NOTES & COMMENTS

Physician Ownership and Use of In-Office Advanced Diagnostic Imaging Equipment: Are IDTF Standards a Meaningful Response to Overutilization, Quality, and Costs?

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ABSTRACT: The increase of physician ownership and use of in-office advanced diagnostic imaging equipment (magnetic resonance imaging, positron emission tomography, and computed axial tomography) has led to concerns about overuse, quality, and increased costs. The requirement that a physician or non-physician practitioner furnishing diagnostic testing services (1) enroll as an independent diagnostic testing facility (IDTF) for each practice location furnishing these services and (2) comply with the performance standards of 42 C.F.R. § 410.33 would represent a major step toward curbing potential advanced diagnostic imaging self-referral overutilization, improving quality, and lowering costs.

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In-Office Advanced Diagnostic Imaging Equipment

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Introduction

Over the past 10 years, the volume of advanced diagnostic imaging services performed in the United States has grown, as patient diagnosis has become less invasive, and diagnostic imaging equipment more advanced. Physicians, faced with reimbursement rate decreases for traditional physician services (both real and threatened), have looked to ancillary services as an additional source of revenue. The availability and relative affordability of advanced diagnostic imaging equipment, marketed directly to physicians over the Internet and other media, have given physicians the opportunity to provide advanced diagnostic imaging services in their own offices, instead of having the service performed in a hospital or referring the imaging to an out-of-office provider.

As advanced diagnostic imaging equipment becomes safer, demand for non-invasive methods grows and savvy patients request advanced diagnostic imaging. However, the potential arises for overutilization of these services: If a physician owns the advanced diagnostic imaging equipment

1 For purposes of this article, “advanced diagnostic imaging” means magnetic resonance imaging (MRI), positron emission tomography (PET), and computed axial tomography (CT).
equipment and the equipment is in the physician’s office, the physician may, intentionally or unintentionally, tend to order more imaging studies than the physician would otherwise. Recent utilization data raise concern that overutilization of imaging services may be quite real. Direct evidence of higher utilization constituting overutilization is difficult to discern, however.

Physician ownership and use of in-office advanced diagnostic imaging equipment also leads to concern about quality, including questions about the accuracy of image interpretation, the technical quality of the image, and the condition of the imaging equipment. The physician performing a test may lack the proper equipment or trained technicians. The physician interpreting the test may not produce an accurate interpretation, or the image may not be high quality.

The federal law prohibiting physician self-referral, the Stark Law, allows physicians to self-refer patients to their offices for advanced diagnostic imaging pursuant to the in-office ancillary services exception. The Centers for Medicare and Medicaid Services (CMS) could have proposed regulatory restrictions on this exception to the Stark Law to curb potential overutilization and address issues of quality. Instead, on July 7, 2008, CMS, in its Proposed 2009 Medicare Physician Fee Schedule Rule (2009 PFS Proposed Rule), proposed changes to the independent diagnostic testing facility (IDTF) enrollment requirements. CMS proposed to require all physicians and non-physician practitioner organizations to enroll as IDTFs for each practice location furnishing diagnostic testing services (with certain exceptions). Under the proposed rule, a covered physician providing diagnostic testing services would have been subject to the “quality improvement” performance standards contained in the 2007 and 2008 PFS Final Rules, also with certain exceptions.

However, on October 30, 2008, CMS released the 2009 PFS, in which it stated that with the enactment of Section 135 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS was deferring implementation of the proposal to extend IDTF standards to physician offices while it continued to review public comments. Section 135 of the MIPPA requires that the Secretary of Health and Human Services establish an accreditation process for entities furnishing advanced diagnostic procedures by January 1, 2012. CMS stated it will consider finalizing the provisions in a future rulemaking if deemed necessary.

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Implementation of the provisions in the 2009 PFS Proposed Rule would have been a major step toward curbing potential overutilization of in-office advanced diagnostic equipment imaging services, as well as towards improving quality and lowering costs. Requiring physicians performing advanced diagnostic imaging to comply with IDTF standards would:

- ensure that advanced diagnostic imaging is performed using appropriate equipment and by properly trained technicians;
- ensure that qualified physicians interpret the images;
- increase the accuracy of diagnostic testing and reduce the need to perform repeat imaging;
- enhance quality of care;
- reduce spending, as physicians who cannot or are unwilling to meet the standards would be prohibited from seeking reimbursement from Medicare; and
- reduce repeat imaging studies as quality increases, leading to reduced spending.

The IDTF Performance Standards

In the 2007 and 2008 PFS Final Rules, CMS established performance standards for suppliers enrolled in the Medicare program as IDTFs. According to CMS:

These standards were established to improve the quality of care for diagnostic testing furnished to Medicare beneficiaries by Medicare enrolled IDTF and to improve [CMS’s] ability to verify that these suppliers meet minimum enrollment criteria to enroll or maintain enrollment in the Medicare program.

During the 2008 Physician Fee Schedule proposed rule comment period, CMS received comments requesting that the IDTF performance standards in 42 C.F.R. § 410.33 apply to physician and non-physician practitioners who receive Medicare reimbursement and who are enrolled in Medicare as a clinic, group practice, or physician office. Commenters expressed concerns that standards for imaging services were not applied consistently for all imaging centers, and that different regulatory standards would emerge depending on how the imaging facility was enrolled.

