

**Billing and Enrollment Guideline for
PHYS-078 Independent Diagnostic Testing Facilities (IDTF)**

I. Code of Federal Register CFR 410.33

§ 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 supervision to no more than three IDTF sites. The IDTF 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.

(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. Any change in enrollment information must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change.

(3) Maintains a physical facility on an appropriate site. For the purposes of this standard, a post office box or commercial mail box is not considered a physical facility. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, 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.

(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

(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 beneficiaries' questions and respond to their complaints.

(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.

(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.

(62 FR 59099, Oct. 31, 1997, as amended at 64 FR 59440, Nov. 2, 1999; 71 FR 69784, Dec. 1, 2006; & 72 FR 18914, Apr. 16, 2007; FR 66285, November 27, 2007)

II. PUB 100-8 Program Integrity Manual (PIM) Chapter 10, Section 4:

***4.19.1 – IDTF Standards**

(Rev. 286: Issued: 03-13-09; Effective Date: 01-01-09; Implementation Date: 04-0109)

A. IDTF Standards

Consistent with 42 CFR § 410.33(g), each IDTF must certify on its CMS-855B enrollment application that it meets the following standards and all other requirements:

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

• The purpose of this standard is to ensure that suppliers are licensed in the business and specialties being provided to Medicare beneficiaries. Licenses are required by State and/or Federal agencies to make certain that guidelines and regulations are being followed to ensure businesses are furnishing quality services to Medicare beneficiaries.

*• The responsibility for determining what licenses are required to operate a supplier's business is the sole responsibility of the supplier. The contractor is not responsible for notifying any supplier of what licenses are required or that any changes have occurred in the licensure requirements. *No exemptions to applicable State licensing requirements are permitted, except when granted by the state.*

• The contractor shall not grant billing privileges to any business not appropriately licensed as required by the appropriate State or Federal agency. If a supplier is found providing services for which it is not properly licensed, billing privileges may be revoked and appropriate recoupment actions taken.

2. Provides complete and accurate information on its enrollment application. *Change 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.

NOTE: This 30-day requirement takes precedence over the certification in section 15 of the CMS-855B whereby the supplier agrees to notify Medicare of any changes to its enrollment data within 90 days of

the effective date of the change. By signing the certification statement, the IDTF agrees to abide by all Medicare rules for its supplier type, including the 30-day rule in 42 CFR § 410.33(g)(2).

*3. Maintains a physical facility on an appropriate site. For the purposes of this standard, a post office box or commercial mail box, *hotel or motel is not considered an appropriate site. The physical facility, including mobile units, must contain space for equipment appropriate to the services designated on the enrollment application, 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.*

- 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.*

- The requirements in 42 CFR § 410.33(g)(3) take precedence over the guidelines in sections 4.4(A) and 4.4.2 of this manual pertaining to the supplier's practice location requirements.*

- The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).*

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; and

(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.

- The requirements in 42 CFR § 410.33(g)(5) take precedence over the guidelines in sections 4.4(A) and 4.4.2 of this manual pertaining to the supplier's telephone requirements.*

- IDTFs may not use "call forwarding" or an answering service as their primary method of receiving calls from beneficiaries during posted operating hours.*

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 non-relative owned company.

*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 non-relative 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-

- (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).

- By the signature of the authorized official in section 15 of the CMS-855B, the IDTF agrees to comply with 42 CFR § 410.33(g)(7).*

- The supplier is prohibited from directly contacting any individual beneficiary for the purposes of soliciting business for the IDTF. This includes contacting the individual beneficiary by telephone or via door-to-door sales.*

- There is no prohibition on television, radio or internet advertisements, mass mailings, or similar efforts to attract potential clients to an IDTF.*

- If the contractor determines that an IDTF is violating this standard, the contractor should notify its DPSE contractor liaison immediately.*

8. Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTF's, 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.** Enrolls in Medicare 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.

***16.** 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. (Section 1861(w)(1) states that the term "arrangements" is limited to arrangements under which receipt of payments by the hospital, critical access hospital, skilled nursing facility, home health agency or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.)

