Medicare Diagnostic Testing, Anti-Markup Restrictions and IDTF Standards

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GLOSSARY OF KEY TERMS: Unless otherwise noted, for purposes of this outline:

- "**Diagnostic testing facility**" means freestanding (fixed-site or mobile) and physician office-based diagnostic testing facilities (other than rural health clinics and federally-qualified health centers) that furnish the technical and, sometimes, the professional component of diagnostic testing services to patients who are not registered hospital inpatients or outpatients. Examples include fixed-site physician office-based MRI, mobile PET units, freestanding sleep labs, and freestanding diagnostic cardiac cath labs.

- "**HOPD diagnostic facility"** means a hospital- or provider-based diagnostic testing facility furnishing diagnostic testing services to registered hospital outpatients.

- "**Diagnostic testing service"** means an imaging or other diagnostic test, including a pathology service, payable under the Medicare physician fee schedule or the hospital outpatient prospective payment system or OPPS, but excluding clinical laboratory services payable under the Medicare clinical laboratory fee schedule.

- "**Technical component**" means the imaging equipment and supplies, and the services of a technologist.

- "**Professional component**" means the professional interpretation or read of the diagnostic test.

I. MEDICARE COVERAGE.

A. Basis for Medicare Coverage of Diagnostic Testing Services.

1. Statutory Basis. The statutory basis for Medicare coverage of diagnostic testing services by diagnostic testing facilities and HOPD diagnostic facilities is coverage of "medical and other health services" under Medicare Part B. Social Security Act (hereinafter "**SSA**") § 1832(a)(1) (42 U.S.C. § 1395(k)(a)(1)) (defining scope of Medicare Part B services); SSA § 1861(s)(2)(c), (3), (13), (15); 42 U.S.C. § 1395x(s)(3), (13), (defining "medical and other health services" and "screening mammography").

2. Regulatory Basis. See 42 C.F.R. § 410.10(e) (defining "medical and other health services"); § 410.28 (conditions of coverage for

diagnostic testing of outpatients by hospitals and CAHs); § 410.32 (conditions of coverage for diagnostic tests); § 410.33 (Independent Diagnostic Testing Facilities); § 410.34 (conditions of coverage for mammography services); and § 486.100-110 (conditions of coverage for portable x-ray suppliers).

B. Ordering Imaging Services: What Constitutes an "Order" and Who Must Order the Test?

1. "Order" Defined. An order is a communication from the treating physician/practitioner (defined below) requesting that a diagnostic test be performed for the beneficiary, and may include a request for an additional test for the beneficiary if the result of the initial test ordered yields a certain value *determined by the treating physician/practitioner*. An order may include the following forms of communication:

    a. Signed Writing. A written request signed by the treating physician/practitioner that is hand-delivered, mailed or faxed.

    b. Email. An email from the treating physician/practitioner or his/her office.

    c. Telephone. A telephone call from the treating physician/ practitioner *or* his/her office that is documented by the treating physician/practitioner or his/her office and the testing facility in their respective copies of the beneficiary's medical records.

2. Basic Rule. A diagnostic test must be ordered by the physician or non-physician practitioner (*i.e.*, clinical nurse specialists, nurse practitioners, or physician assistants operating within the scope of their state license and Medicare statutory benefit) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem (the "**treating physician/practitioner**"). According to CMS, tests not ordered by the treating physician/practitioner are not reasonable and necessary and, therefore, not covered. 42 C.F.R. § 410.32(a).

    a. Treating Physician/Practitioner Defined.

        i. A treating physician is defined as a physician who furnishes a consultation, or treats a beneficiary for a

specific medical problem and who utilizes the results of diagnostic tests in the management of the beneficiary's medical condition. Medicare Benefit Policy Manual (Pub 100-2) (hereinafter "**MBPM**"), Ch. 15 § 80.6.1.

ii. Radiologists performing diagnostic procedures are not considered to be treating physicians. Radiologists performing therapeutic interventional procedures are, however, considered treating physicians.

3. Exceptions to this Rule. Unless one of the follow exceptions apply, the testing facility may not perform an additional or different test without a new order from the treating physician.

a. Chiropractic Exception. Prior to January 1, 2008, a physician could pursuant to 42 C.F.R. § 410.32(a)(1) order an x-ray to be used by a chiropractor even though the ordering physician would not treat the beneficiary. Effective January 1, 2008, CMS officially eliminated this exception. See 72 Fed. Reg. 66222, 66327 (2007).

b. Mammography Exception. A physician who meets the requirements for an interpreting physician (as provided in 42 C.F.R. § 410.34(a)(7)) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary. (This does not permit the interpreting physician, however, to order a diagnostic ultrasound study in conjunction with the diagnostic mammogram.)

c. Additional Diagnostic Radiology Test Exception. If the testing facility cannot reach the treating physician/practitioner to change the order or obtain a new order, and documents this in the medical record, then the testing facility may furnish the additional diagnostic test if all of the following criteria apply:

i. The testing center performs the diagnostic test ordered by the treating physician/practitioner;

ii. The interpreting physician at the testing facility determines and documents that, because of the

abnormal result of the diagnostic test performed, an additional diagnostic test is medically necessary;

iii. Delaying the performance of the additional diagnostic test would have an adverse effect on the care of the beneficiary;

iv. The result of the test is communicated to and is used by the treating practitioner in the treatment of the beneficiary; and

v. The interpreting physician at the testing facility documents in his/her report why additional testing was done. MBPM, Ch. 15, § 80.6.3.

d. Interpreting Physician Exceptions. The interpreting physician of a testing facility that furnishes diagnostic testing to a beneficiary who is not a hospital inpatient or outpatient may make the following modifications to an order, without notifying treating physician/practitioner, with proper documentation in the report to the treating physician/practitioner:

i. Test Design. Unless specified in the order, the interpreting physician may determine the parameters of the diagnostic test (*e.g.*, number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media). MBPM, Ch. 15, § 80.6.4.

ii. Clear Error. The interpreting physician may modify an order with clear and obvious errors that would be apparent to a reasonable layperson (*e.g.*, x-ray of wrong foot ordered). MBPM, Ch. 15, § 80.6.4.

iii. Patient Condition. The interpreting physician may cancel an order because the beneficiary's physical condition at the time of diagnostic testing will not permit performance of the test. MBPM, Ch. 15, § 80.6.4.

4. Rule for Diagnostic Tests Performed in Hospital Settings. In contrast to the rule for diagnostic tests performed in non-hospital settings, an order from the treating physician is not required for

diagnostic tests to be performed on hospital inpatients or outpatients.

a. CMS has expressly interpreted 42 C.F.R. § 410.32 [requiring that diagnostic tests be ordered by treating physicians] to apply only to physicians' offices and other freestanding facilities. See 62 Fed. Reg. 59, 048, 59, 057 (Oct. 31, 1997).

b. Medicare's conditions of participation for hospitals provide that "Radiologic services must be provided only on the order of practitioners with clinical privileges…authorized by the medical staff and the governing body to order the services." See 42 C.F.R. § 482.26(b)(4).

c. Medicare will pay for the professional component of diagnostic services provided in hospital settings on a fee schedule basis if the services are "identifiable, direct, and discrete diagnostic services" rendered to a beneficiary. Medicare also requires that the hospital maintain the official interpretation report in the patient's file.

5. Rule for Diagnostic Tests Performed in Independent Diagnostic Testing Facilities ("**IDTFs**"). The federal regulations for IDTFs are significantly more rigorous than regulations for both hospitals and physicians' offices. Specifically, "[a]ll procedures performed by the IDTFs must be specifically ordered in writing by the physician who is treating the beneficiary." 42 C.F.R. § 410.33(d). The regulations also specify that "[t]he IDTF may not add any procedures based on internal protocols without a written order from the treating physicians." *Id*.

C. Performance Requirements: Who Can Provide the Test?[1]

1. Physicians;

2. Group practice of physicians;

3. Approved portable x-ray supplier (x-rays);

4. Independent Diagnostic Testing Facility;

[1] The supplier type listed can provide any diagnostic test unless otherwise noted in parentheses.

5. Nurse practitioner or clinical nurse specialist (if authorized by the State);

6. FDA-certified mammography facility (diagnostic mammography);

7. Qualified audiologist (personally performed audiological testing);

8. Clinical psychologist or qualified independent psychologist (personally performed psychological testing);

9. Physical therapist certified by the ABPTS as a qualified electrophysiologic clinical specialist (personally performed neurodiagnostic tests authorized under State law);

10. Pathology slide preparation facilities (technical component pathology examination services);

11. CLIA laboratories (clinical laboratory tests); and

12. Radiation therapy centers (imaging that is an integral and necessary component of the radiation therapy services).

42 C.F.R. § 410.33.

D. Physician Supervision Requirements: What Level of Physician Supervision is Required? (42 C.F.R. § 410.32(b)). (See Part I.H, *infra*, for physician supervision requirements for HOPD imaging facilities).