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5 Id.
6 Id.
The IDTF performance standards were codified at 42 C.F.R. § 410.33. CMS proposed expanding these standards through the 2009 Proposed PFS Rule by requiring that a physician or non-physician practitioner organization furnishing diagnostic testing services, except diagnostic mammography services: (1) enroll as an IDTF for each practice location furnishing these services; and (2) be subject to the IDTF performance standards, with certain exceptions. Physician and non-physician practitioner organizations would be exempt from IDTF standards concerning comprehensive liability insurance requirements, complaint procedures, posting of standards, posting of normal business hours, and sharing a practice location with another Medicare-enrolled individual or organization.7

The PFS proposed rule defined a “physician or nonphysician practitioner organization” as “any physician or nonphysician organization that enrolls in the Medicare program as a sole proprietorship or organizational entity such as a clinic or group practice.”8

Current performance standards require that an IDTF supervising physician provide supervision to no more than three IDTF sites,9 and be proficient in the performance and interpretation of each type of diagnostic procedure the IDTF performs.10 The supervising physician’s proficiency may be documented by certification in specific medical specialties or subspecialties, or by criteria established by the Medicare carrier for the service area in which the IDTF is located.11

With respect to non-physician personnel, the performance standards require that any non-physician personnel who perform tests for the IDTF show the basic qualifications to perform those tests, and demonstrate training and proficiency by licensure or certification through the appropriate state health or education department.12 If there is no state licensing board, the technician must be certified by an appropriate national credentialing body.13

Upon enrollment, an IDTF must certify that it meets, among others, the following standards and related requirements:

1. The IDTF operates its business in compliance with all applicable federal and state licensure and regulatory requirements for the health and safety of patients.14

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7 Id. at 38,534.
8 Id.
9 42 C.F.R. § 410.33(b)(1).
10 42 C.F.R. § 410.33(b)(2).
11 Id.
12 42 C.F.R. § 410.33(c).
13 Id.
14 42 C.F.R. § 410.33(g)(1).
2. The IDTF makes portable diagnostic equipment available for inspection within two business days of a CMS inspection request.15

3. The IDTF shall disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.16

4. The IDTF must have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturer suggested maintenance and calibration standards.17

5. The IDTF must have technical staff on duty, with the appropriate credentials to perform tests.18

6. The IDTF must permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF’s compliance with the standards.19

Under the proposed rule, if an IDTF fails to meet one or more of the standards delineated in § 410.33(g) at the time of enrollment, its enrollment would be denied. The supplier’s billing privileges would be revoked if the IDTF is found not to meet the standards set forth in § 410.33(g) or § 410.33(b)(1).20

Under the 2009 PFS Proposed Rule, the IDTF performance standards address issues of image interpretation, technical quality of images, and condition of imaging equipment in physician offices. The standards also indirectly address issues of cost and potential overutilization. The standards would fill a gap left open by the Stark Law’s in-office ancillary services exception, which has led to concerns of overutilization, quality, and costs. Those concerns have followed the migration of advanced diagnostic imaging equipment into physicians’ offices.

The Stark Law’s In-Office Ancillary Services Exception

The Stark Law prohibits a physician from making a referral for certain designated health services (DHS) reimbursable by Medicare.21 The term “designated health services” is defined (with certain exceptions

15 42 C.F.R. § 410.33(g)(4)(ii).
16 42 C.F.R. § 410.33(g)(10).
17 42 C.F.R. § 410.33(g)(11).
18 42 C.F.R. § 410.33(g)(12).
19 42 C.F.R. § 410.33(g)(14).
20 42 C.F.R. § 410.33(h).
21 See 42 U.S.C. § 1395nn(h)(5)(A), (B); 42 C.F.R. § 411.351 for the definition of “referral.”
not relevant here) to include radiology and certain other imaging services payable in whole or in part by Medicare.22 “Radiology and certain other imaging services’ are defined to include “…the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine or other imaging services.”23

The Stark Law’s in-office ancillary services24 exception, however, permits referrals otherwise prohibited due to ownership interests and compensation arrangements if the requirements of the exception are satisfied. In general, the requirements relate to:

1. who can perform or supervise the service;
2. where the services may be furnished; and
3. how the services are billed.

The in-office ancillary services exception generally allows referrals for DHS if the following conditions are met:

1. The services are furnished personally by the referring physician, a physician in the same group practice as the referring physician, or an individual supervised by either the referring physician or another physician in the group practice,25 and
2. The services are provided in either of the following locations:
   a. The same building (but not necessarily in the same space or part of the building) in which the referring physician (or another physician member of the same group practice) provides services unrelated to the furnishing of DHS (i.e., a physician’s office) (known as the “same building requirement”),26 or
   b. In the case of a referring physician who is a member of a group practice, a building used by the physician’s group practice for the group’s centralized provision of clinical

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22 42 U.S.C. § 1395nn(a)(1)(A); 42 C.F.R. § 411.351. By regulation, “radiology and certain other imaging services” does not include:
   (1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice; and
   (2) Radiology procedures that are integral to the performance of a nonradiological medical procedure and performed
      a. During the nonradiological medical procedure; or
      b. Immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure. 42 C.F.R. § 411.351.
23 42 C.F.R. § 411.355(b).
laboratory services (i.e., a centralized group practice lab) or the centralized provision of the group’s DHS (other than clinical laboratory services).\textsuperscript{27} A third condition of the in-office ancillary services exception pertains to how DHS may be billed.\textsuperscript{28} Generally, if all three of these requirements are met, services performed in-office are not prohibited referrals under the Stark Law.

