with respect to how it pays for imaging, including reducing physician payments when multiple images are taken on contiguous body parts during the same visit, establishing a cap on payments for certain imaging services, and imposing an antimarkup rule on diagnostic tests. In addition, CMS has made some changes to the Stark rules, which included adding nuclear medicine to the list of designated health services, prohibiting certain per-service or per-click leasing arrangements, and prohibiting physicians from owning entities that sell services to providers that then bill for them under arrangements. Because it is unclear whether these policy changes will have much effect on imaging utilization, CMS will continue to seek new ways to rein in utilization. In the near future, CMS and the US Department of Health and Human Services are likely to attempt to curb utilization not only through postpayment review and education but also through its various initiatives on improving the quality of services furnished to Medicare beneficiaries.

**Key Words:** Self-referral, Stark, payment, utilization


Although the debate rages in Washington and across the country on how best to achieve health care reform and when it can be done, one thing everyone can agree on is that health care spending in the United States is out of control. The Dartmouth Institute put it bluntly: “The U.S. health care system is broken. Health care costs—already the highest in the world—are growing at a rate that poses a serious threat to patients, employers and the nation” [1]. The Dartmouth Institute claimed that health care spending across the United States varies widely from region to region and that higher spending does not necessarily result in better quality. In fact, in what it called the “paradox of plenty,” the Dartmouth Institute noted that access is worse where there are relatively more medical resources, because the more resources available, the more services are ordered. In particular, it notes that the more CT scanners available, the more scans patients will receive [1]. The Medicare Payment Advisory Commission (MedPAC) observed this variation in regions and stated that it is much more pronounced when it comes to imaging, and the difference from region to region for imaging is twice that seen for major procedures. The Office of Inspector General [2] found in a 2007 report that the growth in imaging has varied widely across the states, from a 24% increase to a 1,000% increase.

Similar findings were made by the McKinsey Global Institute [3,4] in a 2007 study that compared spending on health care in the United States with that in the rest of the world. It noted that in 2005, the United States spent $1.9 trillion, or 16% of its gross domestic product, on health care, compared with a median of 8.5% for 13 Organisation for Economic Co-operation and Development countries. McKinsey developed a measure called estimated spending according to wealth. If the United States were to fit this correlation curve, it should be spending about $3,990 per person on health care, yet in 2003, it spent $5,635 per capita. This was 48% higher
than Norway, the country with the next highest spending per capita, and more than twice the average of the other countries. If the United States did fit the average, it would have spent $477 billion less than it did.

What are the causes of the higher spending? According to McKinsey [3,4], it is not because the American population is sicker, despite the high prevalence of some conditions in the United States, such as heart conditions, diabetes, and certain types of cancer. Neither, McKinsey concluded, is it because of the extraordinarily expensive malpractice system, which it calls a “small contributor.” Rather, the higher spending is because the US health system intrinsically is more expensive. What part does imaging play in this? McKinsey stated that in the past, regulatory restrictions and the need for high upfront investment meant that only large facilities were typically able to afford the equipment necessary to provide tests such as MR and CT imaging; however, high procedure reimbursement coupled with low operating costs made it possible for freestanding outpatient centers to operate at costs 20% to 30% lower than those of hospitals. In particular, it noted favorable leasing arrangements for CT and MRI scans. It also noted that manufacturers of imaging and diagnostic equipment advertise to physicians the financial advantages of pursuing additional testing and what the break even point is in terms of the number of scans per day to cover the cost of purchasing or leasing the equipment. McKinsey stated that the pressure to break even or produce a profit is not easily addressed by payers’ reducing reimbursement because physicians can maintain revenue levels by increasing use through “clinical discretion.” The report analyzed the prevalence of MRI and CT scanners (although it indicated that similar results might be obtained for PET, ultrasound, and x-rays). It said that the United States has approximately 54% more CT scanners and 40% more MRI machines per million of population than other developed countries (only Japan has more scanners per capita than the United States). It noted in particular a study comparing the United States with the United Kingdom, which showed that the United States has 4 times the number of CT scanners as the United Kingdom and performs 4 times the number of scans.1 The authors of the study noted that CT scans are routinely requested by emergency room physicians in the United States, whereas in Britain, only leading trauma centers have CT equipment. British radiologists have argued that more people are scanned in the United States than is necessary, and therefore a great deal of money is wasted on tests that produce little benefit.