1. Basic Rule. Unless an exception applies, all diagnostic imaging services payable under the Medicare physician fee schedule, or provided by a facility (other than a RHC or an FQHC) designated by CMS as provider-based[2] must be provided under at least a general level of physician supervision (defined below), and certain specified tests must also be provided under either direct or personal physician supervision (defined below).[3] When direct or personal physician supervision is required, the supervision must be provided throughout the performance of the test. According to CMS, diagnostic imaging services that are not furnished under the specified level of physician supervision are not reasonable and

[2] See 42 C.F.R. § 410.28(e).

[3] Note that, unlike the physician order requirement, which can be satisfied by certain non-physician practitioners, only supervision by a physician (as defined by SSA § 1861(r)) can satisfy the physician supervision requirements.

necessary, and, therefore, not covered. 42 C.F.R. § 410.32(b); Medicare Benefit Policy Manual, Chapter 15, § 80.

2. Exceptions. The following diagnostic tests are excepted from the above physician supervision requirements, but other federal and state law might impose physician supervision requirements:

   a. Diagnostic mammography procedures;

   b. Diagnostic tests personally performed by a qualified audiologist;

   c. Diagnostic psychological testing services performed by a clinical psychologist or an independently practicing psychologist (as defined by program instructions); or furnished under the general supervision of a physician or a clinical psychologist;

   d. Diagnostic tests personally performed by a physical therapist who is certified by the ABPTS as a qualified electrophysiologic clinical specialists and authorized under State law to perform the tests;

   e. Diagnostic tests performed by a nurse practitioner or a clinical nurse specialist authorized to perform the tests under State law; and

   f. Pathology and laboratory procedures listed in the 80000 series of the AMA's CPT book.

3. Levels of Supervision (42 C.F.R. § 410.32; Medicare Benefit Policy Manual, Chapter 15, § 80).

   a. *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

   b. *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the

performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

c. *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

4. Specific Supervision Levels for Specific Imaging Procedures. The specific supervision level for an imaging procedure (or other diagnostic test) is set forth in a column of the National Medicare Physician Fee Schedule Relative Value File, which can be accessed on CMS's website. As a general rule, nuclear imaging, ultrasounds and MRI and CT without contrast media require general supervision, MRI or CT with contrast media require direct supervision, and invasive imaging procedures require personal supervision (which is, as a practical matter, generally satisfied by virtue of the fact that a physician is performing the invasive imaging procedure, *e.g.*, cardiac catheterization).

E. IDTFs. (See Part II below).

F. Portable X-Ray Suppliers. (42 C.F.R. §§ 486.100-110; Medicare Benefit Policy Manual, Chapter 15, § 80.4).

Portable x-ray suppliers must also satisfy specified conditions, summarized below:

1. Legal Compliance. The supplier is in compliance with federal, state and local law regulating the provision of x-ray services.

2. Physician Supervision. The portable x-ray services are provided under the general supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of x-rays for diagnostic purposes.

3. Performance Requirements. The supervising physician either owns the equipment and employs the technicians, or the supervising physician certifies that he or she periodically observes the operator and has verified that the operator and equipment are in compliance with all applicable law.

4. Qualified Operators. The x-rays are provided by qualified technologists who are provided adequate orientation and instruction in the operation of the equipment.

5. Physician Orders and Records. All portable x-ray services performed for Medicare beneficiaries are ordered by a doctor of medicine or doctor of osteopathy and detailed records of the examination are kept and properly preserved.

6. Safety Standards. X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

7. Inspection of Equipment. Inspections of all x-ray equipment and shielding are made by qualified individuals at intervals not greater than every twenty-four (24) months.

NOTE: The scope of the portable x-ray benefit is limited as specified in Medicare Benefit Policy Manual, Chapter 15, § 80.4.3 and 80.4.4. For example, procedures involving fluoroscopy, contrast media, or the administration or injection of a substance are not covered when performed by a portable x-ray supplier.

G. Mammography Facilities. (42 C.F.R. § 410.34).

Medicare covers both diagnostic and screening mammography under certain conditions summarized below:

1. Conditions for Coverage of Diagnostic Mammography Services. Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

   a. They are ordered by a doctor of medicine or osteopathy.

   b. They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of Section 354 of the Public Health Service Act ("PHS Act") (as implemented by 21 C.F.R. part 900).

2. Conditions for Coverage of Screening Mammography Services. Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services

that meets the certification requirements of Section 354 of the PHS Act (as implemented by 21 C.F.R. part 900).

a. Limitations.

i. The service must be, at a minimum, a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of each breast.

ii. Payment may not be made for a screening mammography performed on a woman under thirty-five (35) years of age.

iii. Payment may be made for only one screening mammography performed on a woman over age thirty-five (35), but under age forty (40).

iv. For an asymptomatic woman over thirty-nine (39) years of age, payment may be made for a screening mammography performed after at least eleven (11) months have passed following the month in which the last screening mammography was performed.

H. Coverage Issues for New Imaging Technology.

New imaging technology and modalities may be considered by CMS as investigational or experimental for all or certain clinical indications. As such, these new technologies are not covered by Medicare until a contractor establishes a local coverage determination ("**LCD**") granting coverage, or CMS issues a favorable national coverage decision with respect to the technology. SSA, § 1862(a); 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15(o). Key national coverage decisions regarding imaging services are cited below, the most recent development being the significant expansion of Medicare coverage for positron emission tomography or "**PET**":

1. PET, Medicare National Coverage Determination Manual ("NCD"), § 220.6.

2. Mammography, NCD, § 220.4.

3. Magnetic Resonance Angiography, NCD, § 220.3.

4. Magnetic Resonance Imaging or MRI, NCD, § 220.2.

5. Computerized Tomography or CT, NCD, § 220.1.

6. Ultrasound Diagnostic Services, NCD, § 220.5.

II. INDEPENDENT DIAGNOSTIC TESTING FACILITIES ("IDTF"). (42 C.F.R. § 410.33).

A. What is an IDTF?

An IDTF is a fixed location, a mobile entity, or an individual non-physician practitioner that provides diagnostic tests independent of a physician's office or a hospital.

B. What Entities/Persons Must be an IDTF?

Until recently, the Medicare Program Integrity Manual ("**PIM**"), Chapter 10, § 4.19.1 set forth the following criteria for determining whether an entity must enroll as an IDTF. On July 13, 2007, CMS issued Transmittal 216 revising § 4.19.1 to, among other things, remove the criteria for determining when an entity must enroll as an IDTF. Apparently CMS determined that the PIM was not the appropriate manual for including the IDTF enrollment criteria and, therefore, removed it. CMS is reportedly in the process of determining the best means for conveying these enrollment criteria. In the meantime, CMS indicated that the criteria previously set forth in § 4.19.1 remain in effect despite removal from the PIM.

A supplier of diagnostic tests which is not a physician practice, a hospital, or one of the other approved suppliers of diagnostic tests (see Part I.C., above) must enroll in the Medicare program as an IDTF. This includes transtelephonic and electronic monitoring services, such as pacemaker monitoring, cardiac event detection, and twenty-four (24) hour ambulatory EKG monitoring services. A physician practice *may* need to separately qualify as an IDTF if a "substantial portion" of a physician practice's business involves the performance of diagnostic testing services for outside patients. Certain contractors have informally interpreted "substantial portion" to mean that thirty percent (30%) or more of the practice's Medicare-covered diagnostic tests are performed for individuals who are not patients of the practice, *i.e.*, receive only the technical component of the test from the practice. However, a radiology group that provides the technical component of medical imaging is not required to become an IDTF, provided the group is: (a) owned by radiologists, a hospital, or both; (b) the group ordinarily bills on a global basis and does not purchase a significant number of interpretations; and (c) the group performs a substantial majority of interpretations at the location where the diagnostic tests are performed.

C. Are Companies with Lease Arrangements Required to Enroll as IDTFs?

In a Frequently Asked Question posted on the CMS website on December 16, 2008, CMS stated that companies which lease or contract with a Medicare enrolled provider or supplier to provide: a) diagnostic testing equipment; b) non-physician personnel described in 42 CFR 410.33(c); or c) diagnostic testing equipment and non-physician personnel described in 42 CFR 410.33(c) are not required to enroll as an IDTF. This "exemption" from the IDTF enrollment requirements would appear to apply not only to companies that lease portable or mobile diagnostic testing equipment but also to fixed diagnostic testing sites as well.

D. Can a Hospital or an ASC be an IDTF?

1. Hospitals. Although an IDTF is independent of a physician office and a hospital, a hospital operating entity or other provider or supplier entity may own and operate an IDTF. See Program Memorandum B-00-44 (August 30, 2000). However, an IDTF wholly-owned or operated by a hospital is subject to the seventy-two (72) hour DRG window rule. Further, because of the hospital outpatient bundling rule, an IDTF cannot separately bill for a service ordered by a physician for a registered hospital outpatient pursuant to an encounter with the patient in the hospital. 42 C.F.R. § 410.42(a). Finally, the hospital must carve out any costs incurred in the operation of the IDTF from the reimbursable cost centers on its cost report. 42 C.F.R. § 413.24(d)(7).[4]

2. ASCs. An ASC is not certified to provide diagnostic imaging services. Although the operating entity for a Medicare-certified ASC could become an IDTF, it could not operate an IDTF within ASC space during the ASC's scheduled hours of operation. See PIM, Chapter 10, § 4.19.1 (pre-July 13, 2007 version). The Medicare certification requirements for ASCs prevents an ASC from sharing its space, such as waiting rooms and other common areas, with an imaging facility during the ASC's hours of operation. However, under the new Medicare ASC payment system that became effective January 1, 2008, an ASC can now bill and obtain payment for certain ancillary radiology services that

[4] An independent supplier of diagnostic imaging services that contracts with a hospital to provide imaging services for the hospital's own inpatients and outpatients for which the hospital will bill Medicare is not required to become an IDTF.

are integral to the performance of covered surgical procedures. For more information see:

http://www.cms.hhs.gov/ASCPayment/downloads/ASCQAs123107.pdf.