On September 5, 2007, the third and final phase of rulemaking under the Stark Law (the Phase III Rule) was published, effective December 4, 2007.\textsuperscript{29} Although CMS made no substantive changes to the in-office ancillary services exception in its Phase III Rule publication,\textsuperscript{30} CMS noted:

The in-office ancillary services exception allows a physician to provide DHS to his or her own patients, which may appear to undercut the purpose of the physician self-referral prohibition. Nevertheless, the statutory exception evidences intent by the Congress to permit a physician to furnish DHS to his or her own patients if certain conditions are met. We are considering whether certain types of arrangements, such as those involving in-office pathology labs and sophisticated imaging equipment, should continue to be eligible for protection under the in-office ancillary services exception.\textsuperscript{31}

In the 2008 PFS Proposed Rule,\textsuperscript{32} CMS stated that Congress intended the in-office ancillary services exception to allow provision of certain services necessary to the diagnosis or treatment of a condition for which the patient sought the assistance of the physician.\textsuperscript{33} CMS noted that the medical landscape has changed since the Stark Law was first enacted:

At the time of enactment, a typical in-office ancillary services arrangement might have involved 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

\textsuperscript{28} 42 C.F.R. § 411.355(b)(3)(i)–(v).
\textsuperscript{29} 72 Fed. Reg. 51,012 (Sept. 5, 2007). CMS published Phase III without a comment period and appears to have moved the Stark regulation subject matter to the annual physician fee schedule rulemaking cycle.
\textsuperscript{31} Id. at 51,034.
\textsuperscript{32} 72 Fed. Reg. 38,122 (July 12, 2007).
\textsuperscript{33} Id. at 38,181.
the physician while the patient waited. However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice. The American College of Radiology (ACR) believes that due to their complex, specialized nature, advanced imaging studies that involve CT, MRI, and PET should not be defined as ancillary services and, therefore, should not qualify for the in-office ancillary services exception.

The ACR agrees with CMS that the original intent of the Congress in establishing the in-office ancillary services exemption was to allow patients to receive a test or procedure at the time of the office visit that was truly ancillary to the office visit and necessary to the diagnosis and treatment of the condition that brought the patient to the physician’s office. Congress assumed that such testing would involve simple examinations such as laboratory tests and simple x-rays to visualize a fracture or a pneumonia. Congress simply could not have anticipated the expansion of this regulation beyond its original intended purpose and the subsequent abuse this expansion has permitted. Advanced imaging tests involving CT, MRI and PET clearly do not represent “ancillary” services. These tests are sophisticated imaging examinations, requiring the expertise of specialty physicians and technologists with advanced training in radiation safety, examination design and protocol and interpretation of complex image datasets sometimes involving thousands of images for a single patient. The argument that these tests are necessary to assist the physician at the time of the visit is spurious at best and deceitful at worst.

The ACR contends that in-office imaging may deprive patients of the peer-review benefit of independent interpretation of the diagnostic studies and independent evaluation of the appropriate method of treatment:

When a physician with a clear financial interest is permitted to refer, perform, interpret and act on

34 Id.
36 Id.
the findings of a diagnostic examination or make a financially-motivated decision on a course of [ ] treatment, the patient is deprived of an objective outside review of the process under medical practice standards, peer-review and case-by-case oversight.37

With respect to the perceived benefit to the patient, the ACR notes that CT, MRI, and PET performed at the physician’s office seldom, if ever, occur within the hour for the patient’s convenience.38 According to the ACR, these advanced imaging studies often require separate scheduling and patient preparation such as fasting and pre-ingestion of drugs.39

CMS has requested comments on amendments to the in-office ancillary services exception in light of perceived “abusive arrangements within the physician’s office.”40

Our review of industry trade articles and discussions with trade associations has heightened our awareness of the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices. “Turn-key” operations … for in-office laboratories and other ventures, are being marketed to physicians over the internet.41

CMS declined to issue a specific proposal for amending the in-office ancillary services exception, but solicited comments as to whether changes are necessary, and, if so, what changes should be made.42

The breadth of the Stark Law’s in-office ancillary services exception, advances in technology and practice, and broader applications for advanced diagnostic imaging equipment have led to increased physician ownership and use of such equipment. This increase has led to concerns about overuse, quality and increased costs.

Prevalence of Imaging Services

A recent report indicates medical imaging services have risen at a rate three times faster than physician services overall.43 According to the Wall Street Journal, there are more MRI machines in the Pittsburgh area than in all of Canada; in 2003, there were more than 13 CT scans

37 Id. at 9.
38 Id.
39 Id.
41 Id.
42 Id.
provided for every 100 members of the largest health plan in the Pittsburgh area. Diagnostic imaging services grew more rapidly than any other type of physician service between 1999 and 2003. The total of all physician services grew 22% during that same period. Imaging services, however, grew twice as fast, by 45%. Advanced imaging services and nuclear medicine had the largest increase: MRI of body parts other than the brain grew by 99%, nuclear medicine grew 85%, and CT of body parts other than the head grew 82%

Between 2000 and 2005, spending for imaging services more than doubled, from $6.6 billion to $13.7 billion (an average annual growth rate of 15.7%, compared to a growth rate of 9.6% for all physician services). Spending for imaging services grew at a rate of 16% per year in 2003, 2004, and 2005. Spending for advanced imaging (comprised largely of CAT scans and MRI procedures) grew by 25% during 2005 and 82% from 2003 to 2005. Spending for physician services increased by an estimated 10% in 2005, with 7 percentage points of the growth attributable to the volume and intensity of physicians’ services. According to Herb Kuhn, Director, Center for Medicare Management, CMS, “Growth in spending for physicians’ services has been a notable contributor to the increases in the Part B premium. Rapid increases in spending for imaging services contribute significantly to the increase in spending for physicians’ services.”

