

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 234	Date: JANUARY 18, 2008
	Change Request 5856

Subject: Revision to Instructions Relating to Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)

I. SUMMARY OF CHANGES: This change request incorporates into Pub. 100-08, chapter 10 certain recent revisions to 42 CFR 410.33 pertaining to independent diagnostic testing facilities.

New / Revised Material

Effective Date: January 1, 2008

Implementation Date: April 22, 2008

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	10/4.19.1/IDTF Standards
R	10/4.19.5/Supervising Physicians

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted 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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-08	Transmittal: 234	Date: January 18, 2008	Change Request: 5856
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SUBJECT: Revision to Instructions Relating to Compliance Standards for Independent Diagnostic Testing Facilities (IDTFs)

Effective Date: January 1, 2008

Implementation Date: April 22, 2008

I. GENERAL INFORMATION

A. Background: This change request incorporates into Pub. 100-08, chapter 10, certain recent revisions to 42 CFR §410.33.

B. Policy: The purpose of this change request is to ensure that the provisions in section 4.19, et al., of chapter 10 are consistent with those in 42 CFR §410.33.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
5856.1	The contractor shall note that IDTF changes in ownership, changes of location, changes in general supervision, and adverse legal actions must be reported to the contractor via the CMS-855B within 30 calendar days of the change; all other changes to the IDTF's enrollment information must be reported within 90 calendar days.	X			X						
5856.2	The contractor shall note that for purposes of 42 CFR §410.33(g)(3), a hotel or motel is not considered to be an "appropriate site."	X			X						
5856.3	The contractor shall note that IDTFs that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations under 42 CFR §410.33(g)(3)	X			X						
5856.4	The contractor shall note the additional requirements in 42 CFR §410.33(g)(6) regarding the IDTF's responsibilities in maintaining a comprehensive liability insurance policy.	X			X						
5856.5	The contractor shall note the additional requirements in 42 CFR §410.33(g)(8) regarding the IDTF's responsibilities in maintaining documentation of beneficiaries' written clinical complaints.	X			X						
5856.6	The contractor shall note that effective January 1,	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	2008, – and 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. (NOTE: Existing IDTFs that are sharing a practice location with another Medicare-enrolled organization or individual have until January 1, 2009, to meet the requirements found in 42 CFR §410.33(g)(15)(i).)										
5856.7	The contractor shall note that for IDTF CMS-855B initial applications received on or after January 1, 2008, the filing date of the Medicare enrollment application is the date that the contractor receives a signed provider enrollment application that it is able to process to approval.	X			X						
5856.7.1	The contractor shall note that for IDTF CMS-855B initial applications received on or after January 1, 2008, 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 the contractor; or (2) the date the IDTF first started furnishing services at its new practice location.	X			X						
5856.7.2	The contractor shall note that if it rejects an IDTF CMS-855B 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.	X			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
5856.8	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLN MattersArticles/ shortly after the CR is released. You will receive notification	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements:

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

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

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

VI. FUNDING

A. For *Fiscal Intermediaries and Carriers*: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. For *Medicare Administrative Contractors (MACs)*:

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 allotted 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.

4.19.1 – IDTF Standards

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

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. *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.*

(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. 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*. 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 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--*

(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 includes - 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 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.

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.

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.