CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 216	Date: JULY 13, 2007
	Change Request 5672

SUBJECT: Implementation of New Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)

I. SUMMARY OF CHANGES: This change request incorporates into Pub. 100-08, chapter 10 (hereinafter referred to as chapter 10), new supplier standards that IDTFs must meet in order to bill the Medicare program. It also deletes section 4.19.8, as well as other minor provisions - from the IDTF instructions in chapter 10. Such instructions were removed because they involve general IDTF policy as well as IDTF billing procedures, neither of which come under the purview of provider enrollment.

NEW / REVISED MATERIAL
EFFECTIVE DATE: JANUARY 1, 2007
IMPLEMENTATION DATE: OCTOBER 1, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/Table of Contents
R	10/4.19/IDTF Attachment
R	10/4.19.1/IDTF Standards
R	10/4.19.2/Multi-State IDTF Entities
R	10/4.19.3/Interpreting Physicians
R	10/4.19.4/Technicians
R	10/4.19.5/Supervising Physicians
R	10/4.19.6/Desk and Site Reviews
R	10/4.19.7/Special Procedures and Supplier Types
D	10/4.19.8/Billing Issues

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-08	Transmittal: 216	Date: July 13, 2007	Change Request: 5672

SUBJECT: Implementation of New Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)

EFFECTIVE DATE: January 1, 2007
IMPLEMENTATION DATE: October 1, 2007

I. GENERAL INFORMATION

A. Background: This change request adds to Pub. 100-08, chapter 10 (hereinafter referred to as chapter 10), new supplier standards that IDTFs must meet in order to bill the Medicare program. It also deletes section 4.19.8 - as well as other minor provisions - from the IDTF instructions in chapter 10. Such instructions were removed because they involve general IDTF policy as well as IDTF billing procedures, neither of which fall within the purview of provider enrollment.

B. Policy: CMS Final Rule 1321-FC published, among other things, additional standards in 42 CFR §410.33(g) that IDTFs must meet in order to enroll (and to maintain enrollment) in the Medicare program.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5672.1	As codified in 42 CFR § 410.33(g), the contractor shall ensure that all IDTFs are in compliance with the standards identified in chapter 10, section 4.19.1.	X			X							
5672.2	As codified in 42 CFR § 410.33(e)(1), the contractor shall ensure that all IDTFs that operate across State lines are in compliance with the provisions identified in chapter 10, section 4.19.2.	X			X							
5672.3	The contractor shall ensure that each supervising physician is limited to providing supervision to no more than three IDTF sites.	X			X							
5672.4	The contractor shall note the removal of	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	section 4.19.8 – as well as most IDTF instructions relating to general IDTF policy and billing procedures – from chapter 10.											

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	None. Provider education concerning the new IDTF standards has already taken place through other channels.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): Frank Whelan, (410) 786-1302, frank.whelan@cms.hhs.gov
Post-Implementation Contact(s): Frank Whelan, (410) 786-1302, frank.whelan@cms.hhs.gov

VI. FUNDING

A. ***For TITLE XVIII Contractors*****:** No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. ***For Medicare Administrative Contractors (MAC)*****:** The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Program Integrity Manual
Chapter 10 - Medicare Provider Enrollment

Table of Contents
(Rev. 216, 07-13-07)

4.19 – IDTF Attachment

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

Sections 4.19.1 through 4.19.*7* of this manual contain *provider enrollment* instructions regarding entities that must enroll as and bill for the technical component of diagnostic tests as an independent diagnostic testing facility (IDTF).

4.19.1 – IDTF Standards

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

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 exceptions to applicable State licensing requirements are permitted.*

- *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. 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.

***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 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.

- *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 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).

- *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 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.

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. 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.

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

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.

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.