Although these statistics address imaging services in general, and are not specifically related to in-office imaging services, the data raises concern that the increase in imaging services may be evidence of over-utilization of these services.

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46 Id.
47 Id.
49 Id.
50 Id.
51 Id.
52 Id., under Background.
Potential Overutilization

According to MedPAC, an independent Congressional agency, utilization of imaging services varies widely in the United States. “In fact, the average use of imaging services in one area can be three times the average use in another area. This variation is twice that seen in the use of major procedures.”53 This leads to concern about the value of these procedures. “Perhaps the most significant reason to be concerned about the potential overuse of imaging services is the threefold variation in the number of imaging services provided across the country.”54 A study by Dartmouth researchers Fisher and Wennberg indicates that geographic areas with a disproportionate use of health services do not have better health outcomes.55 “Those researchers also find that wide variations in the use of discretionary services, such as imaging and diagnostic tests, are sensitive to the supply of physicians and hospital resources rather than to the health status of the population.”56 In a different study, these same researchers found that Medicare beneficiaries in the regions where more imaging services were rendered did not have higher survival rates than beneficiaries in other regions.57

CareCore National, an imaging benefit manager, administered a preauthorization program that compared physician requests for imaging services with clinical criteria based on medical necessity. CareCore found that 16 percent of physician requests for MRI, and 9 percent of requests for CT scans, were not consistent with the criteria.58 According to MedPAC, “These requests represent potential overuse or misuse of imaging services.”59

Kouri et al. concluded that in general, increased financial incentives, such as those inherent in self-referral, lead to more imaging, and that self-referral involves overutilization.60 In their review of the
literature, Kouri et al. reported on “landmark” studies that extended earlier evidence of higher rates of procedures by self-referring physicians. In one such study by Hillman et al., researchers analyzed the health insurance claims of employees of several large corporations and their dependents. Hillman et al. found (depending on the specialty and symptoms) that self-referring physicians performed imaging 2.4 to 11.1 times as often as radiologist-referring physicians. The study also found self-referring physicians generated 3.0 to 17.1 times higher imaging costs per episode than radiologist-referring physicians. In a subsequent study, Hillman et al. studied insurance claims of beneficiaries of United Mine Workers’ health and retirement funds. The researchers again found self-referring physicians used imaging 1.7 to 7.7 times more frequently than did radiologist-referring physicians.

The Kouri et al. literature review was published in 2002 and, therefore, the weight of the review’s findings must be examined in that context. In a more recent survey, however, using data from a large California insurer, researchers examined the self-referral status of providers who billed for advanced imaging in 2004 for MRI, CT, and PET. The researchers found that approximately 33 percent of providers who submitted bills for MRI scans, 22 percent of those who submitted bills for CT scans, and 17 percent of those who submitted bills for PET scans were classified as “self-referral.”

In 2004, nonradiologist physicians who were members of small to medium-size groups [those with less than 100 members] and engaged in self-referral accounted for 33 percent of the providers that billed the insurer for MRIs but only 11.5 of the statewide total. Such physicians represented 17 percent of providers who

61 Id.
64 Id. at 844–45.
65 Id. at 845.
66 Id. (citing B.J. Hillman et al., Physicians’ Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population, 268 JAMA 2050–54 (1992)).
67 Id.
69 Id. at 415.
billed for PET in 2004, yet their share of statewide PET volume exceeded 25 percent. Moreover, for both of these highly reimbursed advanced imaging technologies, the share of statewide volume billed for by such physicians has grown dramatically since 2000. These physicians accounted for 22 percent of providers who billed for CT procedures in 2004, but their share of statewide volume was less than 7 percent. Nonetheless, the share linked to these self-referring providers had greatly increased.\textsuperscript{70}

These numbers reflect the growing trend of self-referrers billing for advanced diagnostic imaging.

Direct evidence of higher utilization constituting overutilization is difficult to discern. Indeed, the American Association of Orthopaedic Surgeons disputes the contention that higher utilization of imaging services is wholly inappropriate.

Advances in technology, the shift in site of services from hospitals to the in-office setting, and higher standards of patient care have all contributed to the increased use of imaging, though few, if any, would argue that these are negative changes in the direction of health care…. Since radiologists clearly control most of the imaging done in the United States, if there is indeed concern about inappropriate utilization, it makes sense to also examine the utilization practices of radiologists.\textsuperscript{71}

Nevertheless, extensive literature and data exist demonstrating that physicians who have a financial interest in advanced diagnostic imaging equipment order more imaging than physicians who do not have such a financial interest. The ubiquity of this finding and the difference in magnitude of the frequency of imaging by self-referrers as opposed to non-self-referrers leads to the conclusion that physician ownership and use of advanced diagnostic imaging equipment is a primary cause of the higher imaging utilization by self-referrers.

