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ATTORNEYS

**MEDICARE REQUIREMENTS
FOR DIAGNOSTIC IMAGING SERVICES
PROVIDED TO HOSPITAL OUTPATIENTS
“UNDER ARRANGEMENTS”**

May 12, 2009



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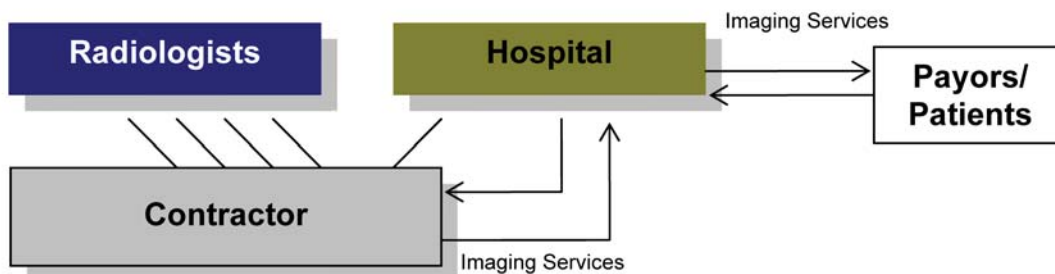
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This Memorandum describes Medicare requirements applying to the provision of diagnostic imaging services to hospital outpatients “under arrangements.” These requirements will be of interest to hospitals and radiologists considering entering into such an arrangement or restructuring a freestanding imaging center arrangement. (Such parties may also wish to consider other types of arrangements, such as leasing arrangements, that are beyond the scope of this discussion.) This Memorandum is intended for informational purposes only and does not constitute legal advice.

Description of “Under Arrangements” Structure. The following discussion assumes that a hospital contracts with an entity (the “Contractor”) for the provision of outpatient diagnostic imaging services to the hospital “under arrangements” at the other entity’s location. The term “under arrangements” is Medicare terminology used to indicate that a hospital has arranged for others to provide services on the hospital’s behalf. The Contractor provides the space, equipment, staff and supplies necessary to provide the technical component of the imaging services on behalf of the hospital. However, the hospital is the provider of imaging services and bills patients and payors for the technical component of imaging services under the hospital’s provider agreements and provider numbers. The hospital pays the Contractor a fair market value fee for providing the imaging services on behalf of the hospital.

The Contractor could be an unrelated entity or could be a joint venture between the hospital and other persons. As a result of recent changes to regulations under the Stark Law, generally, effective October 1, 2009, physicians will not be permitted to own interests in the Contractor if they refer services provided “under arrangements.” However, physician ownership will still be permissible if the hospital is located in a rural area and at least 75% of the services provided “under arrangements” are provided to patients who reside in a rural area, or if the diagnostic imaging services¹ are ordered by radiologists pursuant to a consultation and furnished by or under the supervision of the radiologist or of a radiologist in the same group practice, as in the following illustration:



- Hospital is the provider of imaging services
- Payors pay hospital
- Hospital pays joint venture for services on fair market value basis

¹ However, this exception does not apply to interventional radiology services, which generally cannot be provided “under arrangements” by an entity with referring radiologist ownership unless the rural exception applies.

Medicare Coverage of Outpatient Diagnostic Imaging Services and Services Provided by Hospitals “Under Arrangements.” In order for diagnostic imaging services provided by a hospital “under arrangements” to be covered under Medicare Part B, the services must be provided in a manner that satisfies all applicable Medicare requirements, including the Medicare coverage requirements, applicable requirements of the Medicare Conditions of Participation for hospitals, physician certification requirements, and physician supervision requirements.

Medicare Coverage Requirements. Medicare Part B covers diagnostic services furnished to outpatients by or under arrangements made by a hospital if the hospital ordinarily furnishes the services to its outpatients for diagnostic study. Covered services (i.e., services not generally excluded from coverage under the Medicare program) must meet the following conditions: (1) they must be furnished while the patient is in a period of entitlement; (2) they must be furnished by a facility or other entity as specified in 42 C.F.R. §§ 410.14 through 410.69; and (3) if subject to physician certification requirements, they must be appropriately certified by the physician as being medically necessary.

Medicare Part B pays for diagnostic services furnished to hospital outpatients if those services: (1) are furnished by, or under arrangements made by, a participating hospital; (2) are ordinarily furnished by, or under arrangements made by, the hospital to its outpatients for the purpose of diagnostic study; and (3) would be covered as inpatient hospital services if furnished to an inpatient. When a hospital makes arrangements with others for diagnostic services, such services are covered under Medicare Part B as diagnostic tests whether furnished in the hospital or in other facilities. If the diagnostic services are furnished at a facility that CMS designates as having provider-based status, then the diagnostic services must be furnished under the appropriate level of physician supervision. Under general supervision at a facility accorded provider-based status, 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 facility.

Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient during an encounter by an entity other than the hospital unless the hospital has “arrangements” with that entity to furnish that particular service to its patients. Three things are required: a hospital outpatient, an encounter, and an arrangement. These terms are defined as follows:

- A “hospital outpatient” is a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (rather than supplies alone) from the hospital.
- An “encounter” is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital medical staff bylaws, to order or furnish hospital services for diagnosis and treatment to the patient.
- An “arrangement” is one under which the Medicare payment made to the hospital that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services.