The McKinsey Global Institute [3,4] concluded that, given what it called the direct correlation between the number of CT and MRI scanners and the volume of procedures they perform, the excess capacity results in $40 billion of additional cost to the US health care system. McKinsey projected that in 2006, 1 in every 4 US citizens would undergo a CT scan. It stated that its conclusions were in line with other research showing that self-referring physicians order 2 to 8 more scans than the average physician and with evidence showing that not all these scans are necessary.

MedPAC noted in its 2005 report that imaging services have been growing much more rapidly than other services paid under the Physician Fee Schedule. Between 1999 and 2002, the per beneficiary average annual growth rate in the use of Physician Fee Schedule imaging services was twice as high for all Physician Fee Schedule services. Use of the following types of imaging services increased by 15% to 20% per year: MRI of parts of the body other than the brain, nuclear medicine, CT imaging of parts of the body other than the head, and MRI of the brain. Between 2002 and 2003, the growth rate slowed a little bit but was still almost twice as high as the growth rate for all other Physician Fee Schedule services. The Office of Inspector General’s [2] 2007 report, mentioned earlier, stated that advanced imaging paid under the Physician Fee Schedule grew 4-fold from 1999 to 2005, so that it now represented almost one-quarter of all advanced imaging paid under Medicare.

Over the years, studies focusing specifically on self-referral have shown a tendency for increased utilization of services, including imaging services, when referring physicians have ownership interest in the services. Although there may be those who continue to challenge the notion that self-referral and increased utilization go hand in hand, the real question—the dilemma, if you will—is not whether it exists but what, if anything, to do about it, and how to go about doing something. In June 2008, the US Government Accountability Office (GAO) [6] issued a report on Medicare Part B imaging services. In that report, GAO stated,

Policymakers face a particular dilemma with respect to spending for imaging services, one of the fastest-growing set of services paid for under the Medicare Part B physician fee schedule. On the one hand, cutting-edge imaging technology, such as [CT and MRI] scans, help diagnose and treat life-threatening diseases like cancer and heart disease; these technologies enable physicians to perform a wide range of less-invasive medical tests and procedures and can foster earlier diagnosis, quicker recovery, shorter hospital stays, and reduced disability than more invasive surgical or other procedures. On the other hand, in recent years, spending for CT scans, MRIs, and other imaging services paid for under the Medicare physician fee schedule has experienced double-digit growth.

One might add that along with the potential for health insurers to pay too much for imaging, increased utiliza-

---

1 See also Baker et al [5], who demonstrated clear relationships between the availability of CT and MRI scanners and their use.
tion carries with it the health risks associated with excessive radiation exposure [7]. And it is not clear that there is even a trade-off between the benefits of more imaging and the increased costs of the imaging. MedPAC has noted that in an unpublished study, the Dartmouth researchers found that regions providing more imaging services do not have better survival rates among Medicare beneficiaries. The study examined whether long-term survival in 3 cohorts—patients with heart attacks, those with colon cancer, and those with hip fractures—varied in regions with higher and lower imaging use and concluded that increased use of imaging services was not associated with improved survival in any of the 3 study populations.

CMS has taken some action with respect to how it pays for imaging. Since January 1, 2006, it has reduced physician payments when multiple images are taken on contiguous body parts during the same visit. Physicians receive the full fee for the highest paid imaging service in a visit, but fees for additional imaging services are reduced by 25%. The reduction is applied only to the technical component (TC).