\textsuperscript{70} Id. at 422.

Concerns about Quality: Interpretation Accuracy, Technical Quality, and Equipment Condition

Physician ownership and use of in-office advanced diagnostic imaging equipment also leads to concern about quality, including the accuracy of the image interpretation, the technical quality of the image, and the condition of the imaging equipment. The physician performing the test may lack the proper equipment or trained technicians. The physician interpreting the test may not produce an accurate interpretation of the image, or the image may not be high quality.

Kouri et al., in their review of the literature regarding physician self-referral for diagnostic imaging, found that deficiencies, including image quality, are up to 10 times as common among nonradiologists as among radiologists; although some specialists, such as cardiologists and orthopedics, have records roughly matching those of radiologists. Kouri et al. looked at three subtopics related to quality:

1. accuracy of interpretation;
2. technical quality; and
3. condition of the equipment.

Interpretation accuracy

In one study reviewed by Kouri et al., a panel of radiologists and emergency physicians examined 120 radiographs. The radiologists’ interpretations were more accurate, more sensitive, and more specific than those of the emergency physicians. Furthermore, “[r]adiologists correctly interpreted 82% of cases that were identified by the consensus panel as ‘critical’ compared with 48% correctly interpreted by emergency physicians.” In a different study involving 555 consecutive CT scans among patients seen at the emergency room of a county hospital, researchers found approximately 39% nonconcordance between attending physicians and radiologists. About 24% of the emergency room physicians’ interpretations had potentially clinically significant false-positive or false-negative interpretations. In a separate study, a review of physicians’ interpretations of CT scans with preidentified...
findings found 83 percent accuracy of interpretations among neurologists and radiologists, versus 67 percent among emergency physicians.\textsuperscript{79} “In that study, 52 percent of radiologists, 40 percent of neurologists, and seventeen percent of emergency physicians correctly identified hemorrhage.”\textsuperscript{80}

In another study examined by Kouri et al., board-certified radiologists, radiology residents, and nonradiologist physicians studied chest radiographs for accuracy.\textsuperscript{81} The interpreters reviewed a standardized, clinically confirmed set of chest radiographs. The board-certified radiologists’ interpretations were the most accurate, followed by the radiology residents, and then nonradiologist physicians.\textsuperscript{82} In another study, board certified radiologists examined interpretations of chest radiographs by seven nonradiologists and three radiologists.\textsuperscript{83} Five clinically serious errors of interpretation were found among the 68 radiographs interpreted by the nonradiologists. In the radiologists’ pool, two minor errors of interpretation were found.\textsuperscript{84}

The studies do not prove that all physicians interpreting images without advanced image interpretation training produce less accurate, less sensitive, and less specific image interpretation than physicians with more advanced image interpretation training. The studies do not prove that all radiologists produce more accurate, more sensitive, and more specific image interpretation than nonradiologists. Kouri et al. did not discuss the quality of the imaging equipment used by the radiologists and the nonradiologists, or the training and experience of the radiologists and the nonradiologists. Quality of imaging equipment and training and experience of the physicians interpreting the images are factors in determining the relative quality of image interpretation.

The evidence on whole, however, suggests that individuals with advanced training in image interpretation provide more accurate, more sensitive, and more specific interpretation of advanced diagnostic images. Accurate, sensitive, and specific image interpretation leads to decreased diagnostic error, decreased costs (as the necessity of repeat imaging decreases), and quality patient care. These studies indicate the importance of the training of the physician interpreting advanced diagnostic images.

\textsuperscript{79} Id. (citing D.L. Schriger et al., Cranial Computed Tomography Interpretation in Acute Stroke: Physician Accuracy in Determining Eligibility for Thrombolytic Therapy, 279 JAMA 1293–97 (1998)).
\textsuperscript{80} Id.
\textsuperscript{81} Id. at 846 (citing E.J. Potchen et al., Measuring Performance in Chest Radiography, 217 Radiology 456–59 (2000)).
\textsuperscript{82} Id.
\textsuperscript{83} Id. at 846 (citing K.D. Hopper et al., Diagnostic Radiology Peer Review: A Method Inclusive of All Interpreters of Radiographic Examinations Regardless of Specialty, 180 Radiology 557–61 (1991)).
\textsuperscript{84} Id.
Technical quality

Accurate interpretation of diagnostic imaging requires quality images. In one study reviewed by Kouri et al., Pennsylvania Blue Shield examined the image quality of 98 chest radiographs. The study found “five inadequately marked films, 21 incomplete reports, and eight problems in the technical quality of the image among the nonradiologists’ radiographs.” On a larger scale, Pennsylvania Blue Shield conducted a quality audit of more than 1,000 radiographs obtained by physicians and other providers. Rates of unacceptable chest image quality were highest among nonradiologists and lowest among radiologists.

In another study, U.S. Healthcare looked at the quality of sonography in a number of freestanding radiology centers, obstetric and gynecology offices, and hospitals. “More than half [of] the examinations performed by self-referring physicians did not meet guidelines established by the American Institute of Ultrasound in Medicine, the American College of Obstetrics and Gynecology, or the American College of Radiology.”

