Medicare Payment Is Contingent on Appropriate Supervision of Diagnostic Tests and Proper Use of Radiologist Assistants: Is Your Practice Meeting the Current Requirements?

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The Medicare rules governing the supervision of diagnostic tests have changed over time, as have the skills and training of radiologist assistants, who may have the education and clinical skills to deliver surgical and invasive procedures often performed as part of radiology practice. However, for the purposes of Medicare coverage, radiologist assistants are not yet recognized as independent providers or suppliers whose services are reimbursed separately from those of radiologists. As a result, services rendered by radiologist assistants are significantly limited by the Medicare physician supervision requirements and other Medicare billing rules. The authors describe the Medicare coverage and payment rules for working with radiologist assistants in hospital and nonhospital settings for both diagnostic testing and surgical or invasive procedures. The article also includes a summary of the current Medicare supervision requirements for a diagnostic test on the basis of the place of service: hospital, physician office, or independent diagnostic testing facility.

\textbf{Key Words:} Diagnostic tests, radiologist assistants, Medicare, IDTF, general supervision, direct supervision, personal supervision, invasive procedure

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Diagnostic tests generally require some level of physician supervision in order to be covered by third-party payers, including the Medicare and Medicaid programs. Although it is easy to understand the reason behind this payment policy, it can be challenging for radiologists and hospitals to determine, and then implement, the appropriate level of supervision in a particular clinical setting. Adding to the complexity is the fact that the rules governing supervision of diagnostic tests have changed over time, as have the skills and training of radiologist assistants, such as registered radiologist assistants and radiology practitioner assistants, who may be involved in the delivery of services.\textsuperscript{1}

The level of supervision required for a diagnostic test affects how a hospital or imaging center staffs imaging services. When considering how to efficiently and appropriately perform the technical components of diagnostic tests, radiologists and hospitals are faced with the question of how to determine where radiologist assistants fit into the clinical practice, given their training, the scope of practice laws, and Medicare supervision rules. Unlike nurse practitioners and physician assistants, radiologist assistants do not have their own benefit category in the Medicare program and therefore may not enroll and bill the Medicare program for their services [1,2, §60.2]. In other words, radiologist assistants are not recognized providers or suppliers for the purposes of payment under the Medicare program. As a result, the services rendered by radiologist assistants are significantly limited by the physician supervision requirements.

Like all health care services covered by Medicare, diagnostic tests must be performed in conformance with the applicable coverage rules in order to receive and retain payments for the services. Several factors affect the required level of physician supervision and the appropriate method of billing for the related service, including (1) whether the service was provided in a hospital or nonhospital setting, (2) the necessary level of physician supervision as dictated by CMS, (3) the involvement of radiol-
ogist assistants, and (4) whether the service is a diagnostic test or nondiagnostic procedure (ie, a surgical or other invasive procedure). Each of these factors affects clinical practice, in addition to whether the diagnostic tests are covered by Medicare or other third-party payers.

In this article, we first describe the current Medicare rules governing coverage and payment of diagnostic tests and the limitations those rules impose on the services performed by radiologist assistants. We also provide a detailed discussion of how the physician supervision rules are applied in a radiology clinic or physician office, an independent diagnostic testing facility (IDTF), and a hospital outpatient facility. It should be noted that this article does not address the clinical or technical competency of radiologist assistants or state law governing their scope of practice but is limited to the Medicare coverage and payment of services rendered in whole or in part by radiologist assistants.

MEDICARE COVERAGE AND PAYMENT OF DIAGNOSTIC TESTS

The Social Security Act requires that the Medicare program cover the technical and professional components of diagnostic tests performed in compliance with rules issued by CMS. According to those rules, the technical component of each diagnostic test is subject to supervision requirements adopted, and recently revised, by CMS. Historically, for diagnostic tests performed in physician offices and IDTFs, 1 of 3 levels of supervision will apply: general, direct, or personal. General supervision requires a procedure to be furnished under a radiologist’s overall direction and control, but the radiologist’s presence is not required during the performance of the procedure. Direct supervision requires a radiologist to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. Finally, personal supervision requires a radiologist to be physically present in the room and attend the performance of the procedure. [3] When direct or personal supervision is required, physician supervision must be provided throughout the performance of the test [3,4].