Second, since January 1, 2007, CMS has established a cap on the Physician Fee Schedule payments for certain imaging services at the payment levels established in Medicare’s Hospital Outpatient Prospective Payment System (HOPPS). This means that payment for the TC of an image taken in a physician’s office does not exceed what Medicare pays for the TC of the same service performed in a hospital outpatient department. For example, in 2006, Medicare paid $903 under the Physician Fee Schedule for MRI of the brain, but it paid $506 for the same test under HOPPS. Under the Deficit Reduction Act of 2005 (DRA) payment change, in 2007, Medicare paid the lesser amount for this MRI, regardless of whether it was performed in a hospital outpatient department or in a physician’s office. In a September 2008 report, GAO noted the results of the DRA cap [8]. It stated that in 2007, the HOPPS cap resulted in reduced physician fees for the performance of about 1 in 4 imaging tests overall, and fees for advanced imaging tests were more likely than fees for other imaging tests to have been paid at the HOPPS rate. Of the 65.9 million physician imaging tests performed in 2007, about 23% were paid at the HOPPS rate. Fees for about 65% of the 13.3 million advanced imaging tests, which constituted about 20% of the total volume of imaging tests performed in 2007, were paid at a lower rate as a result of the HOPPS cap. In contrast, the fees for relatively few other imaging tests were affected by the cap, as about 13% of the 52.7 million other imaging tests performed in 2007 were paid at the HOPPS rate.

Third, CMS has expanded the diagnostic test rules to impose an antimarkup rule on the TC and the professional component (PC) of a diagnostic test. Under the revised rules, the TC or PC of a diagnostic test will be subject to the antimarkup payment limitation if the TC is not performed by a physician who bills at least 75% of services through the billing group or if the TC is not performed in the same building as where the test was ordered. The same rules apply to the PC of a diagnostic test.

CMS has also made some changes to the Stark rules. The Stark law was enacted on the basis of the premise that when physicians have a profit interest in services, there is an incentive to overrefer, and that incentive needs to be regulated. The Stark law generally prohibits physicians from referring patients to entities for designated health services, which include imaging, if the physicians or their immediate family members have financial relationships, unless an exception applies (and there are many exceptions). A financial relationship can be direct or indirect and includes both ownership and investment interests as well as compensation relationships. In MedPAC’s 2005 report, it made 3 recommendations for changes to the Stark rules: add nuclear medicine to the list of designated health services, prohibit certain per-service or per-click leasing arrangements, and prohibit physicians from owning entities that sell services to providers that then bill for them under arrangements. While at CMS, I developed rulemaking to implement all 3 recommendations.

With respect to nuclear medicine, MedPAC noted that in the 1998 proposed rule, CMS stated that it considered nuclear medicine, including PET, to fall within the category of “radiology services” covered by the Stark law, but that in the 2001 final rule, CMS reversed course and excluded nuclear medicine on the basis that it was not commonly thought of as radiology. MedPAC noted, however, that the ACR considered nuclear medicine to be radiology. This issue was brought to my attention shortly after I came to CMS in 2005, and my staff and I agreed that nuclear imaging sure looked like radiology to us, so we proposed to add nuclear imaging and nuclear radiation therapy to the list of designated health services, and this was finalized in the fall of 2005, with an effective date of January 1, 2007.

The two other issues identified by MedPAC, per-click leasing arrangements and under arrangements, are also examples of CMS’s taking a hard line in the 1998 proposed rule, only to retreat in the 2001 final rule. In both cases, I believed CMS got it right the first time, so these were important objectives of mine, and last year, in the Inpatient Prospective Payment System rule, CMS re-

---

2 A CT scan is equivalent to at least several hundred x-rays, creating a small but real cancer risk.
turned to the position in the 1998 proposed rule. Per-click leases, under which physicians receive payment each time equipment leased by the physicians to hospitals is used to treat patients referred by the physicians, seemed to be particularly susceptible to abuse. Physician ownership in service entities, such as freestanding MRI centers, that do not bill Medicare but rather sell the services to hospitals that then bill Medicare seemed to me a rather transparent end run around the general prohibition on physician ownership of designated health services. Both of these provisions become effective October 1, 2009.