E. IDTF Supplier Standards

Effective January 1, 2007, all IDTFs are required to meet certain supplier standards that were incorporated into the Medicare conditions of participation for IDTFs when CMS published of the final rule for the 2007 Medicare Physician Fee Schedule.[5] These standards were further revised and expanded with the issuance of the 2008 Medicare Physician Fee Schedule.[6] Any newly enrolling or re-enrolling IDTFs are required to certify in the Medicare enrollment application that the IDTF currently meets and will continue to meet the following standards:

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

2. The IDTF provides complete and accurate enrollment information. Changes in ownership, changes of location, changes in general supervision and adverse legal actions must be reported within 30 days of the change. All other changes must be reported within 90 days.

3. The IDTF maintains a physical facility on an appropriate site that contains: (a) the equipment necessary to provide the services identified on the enrollment application; (b) facilities for hand washing; (c) adequate patient privacy accommodations; and (d) storage of business and medical records. Mobile units must maintain medical records in a fixed, home office site. IDTFs that provide services remotely and do not see patients at the physical facility are exempt from hand washing and adequate patient privacy requirements.

4. The IDTF must have all testing equipment available at the physical site (excluding portable diagnostic equipment). The IDTF must maintain a current inventory of all equipment by serial and registration numbers, provide this information upon request by a Medicare contractor and notify the contractor of any changes in the

[5] See 71 Fed Reg. 69623, 69784 (Dec. 1, 2006).
[6] See 72 Fed. Reg. 66222, 66285 (Nov. 27, 2007).

equipment inventory within 90 days. For portable diagnostic equipment, the IDTF must maintain a catalog at the physical site of all such equipment, including serial numbers, and must make the portable diagnostic equipment available for inspection within 2 business days of a CMS inspection request.

5. The IDTF must maintain a primary business phone at the physical facility or the home office of the mobile IDTF units under the name of the designated business. The telephone number must be available in a local directory and through directory assistance.

6. The IDTF must have a comprehensive liability insurance policy of at least $300,000 per incident for each location that covers both the place of business and all customers and employees. The policy must be carried by a company that is not owned by a relative and the IDTF must provide the Medicare contractor with contact information for the insurance agent and the underwriter. Any policy changes or cancellations must be reported.

7. The IDTF must agree not to directly solicit patients through any means including, but not limited to, a prohibition on telephone, computer or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician or, to the extent permitted, a nonphysician practitioner who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

8. The IDTF must answer, document and maintain documentation at the physical site of the IDTF of a beneficiary's written clinical complaint. The documentation must include: (a) the name, address, telephone number, and health insurance claim number of the beneficiary; (b) the date the complaint was received, the name of the person receiving the complaint, and a summary of the actions taken to resolve the complaint; and (c) if an investigation was not conducted, the name of the person making the decision and the reason.

9. The IDTF must openly post these supplier standards for review by patients and the public.

10. The IDTF must disclose to the government the identity of any person who has ownership, financial, control or any other legal interest in the IDTF at the time of enrollment or within 30 days of a change.

11. The IDTF must have its testing equipment calibrated and maintained in accordance with the equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

12. The IDTF must have technical staff on duty with appropriate credentials to perform tests and be able to produce applicable federal or state licenses or certificates for such individuals.

13. The IDTF must have proper medical records storage and be able, upon request from CMS, to retrieve such record within 2 business days.

14. The IDTF must permit CMS to conduct unannounced, on-site inspections to confirm the IDTF's compliance with the standards. The site should maintain a visible sign posting the normal business hours and it should be accessible to CMS and beneficiaries during such business hours.

15. Unless the IDTF is hospital-based or a mobile IDTF, the IDTF cannot: (a) share a practice location with another Medicare-enrolled individual or organization; (b) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (c) share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.7 Note: This new standard became effective January 1, 2008. CMS has delayed the implementation date of this standard for one year until January 1, 2009 for existing IDTFs enrolled with Medicare as of January 1, 2008.

F. Supervising Physician Requirement.

1. General Supervision. The regulatory requirements for supervising physicians were revised effective January 1, 2007. An IDTF is still required to have one or more supervising physicians; however, the description of the supervising physician's responsibilities has changed. Prior to January 1, 2007, the regulations specified that a supervising physician was responsible for "the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of non-physician personnel who use the

[7] See 42 C.F.R. 410.33(g) and 72 Fed. Reg. 66222, 66398 (Nov. 27, 2007).

equipment." Effective for the period of January 1, 2007 through December 31, 2007, the language was replaced with what appeared to be a broader standard that the supervising physician is responsible for "the overall operation and administration of the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and *for assuring compliance with the applicable regulations*" (emphasis added).[8] Effective January 1, 2008, all language specifying the scope of responsibilities for a general supervising physician has been entirely removed.[9]

NOTE: The supervising physician does not have to be an employee of the IDTF. However, a group practice cannot be a "supervising physician."

2. Supervision Limits. Effective January 1, 2007, a supervising physician is limited to providing general supervision to no more than three (3) separately enrolled IDTF sites within the United States.[10] There is no specific limit to the number of IDTF sites at which a physician can provide direct or personal supervision services.

3. Proficiency. Each physician providing supervision services, (whether general, direct or personal) must evidence (and attest to having) proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished.[11]

NOTE: CMS has in the IDTF enrollment process collapsed the requirement that an IDTF have one or more supervising physicians (providing general supervision of the facility) and the coverage rule requiring general, direct or personal physician supervision of a diagnostic test (depending on the test). Medicare enrollment of an IDTF requires not only the identification of and attestation of proficiency by the IDTF's general supervising physician(s), but also the identification of and attestation of proficiency by the physician(s) who provide direct and personal supervision of testing at the facility. At least one Part B Contractor has issued a Local Coverage Determination that specifically

[8] See 71 Fed Reg. 69784 and PIM Ch. 10, § 4.19.5. We note that, although the prior quality-related language of § 410.33(b)(1) has been deleted, the PIM cites the prior language as the regulatory standard that should be applied to supervising physicians.
[9] See 72 Fed. Reg. 66398 (Nov. 27, 2007).
[10] Id.
[11] 42 C.F.R. § 410.33(b)(2).

identifies, by CPT code, the credentials that the supervising and interpreting physicians must hold, and the credentials that the non-physician technologists must hold.[12]

G. Non-Physician Personnel Requirements.

Any non-physician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate state health or education department. The IDTF must maintain documentation available for review that these requirements are met. PIM Ch. 10 § 4.19.4.

NOTE: The technician is not required to be an employee of the IDTF.

NOTE: A nurse practitioner, clinical nurse specialist, and physician assistant do not satisfy the credentialing and proficiency standards for the non-physician staff performing tests in an IDTF merely by virtue of their education and training. However, when performing diagnostic testing within the scope of their license and billing Medicare directly or through a proper reassignment to a group practice, these practitioners are not subject to physician supervision requirements.

H. Multi-State Entities.

An IDTF that operates across state boundaries must maintain documentation that its supervising physicians and technicians are licensed and certified in each of the states in which it is furnishing services. In the final rule for the 2007 Medicare Physician Fee Schedule, CMS clarified that for multi-state entities, the "place of service" on a claim form means the place where the service was actually delivered to the patient. Therefore, when an IDTF performs the entirety of a diagnostic test at the beneficiary's location, the beneficiary's location is the "place of service." If one r more aspects of the diagnostic test are performed at the IDTF, the IDTF is the place of service.[13]

I. IDTF v. Radiology Practice Enrollment.

As discussed in Section II.B., radiology practices (and radiology-hospital joint ventures) do not necessarily need to enroll in the Medicare program as IDTFs. Thus, imaging facility developers such as hospitals and

[12] See NHIC LCD L22698 at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=22698&lcd_version=34&basket=lcd%3A22698%3A34%3AIndependent+Diagnostic+Testing+Facilities+%28IDTF%29+%2D+Revised%3ACarrier%3ANHIC%7C%7C+Corp%2E+%2831140%29%3A#top .