The appropriate supervision level for a diagnostic test is designated in the Relative Value File as published in the Medicare Physician Fee Schedule and may also be found on the CMS Web site (https://www.cms.gov/PhysicianFeeSched/PFSRVF/list.asp). A designation of “1” in the column designating “physician supervision of diagnostic procedures” indicates that the test requires general supervision. A “2” indicates that the test requires direct supervision of a physician. A “3” indicates that the test requires the personal supervision of a physician. If the Current Procedural Terminology® (CPT®) code includes a “9,” the supervision rules do not apply, and the physician must personally perform the services to be able to bill for them.

Unlike diagnostic tests, surgical or other invasive procedures do not have separate professional and technical components and are not subject to the supervision requirements. These procedures must be personally furnished by physicians or nonphysician professionals enrolled in the Medicare program (ie, physician assistant or nurse practitioner) or, if furnished in a physician office, “incident to” a physician’s professional service. “Incident to” is a Medicare term that describes a covered service that is an integral part of the physician’s professional service but provided by someone other than the physician. As described further below, Medicare will pay a physician practice for “incident to” services only when the services are performed in a physician office. As a result of this distinction, it is important to consider whether the service being performed is in fact purely a diagnostic test, or whether it involves a procedure requiring a physician to personally render the service.

SUPERVISION OF REGISTERED RADIologist ASSISTANTS AND RADIOLOGY PRACTITIONER ASSISTANTS

In many states, radiologist assistants are legally permitted to perform a wide range of clinical services and, as a practical matter, have the education and clinical skills necessary to enhance a radiology practice. However, the current Medicare coverage rules provide several obstacles to using the full range of services radiologist assistants are trained to perform. In the hospital setting, there is no separate Medicare payment for services performed by physician-employed auxiliary personnel, regardless of whether a radiologist supervises the performance of the services. Payment for the services of nonphysician auxiliary personnel, such as radiologist assistants, is made solely to the hospital as part of its reimbursement by Medicare under the hospital prospective payment system. In the physician office setting, separate Medicare payment is only made for nontesting services furnished “incident to” a physician’s services; however, this requires direct supervision and is inapplicable to diagnostic tests.

The limitations imposed on billing for the services of radiologist assistants significantly affect the utilization of these professionals at a time when hospitals and radiologists seek opportunities to reduce the cost of health care services. These concerns are further compounded by the requirements for personal supervision that apply to many diagnostic tests. It is also worth noting that the rules governing coverage and payment of Medicare services are narrower than what a radiologist assistant may otherwise
be permitted to do under the scope of practice laws in many states.

**DIAGNOSTIC TESTS PERFORMED IN A RADIOLGY CLINIC OR PHYSICIAN OFFICE**

When diagnostic services are performed within a physician office or an IDTF, the technical and professional components are paid under the Medicare Physician Fee Schedule and subject to the appropriate level of physician supervision designated in the Relative Value File [4,5]. Services that are not furnished with the required level of supervision are not reasonable and necessary and therefore are not covered by the Medicare program. When considering whether the level of supervision is met, it is important to note that the services of radiologist assistants are reimbursed to the physician practice or IDTF through the practice expense relative value units of the technical component payment. This payment represents the cost of medical supplies, equipment, and nonphysician clinical labor, including the services of a radiologist assistant.² Physicians, physician offices, and IDTFs that fail to adequately supervise radiologist assistants for billed services may be subject to an overpayment liability.

