Performing a Test in an Office Setting Without an Order

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The scenario is a familiar one. A radiologist in a nonhospital setting [1] receives an order to perform a diagnostic test,[2] but in the professional judgment of the radiologist, there are variables that justify performing additional or different tests than those delineated in the treating physician's referral.[3] From a purely medical standpoint, and assuming the validity of the radiologist's judgment, common sense could lead a person to believe that the radiologist should be free to conduct further tests without the need to contact the referring physician. However, the regulatory labyrinth that governs the activities of radiologists is a murky one, and a radiologist who fails to heed regulatory constraints on his or her ability unilaterally to deviate from the original order for diagnostic testing may be exposed to an array of civil and criminal sanctions.

This column addresses the contours of the regulatory landscape radiologists in nonhospital settings must navigate and presents the rules that govern the ordering of diagnostic tests; the circumstances in which radiologists, in their capacity as interpreting physicians, may modify original referrals without authorization from the treating physicians; and insulating steps radiologists can take against accusations of regulatory malfeasance.

THE GENERAL RULE: NO DIAGNOSTIC TESTS WITHOUT A REFERRAL FROM THE TREATING PHYSICIAN

It is important that Medicare regulations clearly state that all diagnostic tests payable by Part B carriers must be ordered by the treating physician [1]. Specifically, 42 USC § 410.32(a) [1] expressly provides,

> All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician 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. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

The general rule is that a testing facility,[4] which includes radiologists, lacks authority to alter the type of diagnostic test requested by the treating practitioner without first obtaining a new order [4, § 15021(B)]. The same rule applies to all procedures performed by independent diagnostic testing facilities (IDTFs).[5] However, it should be noted that the general rule does not apply to diagnostic tests in hospital settings relating to inpatients or outpatients (see footnote 1).

This general rule applies even when a radiologist feels that an ordered diagnostic test is "clinically inappropriate or suboptimal" and that a different test should be performed and when the result of an ordered test is normal and the radiologist determines that another diagnostic test should be performed. Thus, for instance, when a radiologist believes that a magnetic resonance imaging (MRI) scan rather than a computed tomographic scan should be performed, or that, on the basis of the clinical indication, a MRI scan should be performed despite a normal finding stemming from a renal sonogram, the radiologist cannot conduct the unordered test without obtaining another order from the treating physician [4, § 15021(C)].

THE REASON FOR THE GENERAL RULE

The general rule is designed "to prevent the practice of some testing facilities to routinely apply protocols which require performance of sequential tests" [4, § 15021(C)]. The prohibition set forth by the general rule is intended to prevent overutilization as a result of cascade testing and to "address situations in which there is a pattern of the testing entity's adding procedures to those ordered by the patient's personal physician" [9]. This rationale is consistent with statutory law, which states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury [10, § 1862(a)(1)(A)]. In the eyes of the law, diagnostic tests are not considered "reasonable and medically necessary" unless the tests are ordered by a practitioner who will use them to manage the patient's care [9].

The underlying purpose of the general rule also relies on the assumption that a treating physician has greater familiarity with the medical history and needs of a patient. Although this is often the case, radiologists, on the basis of their own expertise or test results, will be in a unique position to know what tests should be performed for a patient. Fortunately, the law pro-

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vides exceptions to the general rule. These exceptions revolve around common clinical scenarios and are designed to serve the health and safety of patients.

EXCEPTIONS TO THE GENERAL RULE

First, a radiologist is allowed to perform an additional diagnostic test without a new or modified order if all of the following factors are present [4, § 15021(D)]:

1. The radiologist is unable to contact the treating physician to obtain a new or modified order.
2. The radiologist performs the diagnostic test ordered by the treating physician or practitioner.
3. The radiologist 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.
4. Delaying the performance of the additional diagnostic test would have an adverse effect on the care of the patient.
5. The result of the test is communicated to and is used by the treating physician or practitioner in the treatment of the patient.
6. The radiologist at the testing facility documents in his or her report why additional testing was done.

To avoid potential liability or allegations that a test was improperly performed without a proper order, a radiologist should document in the patient's medical record that all of the above requirements were satisfied [1, ¶ (d)(2)].

Second, there are a number of additional specific exceptions to the general rule that allow radiologists to modify orders under certain limited circumstances. Again, it is imperative that a radiologist have appropriate, contemporaneous documentation that an order was modified or added in compliance with the requirements of the applicable exception [4, § 15021(E)]:

1. The radiologist may determine, without notifying the treating physician or practitioner, the parameters of the diagnostic test (eg, the number of radiographic views obtained, the thickness of tomographic sections acquired, the use or nonuse of contrast media).
2. The radiologist may modify, without notifying the treating physician or practitioner, an order with clear and obvious errors that would be apparent to a reasonable layperson, such as the patient receiving the test (eg, an x-ray of the wrong foot was ordered).
3. A radiologist may cancel, without notifying the treating physician or practitioner, an order because the beneficiary's physical condition at the time of diagnostic testing will not permit the performance of the test. When an ordered diagnostic test is cancelled, any medically necessary preliminary or scout testing performed is payable.
4. A physician who meets the statutory qualification requirements for an interpreting physician may order a diagnostic mammogram on the basis of the findings of a screening mammogram even though the physician does not treat the beneficiary [1 ¶ (a)(2)].