[13] See 71 Fed Reg. 69784 and PIM Ch. 10, § 4.19.2.

radiologists have the option of enrolling the facility in the Medicare program as an IDTF or as a radiology practice. The advantage of enrolling the facility as a radiology practice is that the facility would not be subject to:

1. The fifteen supplier standards;

2. A site survey;

3. The proficiency standards for supervising and interpreting physicians; and

4. The written order requirement for IDTFs.

The radiology practice may also be able to perform more procedures than IDTFs; IDTFs may perform only tests and those "additional services related to, or generally considered required for, performing a diagnostic test" such as injections. The disadvantage of enrolling as a radiology practice is that the facility must bill globally and cannot purchase a significant number of interpretations, and must perform the substantial majority of interpretations at the location where the diagnostic tests are performed.

J. Dual Enrollment

Historically, Chapter 10 of the old Medicare Program Integrity Manual contained language in §5.1 et seq. that specified that if an entity's performance of outside diagnostic testing constituted a substantial portion of the entity's business, those diagnostic testing services were a sufficiently separate business so as to require the entity to enroll as an IDTF and bill separately for diagnostic tests furnished to those Medicare beneficiaries who were not patients of the practice. The pertinent portion of the manual stated:

> if a substantial portion of the entity's business involves the performance of diagnostic tests, the diagnostic testing services may be a sufficiently separate business to warrant enrollment as an IDTF *(it is considered independent for purposes of enrollment).* In that case, the physician or group can continue to be enrolled as a physician or a group practice of physicians, but must also enroll as an IDTF. The physician or group can bill for professional fees and the diagnostic tests they perform on their patients using their billing number. However, the practice must bill as an IDTF for diagnostic tests furnished to Medicare beneficiaries who are not patients of the practice. *The carrier should advise the entity how to bill for physician office tests versus IDTF tests and advise the claims personnel of the dual enrollment.* See Old

> Medicare Program Integrity Manual Ch. 10, § 4.19.1 (emphasis in original).

In 2007, however, CMS issued Transmittal 216, which contained revised manual instructions that did not include the previous language. See Medicare Program Integrity Manual, Ch. 10, § 4.19.1.

CMS is reported to be considering whether a non-radiology physician practice must enroll as an IDTF if a substantial portion of its business involves the performance of diagnostic testing for tests ordered by physicians from outside their practice.

III. "INCIDENT TO" AS AN ALTERNATIVE BASIS OF COVERAGE? (42 U.S.C. §§ 1395x(s)(2)(A); (s)(3); 42 C.F.R. § 410.26).

The 2002 Medicare Physician Fee Schedule update (the "**2002 Update**") added a substantial new subsection to the "incident to" regulation, effective January 1, 2002. 66 Fed. Reg. 55245, 55328 (codified at 42 C.F.R. § 410.26). The regulation states that Medicare Part B pays for services and supplies "incident to" the service of a physician (or other practitioner). "Services and supplies" is defined to exclude services and supplies specifically listed in the SSA as a separate benefit included in the Medicare program, *e.g.*, diagnostic tests covered under Section 1861(s)(3) of the SSA. Based on this definition, diagnostic testing furnished to non-hospital patients is not covered as an "incident to" service, because it has an independent basis for coverage. Although the preamble to the 2002 Update appeared to state plainly the very contrary proposition (*i.e.*, that "incident to" services and other bases for coverage are not mutually exclusive), CMS clarified in the 2003 Medicare Physician Fee Schedule update (the "**2003 Update**"), that, except for physical and occupational therapy services (which have an independent basis for coverage at Section 1861(s)(2)(D)), "incident to" coverage does not extend to services and items having an independent basis for Medicare Part B coverage. 67 Fed. Reg. 79966, 79994 (Dec. 31, 2002). Thus, imaging services performed in a physician's office are not subject to the "incident to" coverage rules.

IV. Anti-Markup Rule (Formerly, the Purchased Diagnostic Test Rule). (42 U.S.C. 1395u(n); SSA, § 1842(n); 42 C.F.R. § 414.50(b)).

A. Statutory Basis

The Anti-Markup Rule implements the statutory prohibition against an ordering physician billing Medicare in excess of the net charge for a diagnostic test that is not performed or supervised by the ordering physician or another physician with whom the ordering physician shares a practice. The Anti-Markup Rule applies to all diagnostic tests covered

under Section 1861(s)(3) of the SSA and paid for under 42 C.F.R. § 414.1 et seq., except clinical laboratory tests (which have their own special billing and payment rules).

B. The Rule Prior to January 1, 2008, and the Rule From January 1, 2008 Through December 31, 2009

For many years prior to January 1, 2008 the Anti-Markup Rule was known as the Medicare "Purchased Diagnostic Test Rule" or PDT Rule. The PDT Rule prohibited a physician from marking up to the Medicare program the charge for a purchased diagnostic test. Purchased tests billed by a physician would be paid the lower of the purchase price, the physician's charges, or the Medicare allowable amount. The PDT Rule did not apply to clinical laboratory tests (which are subject to their own special billing and payment rules), or the professional component of a diagnostic test, and health lawyers primarily focused on the issue of what distinguishes a purchased diagnostic test from a test performed through a lease or other arrangement between the billing physician and a diagnostic testing supplier or manager. In its 2008 Medicare Physician Fee Schedule final rule ("**2008 MPFS**"), CMS made significant changes to the PDT rule. First, CMS applied the rule (now referring to it as the Anti-Markup Rule ("**AMR**")) to both the technical *and* professional component of diagnostic tests. Second, CMS extended the AMR to diagnostics ordered and billed by "suppliers" other than physicians. Third, CMS introduced a new site-based trigger for the AMR's payment limitation.[14] However,

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[14] More specifically, the 2008 MPFS provides that the payment limitation applies if the ordering physician or other supplier bills for the technical and/or professional component of a diagnostic test and that technical or professional component is:

(1) Performed at a site other than the *office of the billing physician* or other supplier; or

(2) Purchased from an "outside supplier."

If the billing physician is part of a group practice, the "*office of the billing physician*" is defined as the space [not building] in which the group practice provides substantially the full range of patient care services that the group practice provides generally. An "*outside supplier*" is any person or entity that is not an employee of the billing physician and *who does not reassign* his/her/its right to Medicare payment to the physician practice.

If the diagnostic test trips either one of these triggers, Medicare payment to the billing physician (less applicable deductibles and coinsurance) may not exceed the lowest of the following amounts:

(1) The performing supplier's *net charge* to the billing physician or other supplier.

(2) The billing physician or other supplier's actual charge.

(continued…)

responding to complaints about these rule changes, CMS made substantial revisions to the AMR, effective January 1, 2009.

C. The Rule Effective January 1, 2009.

1. CMS Redesigns the AMR. In its 2009 Medicare Physician Fee Schedule final rule ("**2009 MPFS**"), CMS abandoned its long-standing application of the AMR to diagnostic tests that are "purchased." Instead, the revised AMR, effective January 1, 2009, focuses on tests for determining when the performing physician (in the case of the professional component) or supervising physician (in the case of the technical component) shares a practice with the ordering/billing physician practice. The 2009 MPFS gives physician practices and other suppliers the option of relying on either of two alternative tests in determining whether a diagnostic test is performed or supervised by a physician sharing a practice with the billing physician or other supplier. (CMS clarified that technical component diagnostic tests that do not require any physician supervision for purposes of Medicare coverage and payment are not subject to the AMR.) A physician practice or other supplier can rely on one alternative test for purposes of the technical component of a diagnostic test, and the other alternative test for purposes of the professional component of the same diagnostic test. Each test is discussed below.

2. "Substantially All" Test. The professional and technical components of a diagnostic test will be deemed to be performed (in the case of the professional component) or supervised (in the case of the technical component) by a physician sharing a practice with the billing physician or other (ordering) supplier if he or she furnishes at least 75 percent of his or her professional services through such billing physician or other (ordering) supplier. This 75 percent test simply requires that, at the time the billing physician or other (ordering) supplier submits a claim for a diagnostic test, it has a "reasonable belief" that either the performing physician furnished at least 75 percent of his or her professional services through the billing physician or other (ordering) supplier for the 12 previous months, or will furnish at

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(3) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

least 75 percent of his or her professional services through the billing physician or other (ordering) supplier for the next 12 months.

The "substantially all" test is indifferent to whether the performing physician is an employee or an independent contractor of the billing physician or other (ordering) supplier, or whether the diagnostic testing is performed in the same office or building where the billing practice provides the full range of its physician services. Thus, for example, if the interpreting radiologist for a diagnostic CT is an employee of an ordering group practice, the radiologist could perform the interpretation at any location, provided the employed radiologist performs at least 75 percent of his or her professional services through the billing group practice. (If the radiologist is an independent contractor, the radiologist would still need to perform the interpretation in the group's facilities to comply with the Stark Law.) In addition, if a group practice has multiple medical office sites, and the practice has centralized its advanced diagnostic imaging services in a building or office suite where only some of the practice's physicians practice, or where the practice does not maintain medical offices, the AMR's payment limitation won't apply so long as the "substantially all" test is met. Consequently, the "substantially all" test will be especially attractive to larger, integrated multi-site group practices that have sufficient diagnostic testing volume to justify hiring one or more interpreting or supervising physicians who will provide at least 75 percent of their patient care services through the group.