In the physician office setting, the Medicare program pays for auxiliary personnel, such as a radiologist assistant, to provide nondiagnostic testing services (eg, surgical or other invasive procedures in the 20000-69999 series CPT codes) to a Medicare patient if such service is “incident to” a physician’s service³ [2, §60.2]. For a radiologist assistant’s services to be covered “incident to” the services of a physician, the nondiagnostic testing services must be (1) an integral, although incidental, part of the physician’s professional services; (2) commonly rendered without charge or included in the physician’s bill; (3) of a type that are commonly furnished in physicians’ offices or clinics; and (4) furnished under the physician’s direct supervision. Direct supervision in the office setting means the physician must be present in the office suite and immediately available and able to provide assistance and direction throughout the time the service is performed. Direct supervision of the surgical or other invasive procedure does not mean that the physician must be present in the same room with the aide [2, §60.1]. In addition to the foregoing limitations, only those nondiagnostic services that are within the radiologist assistant’s scope of practice may be furnished by the radiologist assistant.

**SPECIAL RULES GOVERNING INDEPENDENT DIAGNOSTIC TESTING FACILITIES**

The Medicare program applies additional limitations and certification standards on imaging centers enrolled as IDTFs. First and foremost, Medicare covers only diagnostic tests performed in an IDTF. Surgical and other invasive procedures are not covered when performed in an IDTF regardless of the type of professional performing such procedures [7]. In addition, supervising physicians must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. Similar to the hospital outpatient and physician office settings, diagnostic tests performed in an IDTF must be supervised by a physician at the level of supervision identified in the Medicare Relative Value File. Because of these limitations, a radiologist assistant may not provide services independent of a physician in the IDTF setting, regardless of the assistant’s professional training or the scope of services permitted under state law.

**DIAGNOSTIC TESTS PERFORMED IN AN OUTPATIENT HOSPITAL FACILITY**

The supervision requirements for diagnostic services provided by hospital-based facilities have been the subject of several recent Medicare rules and transmittals. Most recently, the 2010 Medicare Hospital Outpatient Prospective Payment (HOPPS) rule addressed the supervision requirements for all hospital outpatient diagnostic tests. Beginning January 1, 2010, all diagnostic tests provided by a hospital (1) in the main buildings of a hospital, (2) in a provider-based department of a hospital, or (3) in a nonhospital location that provides services “under arrangement” must be performed at the same level of the physician supervision requirements described in the Medicare Physician Fee Schedule Relative Value File, which indicates whether the supervision of a particular test must be general, direct, or personal.

The revised supervision requirements now apply a standardized approach across service settings and provide additional consistency in what is required of hospital outpatient diagnostic services. This standardized approach to supervision levels was not always in effect. When CMS promulgated the HOPPS update for calendar year 2000, the rules provided that diagnostic services performed by a “provider-based” entity affiliated with the hospital located off-campus were subject to the same levels of physician supervision (general, direct, and personal) requirements listed in the Relative Value File for a particular diagnostic test. At the

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² A previous article in JACR [6] also described this treatment of the practice expense component under the Medicare Physician Fee Schedule, as well as other issues related to the scope of practice of radiologist assistants and radiology practitioner assistants.

³ IDTFs are permitted to perform only diagnostic tests. Surgical and other invasive procedures cannot be performed in an IDTF, nor can “incident to” services be performed in a hospital.
time, direct and personal supervision rules did not apply to services performed on a hospital campus.

Then, in the final HOPPS rule for calendar year 2009, CMS clarified that the same supervision requirements applied to services furnished to Medicare outpatients in both on-campus and off-campus facilities. A commentator to the November 18, 2008 HOPPS update requested clarification regarding the supervision required for diagnostic services furnished in an on-campus facility. CMS responded by noting that regulatory language at 42 CFR § 410.28(e) does not distinguish between on-campus and off-campus providers. CMS then went on to state that “all provider-based departments, whether on or off the hospital’s main campus, should follow the requirements of [the Medicare Physician Fee Schedule] or their Medicare contractor, as appropriate, for individual diagnostic facilities.”