As with the discussion regarding accuracy of image interpretation, the studies regarding technical quality do not prove that all physicians performing imaging studies without advanced training produce non-quality images. Nor do the studies prove that all radiologists produce quality images. Again, the quality of the imaging equipment used, training, and experience was not discussed in Kouri et al.’s review—and all are factors in determining the relative quality of the images. The evidence on the whole, however, suggests that those physicians receiving advanced training in imaging produce quality imaging.

Condition of equipment

For quality images and accurate interpretations, advanced diagnostic imaging equipment must be kept in proper condition. According to MedPAC, providers vary in their ability to perform quality imaging procedures. In one study, BlueCross BlueShield of Massachusetts
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inspected 1,000 imaging providers to evaluate the quality of their equipment and technical staff.92 The study found a significant number of providers were using equipment for which they were not trained and/or certified.93 The study also found that almost 33 percent of providers inspected had at least one serious deficiency (film processing problems, failure to monitor radiation exposure, poor image quality, or the lack of an equipment calibration report).94 Eleven percent of the providers had problems that could not be remedied easily.95

In another study, a health plan that inspected approximately 100 nonradiologist offices that provided radiography services identified serious problems in 78 percent of the offices, including lack of proper image identification and use of equipment that had not been inspected during the previous year.96 According to MedPAC, “[S]ome providers fail to meet standards because their imaging equipment is old or not working properly. Physician offices sometimes acquire used equipment from a hospital and continue to use that equipment beyond its useful life.”97

Poor condition of advanced diagnostic imaging equipment may lead to poor images, inaccurate interpretations, and issues of patient safety.

Concerns about increased costs

The availability and relative affordability of advanced diagnostic imaging equipment marketed directly to physicians over the internet and other media have given physicians the opportunity to provide advanced diagnostic imaging services in their own offices, instead of having the service performed in a hospital or referring the imaging to an out-of-office provider. As advanced diagnostic imaging equipment has migrated to physicians’ offices from freestanding and hospital settings, the potential for increased costs has risen.

According to one estimate, utilization of radiology services for diagnosis and treatment increases by approximately 9 percent per year.98 According to another estimate, the sales of ultrasound, MRI, CT, and

92 Kouri et al., at 846 (citing D.K. Verrilli et al., Design of a Privileging Program for Diagnostic Imaging: Costs and Implications for a Large Insurer in Massachusetts, 208 RADIOL 385–92 (1998)).
93 Id.
95 Id.
PET machines equaled about $2.9 billion in 2000, with an increase to $3.9 billion in 2005. The estimators expect over 25,000 new ultrasound machines and 8,000 more CT and MRI machines to be purchased between 2000 and 2005. A major vendor of MRI machines expected all of the growth in MRI sales between 2001 and 2005 to occur outside the hospital setting.

The evidence is clear—spending on advanced diagnostic imaging has greatly increased in the past decade. Increased spending does not necessarily correlate to overutilization, as other factors may be at play. Increased spending does not necessarily correlate to poor patient care; in fact, it may correlate with better patient care. Nevertheless, as the costs of providing imaging services remain constant or decline, and the volume of imaging services increases, overall costs to payers reimbursing physicians for imaging services increase. Higher utilization leads to higher costs.

Evidence in Support of Extending the IDTF Standards

The statistics and studies cited above raise concerns about overutilization of imaging services. As advanced imaging equipment migrates to physician practices, and with the limited restrictions of the Stark Law’s in-office ancillary services exception, these concerns have migrated to physicians’ offices as well. Physician ownership and use of advanced diagnostic imaging equipment raises questions about quality, including the accuracy of the image interpretation, the technical quality of the image, and the condition of the imaging equipment.

If the IDTF standards of 42 C.F.R. § 410.33 are eventually applied to physician-owned in-office advanced diagnostic equipment, as proposed in the 2009 PFS Proposed Rule, the requirements would constitute a major step in the direction of curbing potential overutilization of in-office advanced diagnostic equipment imaging services, as well as in improving quality and lowering costs. At least one large HMO has experimented with standards and privileging for diagnostic imaging. As discussed in the following section, the results of that program indicate that standards and privileging for diagnostic imaging can increase quality and decrease utilization.

The Moskowitz et al. report

One HMO sought to determine if a set of guidelines limiting imaging privileges of nonradiologist physicians could decrease imaging

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99 Barbara M. Rothenberg, BlueCross BlueShield Ass’n, Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging 1 (2003), available at www.bcbs.com/blueresources/cost/Medical_Tech_Drivr_Rept_10.pdf. Some of these machines, of course, will replace existing machines.
100 Id. (citation omitted).
costs, while ensuring that equipment and personnel providing imaging were of high quality.\textsuperscript{101} The HMO’s goals were to reduce utilization of imaging tests “that were noncontributory to patient treatment and… thus were inappropriate,” and “to deliver the most cost-effective, high-quality imaging product.”\textsuperscript{102} The HMO established a radiology advisory committee to establish guidelines on who could perform imaging studies in their office practice. Imaging studies that could be performed by nonradiologists were identified based on the physician’s specialty and expertise. Images obtained by primary care physicians had to be interpreted by a radiologist, who would bill for the professional component.\textsuperscript{103} Radiology offices used technologists to perform radiographic examinations and had a quality assurance program in place.\textsuperscript{104}