Thus, radiologists are not totally hamstrung in their ability to conduct unordered tests, particularly when delaying the performance of an additional diagnostic test would have an adverse effect on the care of the patient [9].[6]

A RADIOLOGIST'S BEST DEFENSE: DOCUMENTATION

When a radiologist, in a nonhospital setting, deviates from the order of the referring treating practitioner, the radiologist exposes himself or herself to two vulnerabilities.

First, to be paid for his or her services, a radiologist must maintain documentation concerning the order for the services billed and showing the "accurate processing of the order and submission of the claim" [1, ¶¶ (3)(i)(A)-(B)]. If a radiologist submits a claim for the performance of a diagnostic test that was not delineated in the treating physician's order and fails to demonstrate, through sufficient documentation, that there was a lawful basis for the deviation, the radiologist will not be paid for performing the diagnostic test upon audit. Absent the requisite documentation, the diagnostic test will not be deemed "reasonable and necessary," and the claim will be denied [1, ¶ (3)(i)(C)].

Second, if there is a pattern of tests being conducted without the requisite authorization and documentation, radiologists may expose themselves to a civil prosecution under the False Claims Act.[7] Under the False Claims Act, treble damages, as well as fines and penalties up to $11,000 per claim, can be imposed on a provider for submitting noncompliant "false" claims to Medicare or other federally funded programs.

To avoid these scenarios, it is essential that radiologists, document their compliance with the factors set forth above, pertaining to the exceptions to the general rule, in those instances in which they alter or supplement the order of a treat-

ing physician. This documentation should be placed in the patient's medical chart and in the documentation provided by the radiologist when submitting the claim for payment. If the radiologist memorializes the applicability of the exceptions set forth above, it is less likely that a claim will be denied or that a radiologist will become the target of a False Claims Act prosecution. Indeed, it is recommended that as part of a radiology practice's compliance program, there should be clear guidelines that provide how, when, and where the practice will document each of the requirements under the applicable exceptions.

FOOTNOTES

[1] The requirement of 42 CFR § 410.32 [1] that a radiologist obtain authorization from the treating practitioner to modify or supplement an order for a diagnostic test does not apply to diagnostic tests in hospitals relating to hospital inpatients or outpatients. See Transmittal 1725 of the Centers for Medicare and Medicaid Services [2], which clarifies 42 CFR § 410.32(a). See also the *Federal Register* commentary of October 31, 1997 [3], specifically stating that the test-ordering provision of § 410.32 does not apply to diagnostic tests furnished in hospitals.

[2] The term *diagnostic test* "includes all diagnostic x-rays, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary" [4, § 15021(A)(1)]. *Medicare Carriers Manual* [4] § 15021(A)(1), which contains the general rule requiring a radiologist to obtain prior authorization from the treating physician before modifying an order, has a crosswalk to the Internet-Only Manuals system of the Centers for Medicare and Medicaid Services [5, § 30.6.10B; 6]. (The transition from a paper-based system to the Internet-Only Manuals system began in October 2003 [7, ¶ 153,623].)

[3] The term *treating physician* refers to "a physician, as defined in § 1861(r) of the Social Security Act, who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem" [4, § 15021(A)(2)]. Notably, a "radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician" [4, § 15021(A)(2)].

[4] A "testing facility" is a "Medicare provider or supplier that furnishes diagnostic tests. A testing facility may include a physician or a group of physicians (eg, radiologist, pathologist), a laboratory, or an independent diagnostic testing facility" [4 § 15021(A)(4)].

[5] 42 CFR § 410.33(d) [8] provides, "All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician 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. (Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).) The order must specify the diagnosis or other basis for the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF's supervising physician is in fact the beneficiary's treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician." An IDTF "may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital" [8].

[6] There are other exceptions to the general rule. A physician may order an x-ray to be used by a chiropractor to demonstrate the subluxation of the spine that is the basis for a beneficiary to receive manual manipulation treatments even though the physician does not treat the beneficiary [1 ¶ (a)(1)].

[7] In *Klein v. The Inspector General* [11], the defendant-physician was excluded for a period of 5 years from participation in the Medicaid program and certain state health care programs on the basis of a conviction for a criminal offense related to the delivery of an item or service under Medicaid or Medicare. The physician had fraudulently entered physicians' names on claim forms, even though the physicians had not ordered the diagnostic tests in question.

REFERENCES

1. 42 CFR § 410.32.
2. Centers for Medicare and Medicaid Services. Transmittal 1725, September 27, 2001. Baltimore, Md: Centers for Medicare and Medicaid Services; 2001.
3. Fed Reg 1997;62(211).
4. Centers for Medicare and Medicaid Services. Medicare Carriers Manual. Baltimore, Md: Centers for Medicare and Medicaid Services.
5. Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual. Baltimore, Md: Centers for Medicare and Medicaid Services.
6. Centers for Medicare and Medicaid Services. Medicare Carriers Manual, part 3—Claims Process, Transmittal 1832, October 31, 2003. Baltimore, Md: Centers for Medicare and Medicaid Services; 2003.
7. Trans-Letter, Med-Guide, September 12, 2003.
8. 42 CFR § 410.33.
9. 62 FR 59048-01, 1997 WL 674391 (F.R.).
10. Social Security Act, Title XVIII.
11. DAB CR253 (1993), 1993 WL 742623 (H.H.S.).

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