Have these 3 policy changes had much effect on imaging utilization? I’m not sure that they have or will. By the time CMS proposed and finalized nuclear medicine as a designated health service, PET was becoming increasingly used in conjunction with CT imaging, so irrespective of whether PET became a designated health service, CT imaging already was, and it would be pretty difficult for someone to contend that PET/CT was not imaging just because PET was involved. Per-click leases seems to be mostly an issue for urologists and their lithotripters and lasers. The revised policy affecting under arrangements may have some effect, or it may just drive arrangements such as MRI and cardiac catheterization back into the office. And one thing I would have liked to do while I was at CMS but was unable to by the time I left, was revise the in-office ancillary services exception.

Under the in-office ancillary services exception, a physician can refer an imaging service to a radiologist or other physician in the same group practice (which would include both employee physicians and physicians who are only independent contractors with the group), and the resulting TC or PC will not run afoul of Stark, provided that it meets certain requirements, including the requirement that the service be performed in the same building as where the group practice has its patient care office, or in another building or office space that is owned by or leased exclusively by the group practice. Note that the in-office ancillary services exception protects both ownership relationships (whereby referring physicians are members or owners of the group) and compensation relationships (whereby referring physicians are only employees or independent contractors of the group). With respect to compensation arrangements, unlike the situation in which a physician has a financial relationship with a hospital that bills Medicare, the in-office ancillary services exception does not require that the compensation be made at fair market value or that it not take into account the volume or value of referrals.

In the calendar year 2008 Physician Fee Schedule proposed rule, CMS solicited comments as to whether it should propose rulemaking to restrict use of the in-office ancillary services exception. CMS stated that it believed that Congress intended to allow for the provision of certain services necessary in the diagnosis or treatment of the medical condition that brought a patient to a physician’s office. It noted that at the time of enactment, a typical in-office ancillary services arrangement might involve a clinical laboratory owned by physicians located on one floor of a small medical office building. Under such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited. CMS expressed its concern that currently, certain in-office ancillary services arrangements seem to be nothing more than enterprises established for the self-referral of designated health services. It noted that it had received comments in response to its physician self-referral rules that stated that the in-office ancillary services exception is susceptible to abuse.

There are certain difficulties in revising the in-office ancillary services exception. One difficulty, or perceived difficulty, is finding the authority to revise this statutory exception, but I think this can be overcome. I believe that there are grants of authority both within the exception itself and in the agency’s general rulemaking authority to change the exception. These changes could be broad, such as requiring that the services be furnished within a certain period of time of the office visit to receive protection under the exception. For example, a CT scan that is scheduled at the time of the office visit but is not performed until 10 days later would not qualify.

A more targeted change would be to require direct supervision to qualify for protection under the exception. The statute requires that a service be “directly supervised.” Moreover, in the 1995 final rule, and again in the 1998 proposed rule, CMS took the position that by specifying “directly supervised,” Congress was obviously referring to the long-standing level of supervision in the payment rules known as “direct supervision.” In yet another reversal of policy in the 2001 phase I final rule, however, CMS took the position that “directly supervised” means whatever the payment rules require for a particular service. Thus, if the payment rules require general supervision, then general supervision is all that is required to comply with the in-office ancillary services exception. Turning the clock back to require direct supervision to comply with Stark is something the agency clearly has the authority to do.

A bigger difficulty in changing the in-office ancillary services exception is the reluctance of CMS to disturb established business arrangements, particularly if it has concerns that patient access or patient expectations would be disrupted. CMS historically has been slow to make changes in the Stark rules, and not particularly aggressive when it does. That was not the case when my deputy, Lisa Ohrin, and I were there, but we have both
left, and it is too early to tell how aggressive the new director and deputy will be (but indications thus far are that they will take some time to review the landscape and will proceed cautiously, at least for the time being). While we were there, we took some criticism from both outside and inside the government (although outside CMS) about our approach. There are many who feel that the rules are too complex and that settled rules should be left undisturbed. I do not agree. Just as the agency and the industry have to adapt to statutory changes, sometimes quickly, so too should the agency be prepared to change its rules when they are no longer working, and so too should the industry be prepared to adapt rather than feeling it has a vested right in the status quo. But my opinion no longer counts.

