

§410.33 Independent diagnostic testing facility.

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). 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; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) and (g) and (h) of this section.

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(l)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

(2) The supervising physician must evidence proficiency in the performance and interpretation of each type of

diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in §410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

(c) *Nonphysician personnel.* Any nonphysician 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. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(d) *Ordering of tests.* 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.

(e) *Multi-State entities.* (1) An IDTF that operates across State boundaries must—

(i) Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and

(ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

(2) The point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

(f) *Applicability of State law.* An IDTF must comply with the applicable laws of any State in which it operates.

(g) *Application certification standards.* The IDTF must certify in its enrollment application that it meets the following standards and related requirements:

(1) Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

(3) Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not considered an appropriate site.

(i) The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment applica-

tion, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

(ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

(4) Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request.

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

(5) Maintain a primary business phone under the name of the designated business. The IDTF must have its—

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance.

(6) Have a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

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(i) Ensure that the insurance policy must remain in force at all times and provide coverage of at least \$300,000 per incident; and

(ii) Notify the CMS designated contractor in writing of any policy changes or cancellations.

(7) Agree not to directly solicit patients, which include, but is 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, 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).

(8) Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(9) Openly post these standards for review by patients and the public.

(10) Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

(11) Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

(12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

(13) Have proper medical record storage and be able to retrieve medical

records upon request from CMS or its fee-for-service contractor within 2 business days.

(14) Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must—

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

(16) Enrolls for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

(17) Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.

(h) *Failure to meet standards.* If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied. CMS will revoke a supplier's billing privileges if and IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.

(i) *Effective date of billing privileges.* The filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

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§ 410.34 Mammography services: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Diagnostic mammography* means a radiologic procedure furnished to a man or woman with signs or symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy-proven benign breast disease, and includes a physician's interpretation of the results of the procedure.

(2) *Screening mammography* means a radiologic procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure.

(3) *Supplier of diagnostic mammography* means a facility that is certified and responsible for ensuring that all diagnostic mammography services furnished to Medicare beneficiaries meet the conditions for coverage of diagnostic mammography services as specified in paragraph (b) of this section.

(4) *Supplier of screening mammography* means a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in paragraphs (c) and (d) of this section.

(5) *Certificate* means the certificate described in 21 CFR 900.2(b) that may be issued to, or renewed for, a facility that meets the requirements for conducting an examination or procedure involving mammography.

(6) *Provisional certificate* means the provisional certificate described in 21 CFR 900.2(m) that may be issued to a

facility to enable the facility to qualify to meet the requirements for conducting an examination or procedure involving mammography.

(7) The term *meets the certification requirements of section 354 of the Public Health Service (PHS) Act* means that in order to qualify for coverage of its services under the Medicare program, a supplier of diagnostic or screening mammography services must meet the following requirements:

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services.* Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *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