3. <u>"Same Building" Test</u>. The professional and technical components of a diagnostic test will also be deemed to be performed (in the case of the professional component) or supervised (in the case of the technical component) by a physician sharing a practice with the billing physician or other (ordering) supplier if: (a) the physician is an owner, employee or contractor of the billing physician or other supplier; and (b) the interpretation or the supervision (as the case may be) is performed in the offices of the billing physician or other supplier. This test has two definitions of "offices of the billing physician or other supplier," one for physicians and other suppliers, and one for "physician organizations" (POs) as defined by the Stark regulations. Stark regulations define a PO as a sole-shareholder professional corporation, a physician practice and a group practice.

For physicians and other (ordering) suppliers that are not POs, CMS defines "offices of the billing physician or other (ordering) supplier" as any medical office space (including diagnostic testing space) in "same building" (as defined by the Stark law) where the *ordering physician regularly furnishes patient care*. The Stark law defines "same building" as a structure with, or combination of, structures that share a single street address as assigned by the U.S. Postal Service, excluding exterior spaces, interior loading docks, parking garages, mobile vehicles, vans and trailers. For physicians and other (ordering) suppliers that are POs, "offices of the billing physician or other supplier" means *space* where the *ordering physician provides substantially the full range of patient care services that the ordering physician provides generally*. Although the literal text of the 2009 MPFS is unclear on this point, CMS clearly intends for "space" to include the same building where the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally. Importantly, for purposes of the "same building" test, the technical component of a diagnostic test is considered to be performed where the test is conducted, *i.e.*, where the equipment and technologists are located, *and* where the supervision is furnished.. All diagnostic tests require at least "general supervision" (*i.e.*, under a physician's overall direction and control), for Medicare coverage. Thus, it is possible that the supervising physician is not in the same building where the diagnostic test is conducted. Thus, in the case of a PO, to meet the "same building" test, an ordering physician may need to provide substantially the full range of his/her patient care services in two buildings -- the "same building" where the test is conducted *and* the "same building" where the supervising physician is present during the performance of testing. In the case of diagnostic imaging, for example, a physician practice is not required to hire a radiologist to perform physician supervision, and more than one physician may serve as the supervising physician for a diagnostic testing facility. However, in such case, the PO should document the physician supervision.

The "same building" test does not accommodate larger, multi-site group practices that have centralized their diagnostic testing at one or two of their sites, and not all of its ordering physicians work at the same buildings where the testing has been centralized. However, the "same building" test will accommodate solo physicians and small group practices that share a diagnostic testing facility with other physicians with medical offices in the "same building" where the diagnostic testing facility is located. In the

preamble to the 2009 MPFS, CMS states that shared diagnostic testing arrangements can meet the "same building" test.

4. Orders by Related Parties. The AMR applies not only to orders by the billing physician or other supplier, but also to orders by a party related to the billing physician or other supplier by common ownership or control as described at 42 C.F.R. § 413.17.

5. "Net Charge" Definition Issue. If a diagnostic test is not performed by a physician who shares a practice with the billing physician or other (ordering) supplier, Medicare payment to the billing physician or other (ordering) supplier for the diagnostic test is limited to the net charge for the test. In the 2009 MPFS, "net charge" means, with respect to the technical component, the net charge of the supervising physician, and, with respect to the professional component, the net charge of the interpreting physician. Such charge cannot reflect the performing or supervising physician's cost of leasing space or equipment from the billing physician or other (ordering) supplier, and, in the case of technical component diagnostic testing furnishing by the billing practice through use of its own diagnostic testing facility, cannot reflect the billing physician's direct and indirect costs of operating the facility *other than* an allocated portion of the salary and/or other compensation paid the supervising physician.[15]

V. Reassignment and Other Billing Issues. (42 C.F.R. §§ 424.70-.90; Medicare Claims Processing Manual, Chapter 1, § 30.2).

A. General Prohibition.

1. Unless an exception applies, Medicare contractors are only permitted to pay the supplier or physician who took assignment from the Medicare beneficiary, and are not permitted to pay anyone else under a reassignment or power of attorney.

2. This rule can affect the ability of an imaging facility to bill Medicare for imaging services because the facility may not have provided the professional and/or technical component of the imaging services pursuant to an assignment from the Medicare

[15] In the 2009 MPFS, CMS indicated that it will continue to consider the idea of simply prohibiting the reassignment of the professional and technical components of diagnostic tests. CMS believes that this would be a simpler approach, but declined to do so at that time because of concerns that it would prohibit non-abusive diagnostic testing arrangements.

beneficiary. For example, a physician practice might purchase the technical component of an imaging service or an IDTF might purchase the professional component of an imaging service.

3. Four exceptions to the general prohibition on reassignment that are potentially applicable to imaging facilities are summarized below.

B. Potential Exceptions.

1. Employment Exception. An IDTF, physician group practice or portable x-ray supplier can bill for the professional interpretations of an employed physician. Medicare Claims Processing Manual ("MCPM"), Ch. 1, § 30.2.6.

2. Anti-Markup Test Exception. Effective March 15, 2010, subject to the AMR, a billing physician or other supplier may bill Medicare for the professional and technical components of diagnostic tests performed by a physician or other supplier who does not "share a practice" with the billing physician or supplier, *i.e.*, may take reassignment from the performing physician or other supplier. (Note: the technical component of a diagnostic test is considered to be performed by the supervising physician.) (These tests, which are subject to the AMR's payment limitation, are referred to as "anti-markup tests," formerly known as "purchased diagnostic tests"). No formal reassignment from the performing or supervising physician is necessary in order to bill for anti-markup tests, provided (a) the billing physician or other supplier keeps on file the name, NPI, and address of the performing or supervising physician; and (b) the performing physician or other supplier is enrolled in the Medicare program. Transmittal 1892, Change Request 6733 (Jan. 15, 2010), deleting MCPM, Ch. 1. § 30.2.9.1, and modifying MCPM, Ch. 1, § 30.2.9. Notably, this manual instruction change effectively repeals the purchased diagnostic and purchased interpretation exceptions to the reassignment prohibition, which excepted all manner of purchased diagnostic tests and interpretations, regardless of whether they were subject to the payment limitation of the AMR., previously known as the purchased diagnostic test rule. As of March 15, 2010, IDTFs and other suppliers billing Medicare for purchased tests and interpretations that are not anti-markup tests, i.e., subject to the AMR payment limitation, must rely on the contractual arrangement exception (discussed below), which means that they must now obtain and file executed 855-R reassignment forms from all of their contracted supervising and interpreting physicians.

(See Part V.C, below, for related changes to billing for purchased tests and interpretations.)

3. Contractual Arrangement Exception. Payment may be made to an entity (i.e., a person, group, or facility) enrolled in the Medicare program pursuant to a reassignment by a physician or other person under a contractual arrangement with that entity, *regardless of where the service is furnished*. Thus, the service may be furnished on or off the premises of the entity submitting the claim on a reassignment basis. MCPM, Ch. 1, § 30.2.7. *However,* the contractual arrangement exception does not, in the case of reassignment of payment for diagnostic testing, obviate the need for a physician practice to comply with the location restrictions imposed by the Anti-Markup Rule's "same building" test (discussed above), or the Stark law's in-office or physician services exceptions, to the extent the Anti-Markup Rule and/or Stark law applies to such diagnostic testing.

   The reassignee and the supplier are jointly and severally responsible for any Medicare overpayment to the reassignee, and the supplier furnishing the service has unrestricted access to claims submitted by the reassignee for services provided by the supplier. 42 C.F.R. § 424.80(d). The billing supplier must file an 855-R reassignment when relying on this reassignment exception.

C. Billing Procedure for Anti-Markup Tests and Reassigned Services

1. Billing/Payment Jurisdiction for Reassigned Services. Effective March 15, 2010, except for anti-markup tests, *i.e.*, tests subject to the AMR payment limitation (discussed below), the billing physician/supplier must bill the contractor that has jurisdiction over the geographic area where the reassigned service was physically rendered. MCPM, Ch. 1, § 10.1.1.3

2. Billing/Payment Jurisdiction and Pricing Policy for Anti-Markup Tests. Effective March 15, 2010, B/MACs must accept claims from physicians/suppliers for anti-markup tests, regardless of whether the service was furnished within the B/MAC's geographic jurisdiction, but is not permitted to accept claims for purchased diagnostic tests and interpretations performed outside the B/MAC's jurisdiction that are **not** anti-markup tests, *i.e.*, subject to the AMR payment limitation. The contractor is to price the test or interpretation based on the locality where the test or interpretation was performed. This manual provision change, which is in Transmittal 1892, reverses the manual instruction in effect since

2005 requiring Medicare contractors to accept claims for *all* purchased diagnostic tests, regardless of where they were performed, and regardless of whether they were subject to the payment limitation under, what was referred to at that time, the purchased diagnostic test rule. This means that IDTFs and other suppliers of diagnostic tests will have enroll in multiple B/MAC jurisdictions and to split-bill the PC and the TC in circumstances where the two components are performed in different B/MAC jurisdictions. MCPM, Ch. 1, §§ 10.1.1, 10.1.1.2, 30.2.9, Ch. 23, § 30.6; Transmittal 1892, CR 6733, January 15, 2010.