Something else CMS did not do was to follow through in the calendar year 2009 Physician Fee Schedule final rule with the proposal to require physician offices to meet the requirements for independent diagnostic testing facilities. CMS was inundated with comments on this proposal and essentially punted, saying that it would defer doing anything until it implemented the accreditation requirements mandated by section 135 of the Medicare Improvements for Patients and Providers Act for advanced imaging, which are effective beginning January 1, 2012.

But what is likely to happen or not happen in the near future? First, what is not likely to happen, at least not this year.

I believe that it is very unlikely that there will be any proposed Stark changes this year of any note, and certainly not something as significant as a wholesale revision to the in-office ancillary services exception.3

I also think that it is unlikely that CMS will propose any more changes this year to the antimarkup rules. That has been a very labor intensive exercise over the past 3 years that has resulted in complex rules, and I do not see any significant changes to them. It is possible that CMS could propose tweaking them to address situations in which certain anatomic pathology codes escape the anti-markup rules because they do not require supervision, but I think that would be about all.

It is possible that CMS could propose to not allow reassignment under certain situations, but this is probably unlikely, at least this year. In answer to those physician group practices that say that they are using their own pathologists or radiologists because they have developed trusted working relationships with them, and that the pathologists or radiologists are more expert than others because they see the same types of work over and over, CMS could say, “Fine, use who you want, but that person and not the group is going to have to bill for the service.” Although I do not think we are likely to see this come out in a proposed rule this year, CMS could adopt this in the next few years. I believe that apart from making significant changes to the in-office ancillary services exception, this would be the most direct and effective way of reducing utilization caused by self-referral.4

And as noted above, CMS has not finalized its proposal to make the independent diagnostic testing facility standards applicable to physician offices because of the accreditation requirement, and given that accreditation is not required until 2012 and the fact that the agency usually does not implement statutory requirements early, it is unlikely that it would apply the independent diagnostic testing facility standards to physician offices any time soon.

So what is CMS likely to do? The US Department of Health and Human Services has said, in response to the June 2008 GAO [6] report referenced earlier, that its Medicare contractors have identified imaging services as an area that poses a high risk to the Medicare Trust Fund and that it was continuing to conduct ongoing medical review and provider education. I think that postpayment review and education are not going to be terribly effective by themselves. Perhaps if CMS’s recovery audit contractors make imaging a subject for medical review, that might have some effect. And if education comes in the form of evidence-based guidelines, that may have some effect.5

What about payment cuts? With regard to reducing payments, the Senate Committee on Finance posed some written questions to the secretary designee, one of which being whether it is necessary to impose further payment cuts given that GAO [8] found in its September 2008 report that Physician Fee Schedule payments for imaging actually declined in 2007 by 12.7% and that utilization for advanced imaging was flattening. The tone of the

---

3 The Senate Committee on Finance recently recommended that the in-office ancillary services exception be amended to require ordering physicians to disclose their ownership in certain imaging services provided through the use of the in-office ancillary services exception [9]. In my opinion, this proposal, if enacted, would do little to curb overutilization and might be counterproductive. That is, it could impede any CMS efforts to modify the exception if the legislation were seen as an endorsement of the use of the exception for sophisticated imaging procedures because it made only a minor tweak to the exception and failed to narrow the scope of the exception.

4 But see Smith-Bindman et al [10], who discussed the dramatic rise in the use of advanced imaging procedures in an environment with no opportunity to profit from self-referral, and thus concluded that legislative efforts that focus entirely on self-referral are likely not sufficient to limit the drivers of imaging.