If the IDTF claims that it is furnishing services under arrangement as described in section 1861(w)(1), the IDTF must provide documentation of such with its initial or revalidation CMS-855 application

The IDTF must meet all of the standards in 42 CFR § 410.33 – as well as all other Federal and State statutory and regulatory requirements – in order to be enrolled in, and to maintain its enrollment in, the Medicare program. Failure to meet any of the standards in 42 CFR § 410.33 or any other applicable requirements will result in the denial of the supplier's CMS-855 application or, if the supplier is already enrolled in Medicare, the revocation of its Medicare billing privileges.

B Sharing of Space and Equipment

Effective January 1, 2008, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not: (i) share a practice location with another Medicare-enrolled individual or organization; (ii) lease or sublease its operations or its practice location to another Medicare-enrolled individual or organization; or (iii) share diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. (See 42 CFR §410.33(g) (15).)

Effective January 1, 2008, if the contractor determines that an IDTF is leasing or subleasing its operations to another organization or individual, the contractor shall revoke the supplier's Medicare billing privileges.

Note that while the prohibition against the sharing of space at a practice location is effective on January 1, 2008, for newly-enrolling IDTFs (including those with applications that are still pending as of January 1, 2008), the space-sharing provision in 42 CFR §410.33(g)(15)(i) for IDTFs that are currently occupying a practice location with another Medicare-enrolled individual or organization will not become effective until January 1, 2009.

C. One Enrollment per Practice Location

The IDTFs must separately enroll each of their practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that each enrolling IDTF can only have one practice location on its CMS-855B enrollment application; thus, if an IDTF is adding a practice location to its existing enrollment, it must submit a new, complete CMS-855B application for that location and have that location undergo a separate site visit. Also, each of the IDTF's mobile units must enroll

separately. Consequently, if a fixed IDTF site also contains a mobile unit, the mobile unit must enroll separately from the fixed location.

For those IDTFs with multiple practice locations that were enrolled prior to the implementation date of this instruction, each practice location of the IDTF must meet all of applicable IDTF requirements, including those listed in this manual. Failure to comply with any of these requirements at any practice location represent the supplier's noncompliance with 42 CFR § 410.33 as a whole, and will result in the revocation of its Medicare billing privileges.

D. Effective Date of Billing Privileges

Effective January 1, 2008, 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. (See 42 CFR 410.33(i).) 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.

A newly-enrolled IDTF, therefore, may not receive reimbursement for services furnished before the effective date of billing privileges.

The contractor shall note that if it rejects an IDTF application on or after January 1, 2008, and a new application is later submitted, the date of filing is the date the contractor receives the new enrollment application.

***E. Leasing and Staffing**

For purposes of the provisions in 42 CFR §410.33, a "mobile IDTF" does not include entities that 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). This is because the provider/supplier is responsible for providing the appropriate level of physician supervision for the diagnostic testing.

4.19.2 – Multi-State IDTF Entities

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

As stated in 42 CFR § 410.33(e)(1), 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 operates; and*
- Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.*

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.

4.19.3 – Interpreting Physicians

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who are providing purchased interpretations to the IDTF (in accordance with Pub. 100-04, chapter 1, section 30.2), as well as physicians who are reassigning their benefits to the IDTF.

The carrier shall ensure and document that:

- All listed physicians are enrolled in Medicare.
- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so.
- All required CMS-855R forms have been submitted.
- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The carrier may need to contact another carrier to obtain this information). If the applicant does not list any interpreting physicians, the carrier need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves. However, the applicant cannot bill globally for interpreting physicians not listed. If an interpreting physician has been recently added or changed, the new interpreting physician must have met all of the interpreting physician requirements at the time any tests were performed.

4.19.4 – Technicians

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

Each non-physician who performs the IDTF diagnostic tests must be listed. These persons are often referred to as technicians.

A. Licensure and Certification

All technicians must meet the standards of a State license or State certification at the time of the IDTF's enrollment. Carriers may not grant temporary exemptions from such requirements. Also, the IDTF must attach a copy of each technician's license or certification with its application.

B. Changes of Technicians

If a technician has been recently added or changed, the updated information must be reported via a CMS-855B change request. The new technician must have met all of the necessary credentialing requirements at the time any tests were performed.