The HMO also evaluated and ensured the technical quality of imaging. Only licensed technologists could perform radiography. Patient safety programs were required. If a practice obtained FDA approval for mammography, only the technical component of a screening mammogram would be paid by the HMO. Physicians desiring to perform sonographic examinations had to be accredited by the American Institute of Ultrasound in Medicine or the American College of Radiology. For vascular sonography, the physician had to be accredited by the Intersocietal Commission for Accreditation of Vascular Laboratories.\textsuperscript{105}

Registered radiology technologists inspected the offices performing imaging. The radiology technologists evaluated the quality of the imaging study, storage and handling of films, patient demographic information on the film, and the presence of a report on each imaging study.\textsuperscript{106}

The HMO’s data prior to instituting the guidelines was compared with data for the calendar year after the program was implemented. The HMO found its guidelines had not caused significant hardship.\textsuperscript{107} “All quality-of-care measures charted by the health plan, including those mandated by accreditation from the National Committee for Quality Assurance and those required by the Health Care Financing Administration, were unchanged by the institution of [the] guidelines.”\textsuperscript{108} The study found a 6% decrease in the number of radiologic examinations per 1,000 examinations.\textsuperscript{109} The study also showed a 31% increase in the

\begin{flushleft}
102 Id.
103 Id.
104 Id.
105 Id.
106 Id.
107 Id.
108 Id. at 11.
109 Id.
\end{flushleft}
number of examinations per 1,000 enrollees performed by radiologists, and a 63% decrease in those performed by nonradiologists. In another comparison of data, the study showed that in the years before the institution of the program, radiology services per 1,000 enrollees increased approximately 5 to 10% per year. In the year after the program was put into effect, the number of radiographs per 1,000 decreased by approximately 20 to 25% from the number expected if the trend continued.

Significance of the Moskowitz et al. report

The Moskowitz et al. report is one of the few that test the impact of standards on imaging. A number of studies compare imaging utilization rates among different physician specialties to demonstrate that self-referring physicians perform more imaging services than non-self-referring physicians. Other studies compare imaging utilization rates in different types of settings (hospital, freestanding facility, and physicians’ offices). The Moskowitz et al. report imposed standards on a given set of physicians and compared utilization data before and after the standards were imposed.

The Moskowitz et al. report demonstrates that a standards program for advanced diagnostic imaging can reduce utilization, provide quality, and decrease costs. The guidelines in the Moskowitz et al. report were similar in a number of respects to the IDTF performance guidelines of 42 C.F.R. § 410.33. Both sets of guidelines restrict who can perform imaging studies based on training and/or specialty. Both sets of guidelines require that trained personnel interpret images. Both sets of guidelines require inspection of offices where diagnostic imaging is performed. The Moskowitz et al. report provides a basis for this article’s premise that imposition of performance standards on physicians or non-physician practitioners furnishing diagnostic testing services will advance the goals of curbing potential advanced diagnostic imaging self-referral overutilization, as well as improving quality and lowering costs.

Practical Considerations

Although CMS deferred implementation of the requirement that physician and non-physician providers enroll as IDTFs, if the proposed rule eventually becomes final, an affected practitioner must enroll as an IDTF for each location furnishing diagnostic testing services and comply with the performance standards. The supervising physician

110 Id.
111 Id.
112 Id.
can provide general supervision to no more than three IDTF sites.\textsuperscript{113} In addition, the supervising physician will have to evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF.\textsuperscript{114} The IDTF will have to maintain documentation of sufficient physician resources during all hours of operation.\textsuperscript{115}

If the IDTF utilizes the services of non-physician personnel to perform tests, the non-physician personnel will have to demonstrate basic qualifications to perform the applicable tests.\textsuperscript{116} The non-physician personnel also will have to demonstrate training and proficiency through licensure or certification by the appropriate state health or education department. The IDTF must maintain documentation of compliance.\textsuperscript{117}

With respect to the certification standards, the IDTF will have to certify in its enrollment application that it complies with all applicable federal and state licensure and regulatory requirements for the health and safety of patients.\textsuperscript{118} The IDTF must report to the Medicare fee-for-service contractor changes in ownership, location, and general supervision, as well as adverse legal actions.\textsuperscript{119}

The IDTF must maintain a physical facility on an appropriate site. (A post office box, commercial mailbox, hotel, or motel is not considered an appropriate site.)\textsuperscript{120} The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application.\textsuperscript{121} The physical facility (with certain exceptions) also must maintain facilities for hand washing, adequate patient privacy accommodations, and storage for both business records and current medical records.\textsuperscript{122}

The IDTF must have all diagnostic testing equipment covered by the IDTF standards available at the physical site (excluding portable diagnostic testing equipment).\textsuperscript{123} With respect to portable diagnostic equipment, the IDTF must keep a catalog of the equipment at the physical site and make the equipment available for inspection within two business days of a CMS request.\textsuperscript{124} The IDTF also must keep a current inventory of all diagnostic testing equipment, provide the information