In order for services provided “under arrangements” to be billed as hospital services and paid for by Medicare, the hospital must exercise professional responsibility over the arranged-for services; a hospital billing services “under arrangements” may not act solely as a billing agent for another party that performs and exercises oversight over the services. This requires the hospital to implement many of the same quality controls as are applied to services furnished by salaried employees, including the following:

- Accepting the patient for treatment in accordance with its admission policies;
- Maintaining a complete and timely clinical record on the patient that includes diagnosis, medical history, physician orders, and progress notes relating to all services received;
- Maintaining liaison with the attending physician with regard to the progress of the patient and the need for revised orders;

- In the case of home health services and outpatient physical therapy or speech-language pathology services, checking that plans of care are periodically reviewed by physicians and securing from those physicians the required certifications and recertifications for the services; and
- Ensuring that the medical necessity of the services is reviewed on a sample basis by the hospital's utilization review committee if one is in place, the facility's health professional staff, or an outside utilization review group (with the hospital remaining responsible for the medical necessity decisions of the outside group).

In addition, the Joint Commission recently released standards applying to services provided under arrangements. Effective January 1, 2009, hospitals will need to incorporate these standards into their "under arrangements" arrangements.

Medicaid Coverage Requirements. At the end of 2008, CMS issued a final rule that may limit the circumstances under which Medicaid will cover hospital outpatient services. Under this rule, Medicaid coverage of hospital outpatient services is limited to services that (1) are Medicare-covered, (2) are furnished in a facility that meets the provider-based status requirements, (3) are not covered under the scope of another Medical Assistance service category under the State Plan, and (4) are not expressly excluded from the definition of "outpatient hospital services" by the State Medicaid agency. With respect to the last condition, CMS gives State Medicaid agencies the authority to exclude services from the definition of "outpatient hospital services" under its State Plan if the services are not generally furnished by most hospitals in the State. Acting under this authority, at least one State has already introduced legislation that, if enacted, would exclude services furnished in hospital outpatient departments if such services are covered in a freestanding facility. Originally, the CMS rule was to go into effect on December 8, 2008; however, a provision in the American Recovery and Reinvestment Act of 2009 imposed a moratorium on CMS, prohibiting it from taking any action to implement the rule until June 30, 2009.

Compliance With COPs. A hospital furnishing services "under arrangements" to its patients must ensure that the services are furnished in compliance with applicable Medicare requirements, including the Conditions of Participation for Hospitals ("COPs") applicable to the service being provided. The COPs contain specific requirements for contracted services, outpatient services, and radiologic services that are applicable to diagnostic imaging services provided "under arrangements" by a hospital.

Under the COPs, the governing body must be responsible for services furnished in the hospital whether or not they are furnished under contract. The governing body must ensure that the hospital is able to comply with all applicable conditions of participation and standards for contracted services, that services performed under contract are provided in a safe and effective manner, and that every Medicare patient is under the care of a doctor of medicine or osteopathy (or other appropriate health care provider). The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

The COPs also contain specific requirements for outpatient services. If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

- Outpatient services must be appropriately organized and integrated with inpatient services.
- The hospital must assign an individual to be responsible for outpatient services, and have appropriate professional and nonprofessional personnel available.

The COPs also contain specific requirements for radiologic services. The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. Standards for radiologic services include the following:

- The hospital must maintain, or have available, radiologic services according to needs of the patients.

- The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel. Proper safety precautions, including adequate shielding for patients, personnel and facilities and appropriate storage, use and disposal of radioactive materials, must be maintained against radiation hazards. Equipment must be periodically inspected and hazards must be promptly corrected. Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure. Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.
- A qualified full-time, part-time, or consulting radiologist (i.e., a doctor of medicine or osteopathy who is qualified by education and experience in radiology) must supervise the ionizing radiology services and must interpret those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
- Records of radiologic services must be maintained. The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations. The hospital must maintain copies of reports and printouts, films, scans and other image records, as appropriate, for at least five years.

Physician Certification Requirements. Although physician certification generally is not required for outpatient hospital diagnostic services ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study, a certification statement is needed for diagnostic services furnished under arrangements by a facility that is not operated by or under the supervision of the hospital or its organized medical staff (e.g., services obtained from an independent laboratory). When a certification is required, the hospital must obtain the required certification and recertification statements, keep them on file for verification by the intermediary, if necessary, and certify, on the appropriate billing form, that the statements have been obtained and are on file. No specific procedures or forms are required for certification and recertification statements; the hospital may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except for delayed certifications, there must be a separate signed statement for each certification or recertification.

Physician Supervision Requirements. Medicare requires that outpatient diagnostic imaging procedures performed in a provider-based department of a hospital be furnished under the level of physician supervision specified in the Medicare physician fee schedule, meaning that, unless otherwise indicated, all diagnostic x-ray and other diagnostic tests must be furnished under at least a general level of physician supervision and that some of these tests also require either direct or personal supervision throughout the performance of the test.² Although there does not appear to be a similar express requirement for diagnostic imaging procedures furnished in a location that does not meet Medicare's provider-based rules, we believe it is prudent that hospitals furnishing diagnostic imaging procedures in such a location structure their operations in a manner that ensures these physician supervision requirements are met. The different levels of supervision are defined as follows:

- 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 nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

² With respect to individual diagnostic tests, the supervision levels listed in the quarterly updated Medicare Physician Fee Schedule Relative Value File apply; or, if a certain diagnostic test is not listed in this publication, the Medicare contractors, in consultation with their medical directors, define appropriate supervision levels.

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

Questions regarding this memorandum may be directed to any of the following, or to the member of the firm who handles your health care matters:

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