3. Claims for Anti-Markup Tests. When billing electronically, more than one test subject to the AMR may be billed on the ANSI X12N 837P electronic format provided that the total purchase amount for each test is separately stated. An electronic claim can include both the technical and professional component of an anti-markup test, even if the two services are not submitted with the same date of service and same place of service codes. When billing on a paper claim (CMS-1500 form), however, a separate claim form must be used for the technical and professional component of an anti-markup test. This enables CMS to determine the appropriate service facility location ZIP code and the purchase price of each component of the test. Global billing is not permitted, meaning that the supplier must line-item bill (or, pursuant to the above restrictions, use separate claim forms) for the technical and professional components of the test. MCPM, Ch. 1, § 30.2.9.

4. Place of Service/Date of Service Transmittal. On February 5, 2010 CMS gave notice that it was rescinding Change Request (CR) 6375 titled, "Place of Service (POS) and Date of Service (DOS) Instructions for the Interpretation (Professional Component) and Technical Component of Diagnostic Tests." This transmittal would have required split-billing of the PC and TC of diagnostic tests if the place of service codes or the dates of service for the two components were not identical. Despite efforts by organizations, including ACR, RBMA, HBMA and MGMA to have CMS withdraw the transmittal, CMS announced last December that it would delay only the date of service portion of the original transmittal. The industry continued to seek a delay of the POS instructions to carriers. CMS declined to do that - until February 5.

   The POS instructions were very controversial and the guidance from carriers on how to implement POS coding varied widely. The

rescission announcement has been met with widespread approval from the industry.

CMS is expected to revisit the issue in the coming year.

VI. MEDICARE PAYMENT.

A. Imaging Facilities.

Imaging facilities are paid under the Medicare physician fee schedule or contractor pricing, and the Medicare Part B deductible and coinsurance obligations apply.

B. Mobile IDTFs v. Portable X-Ray Suppliers.

A portable x-ray supplier can bill and be separately paid for transportation and setup, whereas a mobile IDTF providing the same services cannot.

C. Deficit Reduction Act of 2005; Hospital Outpatient PPS v. Medicare Physician Fee Schedule.

The Medicare physician fee schedule has at times paid substantially better for certain imaging modalities than the hospital outpatient PPS schedule. The Deficit Reduction Act of 2005 capped payment for most medical imaging services paid under the Medicare physician fee schedule at the payment under the hospital outpatient PPS. For purposes of applying the technical component payment cap, "imaging services" are defined as imaging and computer-assisted imaging services, including: X-ray; ultrasound (including echocardiography); nuclear medicine (including PET); MRI; CT; and fluoroscopy. CMS specifically excluded from the payment cap: (a) nuclear medicine services that were either non-imaging diagnostic or treatment services; (b) diagnostic and screening mammography; (c) radiation oncology services that were not imaging or computer-assisted imaging service; and (d) any CPT code that describes a procedure for which fluoroscopy, ultrasound, or another imaging modality which is included in the code, whether or not it is used or employed peripherally in the performance of the main procedure (e.g., CPT code 36122 – bronchoscopy with or without fluoroscopic guidance). This payment limitation is effective January 1, 2007. S. 1932, § 5102(b), and the savings realized by this cap are not subject to budget neutrality.[16] For imaging services that are subject to both the outpatient hospital cap and the multiple procedure reduction described below, CMS will first apply

[16] 71 Fed. Reg 69659-69661.

the multiple procedure reduction and then apply the outpatient cap since this approach generally results in higher payments than if the hospital outpatient cap were applied first.

D. Multiple Procedure Payment Reduction.

Effective January 1, 2006, CMS instituted a 25% payment reduction for a second imaging procedure provided in the same session if the procedure is within the same family of imaging codes and involves a contiguous body area.[17] The Deficit Reduction Act of 2005 provides that the savings from this reduction are not subject to budget neutrality. In both the final 2007 and 2008 Medicare Physician Fee Schedule, CMS elected to maintain the multiple procedure reduction at its current 25% level rather than increasing the reduction to 50% as a result of the outpatient cap described above and information it received from the American College of Radiology demonstrating that a 50% reduction in multiple procedure technical component payments was not justified.[18]

E. Payment Cuts: Equipment Utilization.

The 2010 MPFS Rule adopts an increase in the equipment utilization rate from 50% to 90% for diagnostic equipment costing more than $1 million. The increase will be phased in through a four year transition period that begins January 1, 2010. Beginning 2010, 75% of the practice expense is paid based on the old usage rate of 50% and 25% based on the new 90% rate. The old usage rate makes up 50% of the PE component of the payment in 2011, 25% in 2012, with full implementation in 2013.

When fully implemented in 2013, the overall cuts to the technical component of MRI and CT service will be in the billions of dollars

VII. APPLICATION OF OTHER FEDERAL LAWS.

A. The Stark Law and Imaging Collaborations with Referring Physicians.

Collaborative imaging and other diagnostic testing arrangements with referring physicians may potentially fit within one of the following Stark exceptions:

[17] 70 Fed. Reg. 70115, 70261 and (Table 27) (Nov. 21, 2005).
[18] 71 Fed. Reg. 69662.

1. Non-DHS Referrals. "Radiology and other imaging services" are one of the ten categories of designated health services or "**DHS**" covered by the Stark Law.[19] 42 C.F.R. § 411.351. However, "radiology and other imaging services" does not include invasive radiology services. Accordingly, services such as coronary angiography and endoscopies are not DHS (unless provided as a hospital outpatient service).[20] Because these services are not DHS, joint ventures with referring physicians for these imaging services are not subject to the Stark Law (*e.g.*, cardiac cath labs and GI labs). Nuclear imaging and medicine was added as Stark DHS, effective January 1, 2007. Thus, any PET joint ventures with referring physicians (*e.g.*, medical oncologists) should have been unwound or restructured before the close of 2006.

2. Radiologist Referrals Exception. A referral by a radiologist for diagnostic radiology services pursuant to a consultation requested by another physician is not a referral under Stark, provided the referring radiologist provides or supervises the provision of the service. 42 C.F.R. § 411.351 (defining "referral"). This exception opens the door to imaging joint ventures involving radiologists, but the inclusion of interventional radiologists in such ventures presents a challenge.

3. Anti-Markup Test Exception. In the 2008 MPFS, CMS amended the Stark regulations to provide that a physician does not make a referral to a Stark "entity" if the physician or practice "bills Medicare for the technical or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with 414.50 of this chapter and section 30.2.9 of the CMS Internet-Only Manual, publication 100-4, Claims Processing Manual, Chapter 1 (general billing requirements)."[21]

4. Rural Provider Exception. The rural provider exception permits ownership by referring physicians in an imaging facility located in a rural area (defined as an area that is not in a Metropolitan Statistical Area), provided that at least seventy-five percent (75%)

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[19] For a list of certain designated health services by specific CPT code, see the CMS Physician Self-Referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage.

[20] "Radiology and other imaging services" is defined by reference to a list of CPT/HCPCS codes that is updated every year as part of the Medicare physician fee schedule update. For the latest list, see 72 Fed. Reg. 66222, 66574 (Addendum I)(Nov. 27, 2007)(Reproduced at Appendix A of this Memorandum).

[21] 72 Fed. Reg. 66222, 66400 (Nov. 27, 2007).

of the DHS performed by the facility is provided to residents of a non-MSA. 42 C.F.R. § 411.356(c).

5. In-Office Ancillary Services Exception. Although CMS has declined to create a regulatory exception for physician ownership of a shared imaging facility, it has recognized that such facilities may be possible under the Stark Law if each participating physician practice satisfies the requirements of the in-office ancillary services exception. The in-office ancillary services exception has physician supervision, location and billing requirements. The billing requirement is easy to satisfy, but the supervision and location requirements can present challenges for block lease or other shared DHS facility arrangements. 42 C.F.R. § 411.355(b).

   a. Supervision Requirement. The in-office exception requires that DHS not personally furnished by the referring physician or another member of the same group practice must be furnished by an individual under the supervision of a physician in the group practice. The supervision must satisfy Medicare coverage and payment rules. As noted above in Part I.D., Medicare requires "direct supervision" of certain diagnostic imaging procedures, most notably, MRI or CT with contrast media. Thus, the physician practices considering participating in a shared DHS facility should consider what level of supervision will be required to participate in the shared DHS facility, and how each practice intends to provide the supervision. CMS commented in the Stark Phase III final rule that it believes shared facility arrangements that involve a "per use" scheduling and fee arrangement are unlikely to satisfy the supervision requirement.[22]

   b. Location Requirement. The in-office exception requires that the DHS be provided in one of two places, the "same building" or a "centralized building." Each approach is described below:

      i. "Centralized Building" Approach. Stark regulations define "centralized building" as all or part of a building (including a mobile unit) leased by the group on a full-time basis (24/7) for at least six (6)

[22] 72 Fed. Reg. 51012, 51033 (Sep. 5, 2007).

months and used exclusively by the group practice. 42 C.F.R. § 411.351. Thus, the centralized building approach to satisfying the location test of the in-office exception is not amenable to shared imaging facility arrangements. **NOTE**: It is the proliferation of "pod lab" arrangements that seek protection under the centralized building criteria that CMS is specifically attempting to curb by issuance of the revised Anti-Markup Rule as well as its request for public comments on whether it should narrow the scope of the in-office ancillary services exception to services that are furnished as more of an integral part of a physician's practice.

ii. "Same Building" Approach. Stark regulations define "same building" as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (*e.g.*, lawns, courtyards, driveways, parking lots), interior parking garages, and mobile vehicles, vans, or trailers. 42 C.F.R. § 411.351. DHS will be deemed to be provided in the "same building" as the practice if one of the following three sets of circumstances are satisfied:[23]

(a) The DHS is provided in a building in which: (i) the referring physician or his/her group practice has an office that is normally open to their patients at least thirty-five (35) hours per week; (ii) the referring physician or one of the group practice members regularly practices medicine; (iii) the referring physician or one of the group practice members furnishes physician services to patients at least thirty (30) hours per week; and (iv) the thirty (30) hours per week includes "some" physician services unrelated to furnishing of any type of DHS, although these services may lead to ordering DHS ("services unrelated to DHS").