If the carrier receives notification from a technician that he/she is no longer performing tests at the IDTF, the carrier shall request from the supplier a CMS-855B change of information. If the provider did not have another technician qualified to perform the tests listed on the current application, the supplier must submit significant documentation in the form of payroll records, etc. to substantiate the performance of the test by a properly qualified technician after the date the original technician was no longer performing procedures at the IDTF.

4.19.5 – Supervising Physicians

(Rev. 234; Issued: 01-18-08; Effective: 01-01-08; Implementation: 04-22-08)

A. General Principles

Under 42 CFR § 410.33(b)(1), an IDTF must have one or more supervising physicians who are responsible for:

- *The direct and ongoing oversight of the quality of the testing performed;*
- *The proper operation and calibration of equipment used to perform tests; and*
- *The qualifications of non-physician IDTF personnel who use the equipment.*

Of course, not every supervising physician has to be responsible for all of these functions. For instance, one supervising physician can be responsible for the operation and calibration of equipment, while other supervising physicians can be responsible for test supervision and the qualifications of non-physician personnel. The basic requirement, however, is that all the supervisory physician functions must be properly met at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that are allowed to use different supervisory physicians at different locations. They may have a different physician supervise the test at each location. The physicians used need only meet the proficiency standards for the tests they are supervising.

*Under 42 CFR § 410.33(b)(1), each supervising physician must be limited to providing 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.*

B. Information about the Supervising Physicians

The carrier shall check and document that each supervisory physician: (1) is licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed, and (2) is Medicare enrolled. The physician(s) need not necessarily be Medicare enrolled in the State where the IDTF is enrolled.

In addition:

- The carrier shall verify the licensure for the State where the IDTF is being enrolled for each supervisory physician enrolled with another carrier, based upon the physician's license submission and discussions with the carrier where they are enrolled. • Each physician of the group who actually performs an IDTF supervisory function must be listed.*
- If a supervising physician has been recently added or changed, the updated information must be reported via a CMS-855B change request. The new physician must have met all the supervising physician requirements at the time any tests were performed.*
- If the carrier knows that a listed supervisory physician has been listed with several other IDTFs, the carrier shall check with the physician to determine whether the physician is still acting as supervisory physician for the previously enrolled IDTFs.*

C. General, Direct, and Personal Supervision

Under 42 CFR §410.33(b)(2), if a procedure requires the direct or personal supervision of a physician as set forth in 42 CFR §410.32(b)(3), the carrier shall ensure that the IDTF's supervisory physician furnishes this level of supervision.

The carrier's enrollment staff shall be familiar with the definitions of personal, direct and general supervision set forth at 42 CFR §410.32(b)(3), and shall ensure that the applicant has checked the highest required level of supervision for the tests being performed. Each box that begins with "Assumes responsibility," must be checked. However, as indicated previously, the boxes can be checked through the use of more than one physician.

D. Attestation Statement for Supervising Physicians

A separate attestation statement must be completed and signed by each supervisory physician listed. If Question E2 is not completed, the carrier may assume that the supervisory physician in question supervises for all codes listed in section 2 of the IDTF attachment – unless the carrier has reason to suspect otherwise. If Question E2 is completed, the carrier shall ensure that all codes listed in section 2 are covered through the use of multiple supervisory physicians. With respect to physician verification, the carrier shall:

- Check the signature on the attestation against that of the enrolled physician; • Contact each supervisory physician by telephone (or as part of the required site visit) to verify that the physician: (1) actually exists (e.g., is not using a phony or inactive physician number); (2) indeed signed the attestation; and (3) is aware of his or her responsibilities. If the physician is enrolled with a different carrier, the carrier shall contact the latter carrier and obtain the listed telephone number of the physician.*

4.19.6 – Desk and Site Reviews

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

All new IDTF applications shall receive: (1) a thorough desk review, and (2) a mandatory site review prior to the carrier's enrollment of the applicant and issuance of a billing number. The general purpose of both reviews is to determine whether the information listed on Attachment 2 of the CMS-855B is correct, verifiable, and in accordance with all IDTF regulatory and manual requirements.

A. The General Site Review Process

The site visit shall be performed by qualified employees of either the contractor or an individual or organization with which the contractor has contracted for the performance of this function.