In transmittal 100, issued on December 31, 2008, CMS attempted to clarify that all diagnostic testing services performed for hospital outpatients in a “provider-based” facility (ie, in a hospital), whether located on campus or off campus, are subject to the same levels of physician supervision that are traditionally required for diagnostic tests performed in physician offices, IDTFs, and off-campus provider-based entities. In the same transmittal, CMS removed language from section 20.5.1 of the Medicare Benefit Policy Manual indicating that “physician supervision requirement is generally assumed to be met where the services are performed on hospital premises.”

In the 2010 HOPPS rule, CMS promulgated new rules explicitly applying physician supervision as described in the Medicare Physician Fee Schedule Relative Value File to all hospital outpatient diagnostic services regardless of the location and regardless of whether the service is provided directly by the hospital or under arrangement with another provider. The 2010 HOPPS rule also specified how direct supervision is accomplished in the various hospital settings, including a specific requirement that the supervising physician be present in the off-campus provider-based department of a hospital.

After receiving comments from the public on the 2010 HOPPS rule, CMS adopted additional changes to the definition of “direct supervision” in the calendar year 2011 HOPPS final rule. For outpatient diagnostic services performed in a hospital, direct supervision requires the supervising physician to be “immediately available,” but no longer requires the physician to be present in a particular part of the hospital campus. [8] “Direct supervision” is now accomplished as follows:

- In the case of diagnostic services furnished on-campus, direct supervision is accomplished when the supervising physician is immediately available to furnish assistance and direction throughout the performance of the procedure.
- In the case of diagnostic services furnished off-campus, direct supervision is immediately available to furnish assistance and direction throughout the performance of the procedure.
- In the case of diagnostic services furnished in nonhospital location (ie, services provided “under arrangements” to the hospital in a freestanding diagnostic imaging center or a physician office), direct supervision 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.

CMS did not define the term immediately available in § 410.28(e) but later provided some clarity in transmittal 128 [9], which updates Medicare coverage policies in the Medicare Benefit Policy Manual. In transmittal 128, CMS defines immediate availability as the “immediate physical presence of the physician” but does not specify the time or distance. CMS also provides examples of situations in which a supervisory physician is not “immediately available,” including “situations in which the supervisory physician is performing another procedure or service that he or she could not interrupt.” Another example cited in the transmittal, for services furnished on campus, the supervisory physician may not be so physically far away on campus from the location where hospital outpatient services are being furnished that the physician “could not intervene right away.”

CMS confirmed in the 2010 HOPPS rule that non-physician practitioners, such as nurse practitioners and physician assistants, cannot supervise diagnostic tests. [10] Only physicians can supervise a diagnostic test for a Medicare outpatient. The 2010 HOPPS rule did not require any particular specialty of physician perform the supervision of the test. The final rule provided only that physicians supervising diagnostic tests must be “knowledgeable” about the tests they supervise. This could apply to numerous physician specialties. But in transmittal 128 [11], CMS stated that a supervisory physician must also be “clinically appropriate to supervise the service or procedure” and “must have, within his or her state scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure.”

CMS also stated that a supervising physician must be able “to take over performance of a procedure and, as appropriate to the supervisory physician and the patient, to change a procedure or the course of care for a particular patient.” [12]
NONDIAGNOSTIC PROCEDURES PERFORMED IN A HOSPITAL SETTING

In a hospital setting, nondiagnostic procedures (ie, surgical or other invasive procedures) must be performed by a physician who submits a claim for payment under the Medicare Physician Fee Schedule. The hospital submits a claim for its facility services relative to that same outpatient under the HOPPS, and for inpatients under the diagnostic related group. Assistance rendered by a radiologist assistant relative to such a procedure in a hospital is considered part of the payment made to the hospital, regardless of who employs the radiologist assistant.

Because Medicare does not pay a physician practice for “incident to” services performed in the hospital setting, the physician’s personal performance of the service is required, unless a specific exception applies to the procedure or the procedure is performed under arrangement made by the hospital. \[13\] A physician who relies on a radiologist assistant to perform the nondiagnostic service in the hospital setting may not bill Medicare for the service. The certification statement included on form CMS-1500 states, in pertinent part, “I certify that the services shown on this form were medically indicated personally furnished by me . . . except as otherwise expressly permitted by Medicare . . . regulations.”