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{113} 42 C.F.R. \textsection 410.33(b)(1).
\item \textsuperscript{114} 42 C.F.R. \textsection 410.33(b)(2).
\item \textsuperscript{115} Id.
\item \textsuperscript{116} 42 C.F.R. \textsection 410.33(c).
\item \textsuperscript{117} Id.
\item \textsuperscript{118} 42 C.F.R. \textsection 410.33(g)(1).
\item \textsuperscript{119} 42 C.F.R. \textsection 410.33(g)(2).
\item \textsuperscript{120} 42 C.F.R. \textsection 410.33(g)(3).
\item \textsuperscript{121} 42 C.F.R. \textsection 410.33(g)(3)(1).
\item \textsuperscript{122} Id.
\item \textsuperscript{123} 42 C.F.R. \textsection 410.33(g)(4).
\item \textsuperscript{124} 42 C.F.R. \textsection 410.33(g)(4)(i–ii).
\end{enumerate}
\end{footnotesize}
to the designated fee-for-service contractor upon request, and notify
the contractor of any changes in equipment within 90 days.\textsuperscript{125} The IDTF
must have proper medical record storage and be able to retrieve med-
ical records upon request from CMS or its fee-for-service contractor
within two business days.\textsuperscript{126}

The IDTF must keep a primary business telephone under the name
of the designated business.\textsuperscript{127} That telephone must be located at the
designated site of the business, or within the home office of the mobile
IDTF units.\textsuperscript{128} The telephone numbers must be available in a local
directory and through directory assistance.\textsuperscript{129}

Any person having ownership, financial or control interest,
or any other legal interest, in the IDTF must be disclosed to the
government.\textsuperscript{130}

Probably the most surprising aspect of the proposed final rule is
that the rule would eliminate the ability of practitioners to share diag-
nostic imaging equipment, even if the diagnostic imaging equipment
is located in the “same building,” as defined in the Stark Law.

The IDTF’s testing equipment must be calibrated and maintained
pursuant to the equipment’s instructions and in compliance with
applicable manufacturers’ suggested maintenance and calibration
standards.\textsuperscript{131} The IDTF’s technical staff, with the appropriate creden-
tials to perform the tests, must be on duty at the time the tests are
performed.

The IDTF must allow CMS, including its agents or its designated
fee-for-service contractors, to conduct unannounced, on-site inspec-
tions to confirm the IDTF’s compliance with the standards.\textsuperscript{132}

The standards, if eventually implemented, are potentially a major
change in the use of in-office advanced diagnostic imaging equipment
and should have positive effects on utilization, quality, and costs for
advanced diagnostic imaging services.

Other commentators, however, are pessimistic about the potential
impact of extending the IDTF performance standards for advanced
diagnostic imaging to physicians and non-physician practitioners.

\textsuperscript{125} 42 C.F.R. § 410.33(g)(4)(iii).
\textsuperscript{126} 42 C.F.R. § 410.33(g)(13).
\textsuperscript{127} 42 C.F.R. § 410.33(g)(5)(i).
\textsuperscript{128} Id.
\textsuperscript{129} 42 C.F.R. § 410.33(g)(5)(ii).
\textsuperscript{130} 42 C.F.R. § 410.33(g)(10).
\textsuperscript{131} 42 C.F.R. § 410.33(g)(11).
\textsuperscript{132} 42 C.F.R. § 410.33(g)(14).
According to one commentator in an article entitled “Trying to Regulate Imaging Self-Referral Is Like Playing Whack-A-Mole,” Regulation, by definition, must define precisely the terms of what is to be regulated and how. Inevitably, there will be ambiguity. Worse, since regulation is virtually always influenced by politics, there will be critical exceptions made, and that is the case with self-referral. Such arrangements cannot be rationalized on the basis of quality of care, convenience, access to care, or any of the other explanations commonly offered by the apologists for self-referral. It’s about the money.

The commentator quoted his friend as saying: “‘Finding ways around regulation is the American national past-time.’”

Conclusion

At the inception of the Stark Law, Congress may not have anticipated the technological advancements and concomitant growth in the use of in-office advanced diagnostic imaging equipment. However, the shift from providing advanced diagnostic imaging services in hospitals and freestanding imaging centers to providing such services in physician in-office settings undoubtedly has been beneficial to both physician and patient. A regulatory scheme that prohibits physicians from owning and using advanced diagnostic equipment in their offices goes too far in attempting to address issues of overutilization, quality, and costs. The use of in-office advanced diagnostic equipment allows a physician to more immediately diagnose and treat patient complaints. The physician also can provide a broader range of services to the practice’s patients. The patient may not have to schedule an appointment with another provider or have the imaging performed at a different location. Further, a physician performing in-office studies may help control costs in that the physician may seek alternative (and less costly) forms of treatment and advise the patient on avenues of financial assistance.

A regulatory scheme that allows only certain physicians, such as radiologists, to perform advanced diagnostic imaging studies also goes too far. The physician performing in-office, advanced diagnostic imaging studies, such as an orthopaedic surgeon, may be in a better position to interpret diagnostic tests relevant to the physician’s specialty, and may

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134 Id. (quoting Albert Williams, Ph.D., RAND Corp., 1985).
have better insight into the patient’s problem. A number of physician specialties have advanced training in imaging and interpretation, and those physicians may be as qualified, or in some circumstances more qualified, than radiologists in imaging and interpretation.

It is unfortunate that CMS deferred implementing the requirements that physician and non-physician providers enroll as IDTFs. The standards of 42 C.F.R. § 410.33 strike a balance between completely prohibiting physicians from owning and using advanced diagnostic imaging equipment in their offices and restricting imaging and interpretation to only one specialty. Under these standards, the patients will receive the benefits offered by in-office advanced diagnostic imaging studies and will have the assurance that the supervising physician, technologist, images, equipment, and patient safety programs meet the standards promulgated by the federal and state governments.
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