B. Mobile Units

Mobile units are required to list their geographic service areas in section 4 of the CMS- 855B. Based on the information furnished therein, the carrier shall perform a site visit via the following methods: (1) the mobile unit may visit the office of the site reviewer, or (2) the site reviewer may obtain an advance schedule of the locations the IDTF will be visiting and conduct the site visit at one of those locations.

Units that are performing CPT-4 or HCPCS code procedures that require direct or personal supervision require special attention. To this end, the carrier shall maintain a listing of all mobile IDTFs that perform procedure codes that require such levels of supervision. The carrier shall also discuss with the applicant and all supervisory physicians listed:

- How they will perform these types of supervision on a mobile basis;*
- What their responsibilities are;*
- That a patient's physician who is performing direct or personal supervision for the IDTF on their patient should be aware of the prohibition concerning physician self referral for testing (in particular this concerns potentially illegal compensation to the supervisory physician from the IDTF).*

C. Changes of Information

Addition of Codes

An enrolled IDTF that wants to perform additional CPT-4 or HCPCS codes must submit a CMS-855B change request. If the additional procedures are of a type and supervision level similar to those previously reported (e.g., an IDTF that performs MRIs for shoulders wants to perform MRIs for hips), a new site visit is typically not required, though the carrier reserves the right to perform one.

If, however, the enrolled IDTF wants to perform additional procedures that are not similar to those previously reported (e.g., an IDTF that conducts sleep studies wants to perform ultrasound tests or skeletal x-rays), the carrier shall perform a site visit. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment), and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

If the enrolled IDTF originally listed only general supervision codes and was only reviewed for only general supervision tests, and now wants to perform tests that require direct or personal supervision, the carrier shall promptly suspend all payments for all codes other than those requiring general supervision. A new site visit is required. All IDTF claims for the additional procedures shall be suspended until the IDTF: (1) passes all enrollment requirements for the additional procedures (e.g., supervisory physician, non-physician personnel, equipment), and (2) presents evidence that all requirements for the new procedures were met when the tests were actually performed.

4.19.7 – Special Procedures and Supplier Types

(Rev. 216; Issued: 07-13-07; Effective: 01-01-07; Implementation: 10-01-07)

A. Diagnostic Mammography

If an IDTF performs diagnostic mammography services, it must have a Food and Drug Administration (FDA) certification to perform the mammography. However, an entity that only performs diagnostic mammography services should not be enrolled as an IDTF. Rather, it should be separately enrolled as a mammography center.

B. CLIA Tests

An IDTF may not perform or bill for CLIA tests. However, an entity with one tax identification number (TIN) may own both an IDTF and an independent CLIA laboratory. In such a situation, they should be separately enrolled and advised to bill separately. The carrier shall also advise its claims unit to ensure that the CLIA codes are not being billed under the IDTF provider number.

III. Billing Information related to IDTF's

1. Ambulatory Surgical Centers

An ASC may not bill for separate diagnostic tests they perform during the ASC's scheduled hours of operation (see 42 CFR 416.2). If an entity that owns an ASC performs diagnostic tests in the same physical facility as the ASC but during a time period when the ASC is not in operation, the entity may bill for those diagnostic tests. However, it must do so as an IDTF, thus requiring a separate IDTF enrollment.

2. Portable X-Ray Suppliers

A mobile IDTF that provides x-ray services is not classified as a portable x-ray supplier. Therefore, it cannot bill for transportation (R0070) and setup (Q0092). If it desires to bill for these services, it must also enroll and qualify as a portable x-ray supplier and bill as a portable x-ray supplier in accordance with the portable x-ray supplier billing rules. The carrier shall ensure that an entity that is enrolled as an IDTF and a portable x-ray supplier is not double billing.

3. Therapeutic Procedures

An IDTF may not bill for any CPT or HCPCS codes that are solely therapeutic.

4. Employment Relationships

The IDTF technicians do not have to be employees of the IDTF. They can be contracted by the IDTF. In terms of hospital employment, a technician can be employed by both an IDTF and a hospital (or other entity, including a physician practice). However, he or she cannot be scheduled to perform services for both entities at the same time. If the technician is employed by a hospital, the carrier shall notify the fiscal intermediary that is assigned to the hospital. (This is to ensure that the fiscal intermediary can confirm that the hospital is properly allocating the appropriate portion of all direct and indirect costs associated with the technician.) A technician who is employed by a hospital or physician's office does not automatically qualify as being properly credentialed to perform services for an IDTF.