In addition to these instructions, form CMS-1500 indicates that the rendering provider is the individual who provided the care and that the “Rendering Provider does not include individuals performing services in support roles, such as lab technicians or radiology technicians.” In addition to these instructions, form CMS-1500 states, in pertinent part, “I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me . . . except as otherwise expressly permitted by Medicare . . . regulations.”

Under the False Claims Act, a claim may be false even if the services billed were actually provided, if the purported provider (ie, the enrolled physician, physician assistant, or nurse practitioner) did not actually render or supervise the service \[14\]. Changes to the False Claims Act significantly increase liability for billing Medicare for services that were not performed in compliance with the coverage rules. On May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act, which includes a significant expansion of the scope of liability under the False Claims Act. Before this new legislation, the reverse false claims provision prohibited the use of a false statement or record to avoid or reduce an obligation to pay money to the government. The Fraud Enforcement and Recovery Act broadens this provision to apply to circumstances where an entity knowingly and improperly conceals, avoids or reduces an obligation to pay money to the government, including retention of an overpayment, even if no false statement is made. \[15\]

REQUEST TO REVISE SUPERVISION LEVELS

The ACR, the American Society of Radiologic Technologists, and the American Registry of Radiologic Technologists have requested that CMS make changes to the supervision level required for certain CPT codes when the service is performed with the assistance of an radiologist assistant. By revising the supervision level from personal to direct supervision, radiologist assistants would be able to perform more functions and increase their value to hospitals and radiologists. In the Medicare Physician Fee Schedule final rule for calendar year 2010, CMS acknowledged receipt of these bodies’ comment related to the request to revise the supervision levels. CMS provided the following discussion of this request \[10, p61867\]:

Comment: One commenter requested that CMS revise the supervision level requirement for certain CPT codes when these services are performed with assistance by the Registered Radiologist Assistant.

Response: We appreciate the information provided by the commenters as it will assist in understanding the role these individuals play in the provision of imaging services. \[16\]

To date, CMS has not provided a substantive response to the request, and the supervision levels articulated in the Medicare Physician Fee Schedule remain the same.

CONCLUSIONS

Several key factors affect how diagnostic tests and surgical or other invasive procedures may be performed and covered under the Medicare program. Radiologists should consider whether their current clinical practices are aligned with the requirements for supervision, including whether the practice is using radiologist assistants in a manner that conforms to the Medicare coverage requirements. Compliance with the state scope of practice laws may not be sufficient to ensure compliance when billing Medicare for the service rendered.
Although hospitals and radiologists may seek to reduce the cost of diagnostic services by expanding the role of radiologist assistants, the limitations imposed on billing for the services they perform negatively affect using the services of these professionals and increases the level of physician involvement in every clinical setting. In this era of heightened scrutiny of claims, radiologists, IDTFs, and hospitals are more focused on regulatory compliance than reducing cost through the use of radiologist assistants.

REFERENCES

3. 42 CFR § 410.28(e).
4. 42 CFR § 410.32(b).
5. Social Security Act § 1861(s)(3).
7. 42 CFR § 410.33.
8. Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payment to Hospitals for Graduate Medical Education Costs; Physician Self-referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Reg-
10. Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule, 74 Fed. Reg. 60590 (Nov. 20, 2009) (stating the “we believe it continues to be most appropriate to allow only physicians to provide the supervision of hospital outpatient diagnostic services”).
11. Centers for Medicare and Medicaid Services. 42 CFR Parts 410, 411, 414 et al. Medicare program; payment policies under the Physician Fee Schedule and other revisions to Part B for CY 2010; final rule; Medicare program; solicitation of independent accrediting organizations to participate in the Advanced Diagnostic Imaging Supplier Accreditation Program; notice. Fed Reg 2009;74:61737-2206.
12. Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule, 74 Fed. Reg. 60580 (Nov. 20, 2009).