[23] 42 C.F.R. § 411.355(b)(2).

(b) The DHS is provided in a building in which: (i) the referring physician or his/her group practice has an owned or leased office that is normally open to patients at lease eight (8) hours per week; (ii) the referred patients "usually" receive physician services or a group member; (iii) the referring physician regularly practices medicine and furnishes physician services to patients at this site at least six (6) hours per week; and (iv) the six (6) hours per week includes "some" physician services unrelated to furnishing of any type of DHS.

(c) The DHS is provided in a building in which: (i) the referring physician or his/her group practice has an office that is normally open to patients eight (8) hours per week; (ii) the referring physician or a member of the group regularly practices medicine and furnishes physician services to patients at least six (6) hours per week in that office; and (iii) the referring physician is present in the building during a patient visit when ordering the test or the referring physician or a member of the group practice is present while the DHS is performed.

6. Physician Services Exception. The physician services exception applies, in pertinent part, to the professional DHS performed by a physician in the same group practice as the referring physician. 42 C.F.R. § 411.355(a). This exception could be used, for example, for professional interpretations of imaging ordered by a group practice member and performed by an employed or independent contractor radiologist. However, note that a physician contractor is only a "physician in the group practice" if the physician contractor has a contractual arrangement directly with the group practice and the physician contractor performs the services for the group's patients "in the group practice's facilities."[24] Thus, in order for a group practice to bill Medicare for a professional interpretation of DHS furnished by a contracted physician (pursuant to referrals by

[24] 72 Fed. Reg. 51012, 51082 (Sep. 5, 2007).

group practice owners and employees), the group must arrange for the interpretations to be performed in the group practice's facilities. The location constraints of the Anti-Markup Rule's "same building" test, described above in Part IV, may also apply.

7. Space & Equipment Rental Exceptions. It is not uncommon for a shared diagnostic facility arrangement to involve the lease of space and equipment by a radiology practice that owns an imaging facility to a physician practice that refers patients to the radiology practice for professional component services. Up until December 4, 2007, these lease arrangements were subject to the Stark indirect compensation analysis. However, due to the addition of a new "stand in the shoes" provision implemented by Stark II, Phase III, such space and equipment leases between referring physician practices and radiology practices would need to be structured to meet all the requirements of the space and equipment rental exceptions to the Stark Law.

   a. *"Stand in the Shoes."* Under the new "stand in the shoes" provision, a physician who holds an ownership or investment interest in a "physician organization" is deemed to "stand in the shoes" of the physician organization for purposes of determining the physician's compensation arrangements.[25] A "physician organization" is a physician (including a professional corporation with a sole owner), a physician practice or a group practice as that term is defined under the Stark Law.[26] Thus, a referring physician that is a owner in his or her group practice "stands in the shoes" of his or her group practice, and, thus, has a direct compensation arrangement with any DHS entity (e.g., radiology practice) with which the group practice has entered into a space or equipment lease.

   b. The space and equipment lease arrangements must satisfy all the requirements of the space and equipment rental exceptions, including among other things that space and equipment be "used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor)."[27] In its preamble comments to the Stark II, Phase III, CMS noted

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25 72 Fed. Reg. 51012, 51087 (Sep. 5, 2007).
26 72 Fed. Reg. 51012, 51083 (Sep. 5, 2007).
27 72 Fed. Reg. 50102, 51091 (Sep. 5, 2007).

that, in effect, the exclusive use requirement of the exceptions requires that leases for space and equipment be for established blocks of time.[28]

B. 2009 IPPS Stark Rule Changes (Eff. October 1, 2009) 73 Fed. Reg. 48434, 48751-53 (Aug. 19, 2008)

1. Prohibits "Per Use" Lease Fees. It is currently permissible under the Stark exceptions for space and equipment leases, including the fair market value exception (with respect to equipment), and the indirect compensation exception, to structure the lease payments on a per-use or "per click" basis.[29] In the final 2009 IPPS update, CMS effectively prohibits such fees, effective October 1, 2009. The Stark compensation exceptions potentially applicable to space or equipment leases between a group practice or other referring physician-owned company and a DHS entity (*e.g.*, hospital) were revised to exclude per unit of service rental charges "to the extent such charges reflect services provided to patients referred by the lessor to the lessee." For example, a cardiology group or company owned by cardiologists will not be able to lease a high-resolution CT to the hospital on a "per click" basis since the rent will reflect services provided to patients referred by the lessor-cardiology practice or -cardiologist-owned company to the lessee-hospital for CT angiography services. The lease payments would need to be a fixed, fair market value amount that would not change regardless of the number of studies the hospital actually performs (e.g., $10,000 per month). Although not specifically addressed by CMS, it is debatable whether structuring the provision of space or

[28] 72 Fed. Reg. 51012, 51045 (Sep. 5, 2007). Depending on what CMS means by "block leasing," the notion that "block leasing" necessarily follows from the "exclusive use" standard of the space and equipment rental exceptions could certainly be challenged. "Block leasing" is typically understood to involve fixed periods of time, e.g., every Monday and Tuesday from 8:00 am to 12:00 p.m. for the term of the lease. However, more flexible part-time arrangements, such as arrangements whereby a practice leases by the hour on an as-needed, as-scheduled, basis, or leases a certain number of hours for the term of the lease and uses the time on an as-scheduled basis, do not preclude the lessee from having exclusive (no sharing) use of the space or equipment "when being used by the lessee . . . ." 42 C.F.R. § 411.357(a), (b).

[29] Although the extant Stark exceptions for space and equipment rental currently permit "per click" lease payments, and, apparently permit percentage of collections or other percentage-based payments, "per click" and percentage-based lease payments cannot qualify for the protection of the anti-kickback space and equipment rental safe harbors.

equipment as a "supply" or "management" arrangement, instead of a lease, avoids this prohibition on "per unit of service" payments.[30]

2. Prohibits Percentage Lease Arrangements. Currently, it is apparently permissible under the Stark exceptions for space and equipment leases, including the indirect compensation exception, to structure the lease payments on a percentage of collections, charges, or other percentage basis. In the final 2009 IPPS update, CMS effectively prohibits such fees, effective October 1, 2009. The Stark compensation exceptions potentially applicable to space or equipment leases between a group practice or other referring physician-owned company and a DHS entity (*e.g.*, hospital) were revised to exclude rent formulae based on a "percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space, or, in the case of equipment leasing, the services performed on or business generated through the use of the equipment. For example, a group practice or other referring physician-owned company will not be able to lease an MRI to a radiology practice and structure rent as a percentage of the radiology practice's net technical component collections. The lease payments would need to be a fixed, fair market value amount that would not change regardless of the number of MRI scans the radiology practice actually performs (e.g., $10,000 per month). Although not specifically addressed by CMS, it is debatable whether structuring the

[30] In an FAQ issued January 22, 2009 (I.D. # 9556), CMS confirmed that the prohibition on per unit of service or percentage-based rent for the lease of space and/or equipment is *not* implicated by *services* furnished by a physician-owned company to a hospital or other DHS entity:

> In Phase II, we recognized the common practice of many contractors to provide the tools of their trade in connection with service contracts (69 FR 16091). There, we did not require the use of the exception in §411.357(b) for the lease of equipment whenever equipment was provided as part of a service contract. The same applies in the case of lithotripsy services provided "under arrangements" to a hospital. Provided that a lithotripsy partnership is actually furnishing a service (or a package of services) to the hospital, and not merely leasing equipment over which the hospital would have dominion and control, the hospital may compensate the lithotripsy partnership using a per-unit or percentage-based compensation formula, as long as all of the requirements of a relevant exception are satisfied.

However, note that, if the service provided by the physician-owned company to the hospital or other DHS entity is billed by the hospital as hospital services or other Stark DHS, *and* is not lithotripsy services, the new Stark DHS entity definition (discussed at Part VII.B.3), and the limitations it places on "under arrangements" transactions between hospitals (or other DHS entities) and physician-owned companies, would be implicated.

provision of space or equipment as a "supply" or "management" arrangement, instead of a lease, avoids this prohibition on percentage-based payments.