5. Transtelephonic and Electronic Monitoring Services

Suppliers of transtelephonic and electronic monitoring services (e.g., 24-hour ambulatory EKG monitoring; pacemaker monitoring and cardiac event detection) may perform some of their services without actually seeing the patient. These billing codes include 93733, 93736, 93226, 93232, 93271, 93225, 93231, 93230, 93224, 93014, 95956, 93012, 93731, 93236, 93233, 93040, 93270, 95953 and G0004 – G0008 and G0016. Such entities should be classified as IDTFs, must meet all IDTF requirements, and shall undergo a site visit. As there are currently no specific certification standards for these entities' technicians, the carrier has the discretion to determine whether the technician has sufficient credentials.

If the entity lists codes G0004 – G0008, G0015, G0016, the carrier shall make a written determination that the entity has a person available on a 24-hour basis to answer telephone inquiries. (Use of an answering service in lieu of an actual person is not acceptable.) The person performing the attended monitoring should be listed in section 3 of Attachment 2, and determining the sufficiency of his/her qualifications is at the carrier's discretion. The carrier shall check that the person is available by attempting to contact the applicant during non-standard

business hours; at least one of the contact calls should be made between midnight and 6:00 a.m. If the applicant does not meet the availability standard, the carrier shall deny the application.

PUB 100-08 Program Integrity Manual (PIM) Chapter 10, section 12

6. 12.2.6 Radiation Therapy Centers

(Rev. 236, Issued: 02/01/08, Effective: 01/01/08, implementation: 03/03/08)

Under 42 CFR 410.35, Medicare Part B pays for x-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment. As radiation therapy centers (RTCs) furnish therapeutic services, they are not IDTFs.

For additional background on radiation therapy services, see Pub. 100-04, chapter 13, as well as Pub. 100-02, chapter 15, section 90.

7. 12.2.7 Slide Preparation Facilities

(Rev.236, Issued: 02-01-08, Effective: 01-01-08, Implementation: 03-03-08)

A slide preparation facility furnishes slide preparation and other kinds of services that are payable through the technical component of surgical pathology services. It does not furnish the professional component of surgical pathology services or other kinds of laboratory tests. As such, a slide preparation facility is not an IDTF.

8. Referrals

Nothing in this manual or the CMS-855B shall be construed to authorize billing by an IDTF, physician, physician group practice, or any other entity that violates the physician self-referral prohibition set forth in §1877 of the Social Security Act and related regulations. Carriers shall deny claims submitted in violation of §1877 and demand refunds of any payments that have been made in violation of §1877.

Consistent with 42 CFR § 410.32(a), the supervisory physician for the IDTF (regardless of whether the IDTF is a mobile unit) may not order tests to be performed by the IDTF unless the supervisory physician is the patient's treating physician and is not otherwise prohibited from referring to the IDTF. The supervisory physician is the patient's treating physician if he or she furnishes a consultation or treats the patient for a specific medical problem and uses the test results in the management of the patient's medical problem.

9. Off-Site Interpretations

If an IDTF wants to bill for an interpretation performed by an independent practitioner off the premises of the IDTF, it must meet all instructions identified in Pub. 100-4, chapter 1, concerning purchased interpretations. In this scenario, there is no reassignment of benefits because the purchaser of the test is also considered the supplier of the test. When the technical component of a test is performed by the IDTF and the interpreting practitioner is the practitioner who ordered the test, the IDTF cannot bill for the interpretation. The interpreting practitioner must bill the interpretation since the IDTF cannot bill the interpretation when the interpreting physician is the referring physician.

Reason for Denials

Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter). From 42cfr410.32

***Sources of Information**

*PUB-100-08 Medicare Program Integrity Manual-Change request (CR) *CR 6310, CR5856, CR 5892; CR 5672

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Wisconsin: *Article 05/01/09; Article 03/01/2008; 05/01/2007; Article 09/01/2007;
Illinois: *Article 05/01/09; Article 03/01/2008; 05/01/2007; Article 09/01/2007;
Michigan: *Article 05/01/09; Article 03/01/2008; 05/01/2007; Article 09/01/2007;
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