5 The Senate Committee on Finance [9] has proposed that the secretary be required to work with national standards organizations, physician specialty societies, and others for the purpose of creating appropriateness criteria and use measures. An education and confidential feedback program would be developed to report patterns of adherence to these criteria and measures. Differential payments to physicians would be established, which would include lower payments for ordering physicians who were determined to be far outside the criteria for appropriate ordering.
question indicated that the committee did not think further cuts were advisable. Then-governor Kathleen Sebelius’s response is noteworthy, as she pointed out that the payment reduction was simply because of the DRA-mandated reduction and that per-beneficiary use of the tests subject to the cap increased 7.4%, almost 4 times faster than the 2.0% rate of growth in the utilization of imaging services not subject to the DRA cap. Does this mean that CMS itself would be imposing further payment cuts? I think to do so directly, CMS would probably need statutory authority. I question how effective they would be, at least initially. If physicians are getting paid less for imaging, they may think twice before investing in equipment, but those who have it already may just have the incentive to refer even more because they are getting paid less for each service. Another possibility would be the attempt to create bundled services that would include imaging within the package. That may require statutory authority.

In her written responses to the Senate Committee on Finance, HHS Secretary-designate Sebelius also stated that the president’s budget proposes to authorize private sector management tools for imaging services and that she “would continue to work with Congress on imaging payment reforms and closely monitor the effects on imaging payment reforms on beneficiary access to quality imaging services,” whatever that means [11]. She also responded to concerns that overhead costs associated with radiology benefit managers and preauthorization could limit care to Medicare beneficiaries by saying that radiology benefit management (RBM) organizations’ decisions are based on criteria they develop on the basis of clinical guidelines and that both the Congressional Budget Office and CMS’s Office of the Actuary have estimated Medicare savings from the use of RBM organizations. Of course, the secretary designate stopped short of saying that CMS would adopt the use of RBM organizations, but her comments certainly lean a lot further in that direction than did the skepticism expressed in CMS’s comments to the June 2008 GAO [6] report concerning the feasibility of RBM organizations.

As for profiling and privileging, CMS seems perhaps amenable to them. It has said that profiling fits with its efforts to improve quality and efficiency in Medicare. CMS has contracted with a firm to develop efficiency measures for certain anatomically specific imaging services. (The services are MRI and MR angiography [MRI of the blood vessels] of the brain, lumbar spinal MRI, CT imaging in combination with pelvic CT imaging, mammography, and cardiac single-photon emission CT.)

Given the mantra-like focus on quality at CMS and the Department of Health and Human Services, what I see on the immediate horizon is an attempt to rein in utilization through quality measures. I believe that in the agency’s thinking, one cannot separate unnecessary services from poor quality. As I noted earlier, CMS is already required by the Medicare Improvements for Patients and Providers Act to require accreditation for advanced imaging. What may be more effective, but also consistent with the continuing primacy of quality in CMS’s thinking, is the use of evidence-based guidelines for ordering imaging services. My sense is that a lot of physician self-referral is influenced by the profit motive and that this colors physicians’ discretionary judgment as to whether to order services or the type of services. If evidence-based guidelines exist, at least some of this profit-influenced self-referral will diminish because physicians will have to look the guidelines square in the face and decide to order the services anyway.

I also expect that CMS will attempt to curb utilization through the various demonstration programs it is running to improve quality and the reporting of quality measures. The CMS may also wish to use gain sharing as a means for aligning incentives (which was proposed by MedPAC as a means for addressing utilization). However, I believe the Stark exception for gain sharing that was proposed last year but not finalized is at least a couple years off, and unless or until Congress changes the civil monetary penalties statute (or the Office of Inspector General changes its interpretation of it with respect to paying physicians to reduce medically unnecessary services), it may not matter all that much if the Stark exception is finalized [12].

REFERENCES


To access the article and take the exam, log in to www.acr.org and click on the CME icon located next to the JACR cover. Follow the instructions and answer 3 questions to complete the requirement for CME. Claim the credit and print your CME certificate online. Note: CME for ACR members is free, however you will need to click on the "Buy Now" button and proceed through the shopping cart process in order to receive the credit.

The American College of Radiology is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The American College of Radiology designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit™. Physicians should only claim credit commensurate with the extent of their participation in the activity.