3. Prohibits "Under Arrangements" Transactions with Hospitals. Currently, the entity furnishing Stark DHS (the "DHS entity") is generally the entity that bills for or submits a claim to Medicare for DHS. Effective October 1, 2009, the 2009 IPPS extends the definition to include entities that perform services that are billed by another entity as DHS. 73 Fed. Reg. 48434, 48751. This rule change was intended to prohibit and cause the unwind of so-called "under arrangements" transactions between referring physician-owned companies and hospitals.[31] The rule change achieves this end because, unless the physician-owned company performing the DHS qualifies for the rural investment exception to Stark, the physician-owned company, now a DHS entity, will not have an ownership/investment exception to the Stark law. For example, there are many cardiologist-owned companies that furnish CT angiography, nuclear medicine, and/or diagnostic and interventional cardiac cath lab services to hospitals "under arrangements." These companies have never needed a Stark ownership/investment interest exception because, since the hospital bills for the services, the companies were not DHS entities. Unfortunately, CMS declines to furnish the industry with a "bright-line" definition of what it means for an entity to "perform services" billed as DHS by another entity; although CMS did, in final 2010 MPFS update, request comments on whether it should define or clarify this term, and, if so, how. Additionally, CMS welcomed any information concerning how the industry interpreted and applied the new definition of DHS entity and how under arrangement agreements have been restructured in order to comply with the definition. Questions remain whether certain so-called hospital facility or service "supply" or "management" arrangements implicate the new DHS entity definition.

C. The Anti-Kickback Statute and Collaborative Imaging Arrangements with Referring Physicians.

1. April 2003 OIG Special Advisory Bulletin on Contractual Joint Ventures. In its April 2003 Bulletin, the OIG expressed its concern with certain contractual joint ventures, specifically those

[31] 72 Fed. Reg. 38122, 38186 (Jul. 12, 2007).

having certain indicia, which, as applied to contractual imaging joint ventures, are as follows:

a. New Line of Business. A practice expands into services that can be provided to its existing patients (*i.e.*, MRI studies).

b. Captive Referral Base. The new business predominantly or exclusively serves the practice's existing patient base, and is not intended to expand and serve patients outside of that category.

c. Little or No Bona Fide Business Risk. The practice's primary contribution to the venture is referrals. It makes little or no financial or other investment in the business, assuming only risks such as non-payment for services (which can be planned for based upon historical activity).

d. Status of Manager/Supplier as Potential Competitor to Physician's New Line of Business. The manager/supplier is an actual or would-be competitor of the practice, having the capacity to provide virtually identical services itself and to bill for those services in its own name.

e. Manager/Supplier Provides "Turn-Key" Operation. The manager/supplier provides key services such as management, billing, equipment, personnel and related services, office space, training, and health care items/supplies/services. The greater the total services provided by the manager/supplier, the greater the likelihood that the venture is suspect.

f. Residual Profits for Physician. The practical effect of the entire arrangement is that the practice bills payers for services provided by the manager/supplier, and the profits for the practice vary with the value and volume of the business.

g. Exclusivity. The practice is barred from providing the services of the business to any patients other than its own and/or the manager/supplier is barred from providing services in its own right to the patients of the practice.

The Bulletin also states the OIG's theory that contractual joint ventures involve illegal remuneration in the form of the difference

between what the manager/supplier is paid by the practice and the practice's collections from payors. In other words, the OIG believes that, through a contractual joint venture, the manager/supplier conveys a portion of its profits to the practice. Moreover, the OIG contends that this profit or profit opportunity does not qualify for safe harbor protection, and may implicate the statute.

2. OIG Advisory Opinion 04-08. On June 30, 2004, the OIG issued a negative opinion in response to a proposal by a multi-specialty physician group (the "**Anchor Group**") to form a wholly-owned LLC to develop and operate a physical therapy center (the "**PT Center**"). The LLC would lease the PT Center's space, equipment, and personnel on an as-needed, first-come, first-served basis to the Anchor Group and other physicians in the building with patients requiring physical therapy services (the "**Participating Practices**"). Pursuant to a one-year lease, each Participating Practice would pay monthly rent to the LLC equal to the fair market value lease of the PT Center on a full-time basis divided by the number of Participating Practices. Thus, each Participating Practice would pay equal rent regardless of usage, except that Participating Practices furnishing their own physical therapist would pay less. The LLC would not bill in its own right, but rather each Participating Practice would bill payors for PT services furnished to its patients.

   a. The OIG noted a number of factors in this arrangement that would create an unacceptable level of fraud and abuse risk:

      i. The Participating Practices were sources of referrals to each other.

      ii. Each Participating Practice's lease would not qualify for safe harbor protection because the leases were part-time and did not specify the precise schedule of time that each Participating Practice would use the PT Center and the amount of compensation for each period of time.

      iii. The overlapping, as-needed nature of the leases that would make it difficult to monitor and document fair market value;

      iv. At least some of the Participating Practices would be paying more or less than fair market value for the

space, equipment, and administrative services actually used, which overpayment or underpayment could be remuneration to or from other participants for referrals; and

v. The risk of an unwarranted benefit for the Anchor Group created by basing the rental payments from all the Participating Practices on the total rental value of the equipment, space, and personnel services of the PT Center, rather than on each Lessee's individual usage of the PT Center.

b. The OIG concluded that the proposal could potentially generate prohibited remuneration under the anti-kickback statute, and, thus, the OIG *could* potentially impose administrative sanctions on the Anchor Group in the event it proceeded with the proposal.

3. OIG Advisory Opinion 04-17 (Dec. 17, 2004).

a. *The Facts.* This opinion involved a pathology laboratory lease and management arrangement. The pathology laboratory requesting the opinion (the "**Requestor**") contemplated leasing pathology pod labs on a full-time basis to physician group practices. The Requestor would sublease laboratory space and equipment to a physician group on a full-time exclusive basis, and provide to the group the services of technical laboratory personnel and a pathologist (who would rotate through the multiple pod labs in the building as needed). The physician group would pay the Requestor a fixed monthly fee and a per specimen fee. If the Requestor performed billing and collections on behalf of the practice, the group would pay the Requestor 5% of collections.

b. OIG's Analysis.

i. The OIG noted that the Requestor was an affiliate of an existing provider of pathology laboratory services, and that the Requestor would supply substantially all of the inputs for the pod labs. The physician group would, the OIG found, commit "almost nothing in the way of financial, capital, or human resources to the Path Lab, and, accordingly, would assume no or very little real business risk."

ii. The Requestor contended that the physician group would assume significant business risk by virtue of its financial obligations to the Requestor, but the OIG disagreed, noting that the per specimen fee and percentage of collections payments were not fixed obligations, and that the fixed monthly fee was based on historical utilization of pathology laboratory services by the physician group, and, as such, the group practice was at little risk of not covering the cost of its fixed payment obligation to the Requestor.

iii. The OIG also argued that structuring the pathology laboratory arrangement to fit within the office space and equipment rental safe harbors and the personal services and management contracts safe harbor "would only protect the remuneration paid by the Physician Groups to the Requestor for actual services rendered or space rented. . . ;" it would not protect the physician group's retained profit from pathology services. The OIG believed there was a significant risk that this "retained profit" by the group practice was, in effect, paid to the group by the lab to induce the group to make referrals to its leased lab. In other words, the OIG's theory is that when a retailer of ancillary services enters into a "wholesale" supplier, lessor, or management arrangement with an actual or potential customer, the retailer is effectively conveying to the customer some of the retailer's margin (the difference between what the practice is paying it and what the practice is being paid by payors). This conveyed profit or profit opportunity is not, in the OIG's view, protected by any safe harbor, and, thus, exposes the participants to potential liability.

4. OIG Advisory Opinion 8-10 (Aug. 19, 2008). The second OIG advisory opinion on a contractual joint venture, this opinion involved the purportedly safe harbored lease of a radiation therapy center to a urology group. The OIG declined to issue a favorable opinion, indicating that the "profit opportunity" presented by the safe harbored lease and services arrangement could not be safe harbored, and the arrangement presented a risk that the profit opportunity constituted an improper payment for referrals: "Even

if each of the individual agreements making up the Proposed Arrangement could satisfy the applicable safe harbor conditions under the space and equipment rental safe harbors and the personal services and management contracts safe harbor, the safe harbors would only protect the remuneration paid by the Urologist Groups to the Requestor or to the individual Radiologists for actual services rendered or space or equipment rented."

VIII. MIPPA - SECTION 135 ACCREDITATION REQUIREMENTS.

Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires all non-hospital suppliers of advanced imaging services be accredited by organizations designated by the Secretary of HHS by January 1, 2012, to qualify to provide services to Medicare beneficiaries. In January 2010, CMS published a *Federal Register* notice announcing its approval of the following three national accreditation organizations to accredit suppliers seeking to furnish the technical component of advanced diagnostic imaging services (MR, CT and PET) under the Medicare program: the American College of Radiology, the Intersocietal Accreditation Commission, and The Joint Commission.