## DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services







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# Independent Diagnostic Testing Facility (IDTF) Fact Sheet

This Medicare Learning Network® Fact Sheet provides details of the requirements for an Independent Diagnostic Testing Facility (IDTF) to be enrolled in the Medicare program.

#### Definition

An IDTF is a facility that is independent both of an attending or consulting physician's office and of a hospital. However, IDTF general coverage and payment policy rules apply when an IDTF furnishes diagnostic procedures in a physician's office (see 42 Code of Federal Regulations (CFR) 410.33(a)(1)).

Effective for diagnostic procedures performed on or after March 15, 1999, Medicare Administrative Contractors (MACs) pay for diagnostic procedures under the physician fee schedule when performed by an IDTF. An IDTF may be a fixed location or a mobile entity. It is independent of a physician's office or hospital.

#### **TAKE NOTE**

With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF does not:

- 1. Share a practice location with another Medicare-enrolled individual or organization
- 2. Lease or sublease its operations or its practice location to another Medicare enrolled individual or organization or
- 3. Share diagnostic testing equipment used in the initial diagnostic test with another Medicareenrolled individual or organization

#### **Medicare Enrollment**

An IDTF should be open and operational at the time it submits the CMS-855B application to initially enroll in Medicare.

#### **One Enrollment per Practice Location**

- An IDTF must separately enroll each of its practice locations (with the exception of locations that are used solely as warehouses or repair facilities). This means that an enrolling IDTF can have only one practice location on its Form CMS-855B enrollment application. If an IDTF is adding a practice location to its existing enrollment, it must submit a new complete Form 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.
- Each separately enrolled practice location of the IDTF must meet all applicable IDTF requirements. The location's failure to comply with any of these requirements will result in the revocation of its Medicare billing privileges.

#### **Effective Date of Billing Privileges**

The filing date of an IDTF Medicare enrollment application is the date that the MAC receives a signed application that it is able to process to approval (see <u>42 CFR section 410.33(i)</u>). The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

- · The filing date of the Medicare enrollment application that was subsequently approved by the MAC or
- 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.

IDTFs should note that, if an IDTF application is rejected and a new application is later submitted, the date of filing is the date the MAC receives the new enrollment application.

#### Leasing and Staffing

A mobile IDTF does not include entities that lease or contract with a Medicare enrolled provider or supplier to provide:

- Diagnostic testing equipment
- Non-physician personnel described in 42 CFR section 410.33(c) or
- Diagnostic testing equipment and non-physician personnel described in 42 CFR section 410.33(c). This is because the provider or supplier is responsible for providing the appropriate level of physician supervision for the diagnostic testing.

#### **Multi-State Independent Diagnostic Testing Facilities**

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 (POS) 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 POS. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the POS. (See 42 CFR section 410.33(e)(1)). See Place of Service Issues section below for further information about coding for POS.

#### Requirements for an IDTF Supervising Physician

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

Not every supervising physician has to be responsible for all functions. 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. Each supervising physician must be limited to providing general supervision at no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

Supervising physicians must meet the following criteria:

- 1. Be licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed
- 2. Be enrolled in Medicare; however, the physician(s) need not necessarily be Medicare enrolled in the State where the IDTF is enrolled
- 3. Meet the proficiency tests for any tests he or she supervises
- 4. Is not currently excluded or barred
- 5. Provide general supervision for no more than three IDTF sites

#### Requirements for an IDTF Interpreting Physician

IDTFs are not required to have interpreting physicians. If the IDTF does have such physicians, the IDTF interpreting physician must:

- 1. Be licensed to practice in the State(s) where the diagnostic tests he or she supervises will be performed
- 2. Be enrolled in Medicare
- 3. Not be currently excluded or barred
- 4. Be qualified to interpret the types of tests (codes) listed in the enrollment application

#### Requirements for an IDTF Technician

An IDTF technician must:

- 1. Meet the certification and/or license standards of the State in which tests are performed at the time of the IDTF enrollment and/or at the time any tests are performed
- 2. Be qualified to perform the types of tests (codes) listed in the enrollment application



#### **Performance Standards for IDTFs**

As part of its enrollment application, an IDTF must complete Attachment 2 Independent Diagnostic Testing Facilities of Form CMS-855B. This attachment lists the Independent Diagnostic Testing Facilities Performance Standards, are in 42 CFR 410.33(g). In completing the enrollment application, including Attachment 2, the IDTF certifies that it meets the following standards and all other requirements consistent with 42 CFR 410.33(g).

#### **Requirements for IDTFs:**

| 1 | Operate its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.   |
|---|---|
| 2 | Provide 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 MAC on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 calendar days.   |
| 3 | <ul> <li>Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mail box, hotel, or motel, is not considered an appropriate site. The physical location must have an address, including the suite identifier, which is recognized by the United States Postal Service (USPS).</li> <li>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.</li> <li>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.</li> </ul> |
| 4 | Have all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. A catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers, must be maintained at the physical site. In addition, portable diagnostic testing equipment must be available for inspection within two business days of the Centers for Medicare & Medicaid Services (CMS) inspection request. The IDTF must maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers, provide this information to the designated MAC upon request, and notify the MAC of any changes in equipment within 90 days.  |
| 5 | Maintain a primary business phone under the name of the designated business. The primary business phone must be located at the designated site of the business, or within the home office of the mobile IDTF units. The telephone number or toll free numbers must be available in a local directory and through directory assistance. 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. 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:  • Ensure that the insurance policy remain in force at all times and provide coverage of at least \$300,000 per incident; and  • Notify the CMS-designated MAC in writing of any policy changes or cancellations.   |
| 7 | Agree not to directly solicit patients, which include, but are 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. Non-physician practitioners may order tests as set forth in section 410.32(a)(3).   |

| 8  | Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs this documentation would be stored at their home office.) This includes, but is not limited to the following:  |  |
|----|--|--|
|    | The name, address, telephone number, and health insurance claim number of the beneficiary  |  |
|    | The date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint   |  |
|    | <ul> <li>If an investigation was not conducted, the name of the person making the decision and the reason<br/>for the decision</li> </ul>  |  |
| 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 the MAC within two business days.  |  |
| 14 | Permit CMS, including its agents, or its designated MAC to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must be accessible during regular business hours to CMS and beneficiaries and must maintain a visible sign posting the normal business hours of the IDTF.  |  |
| 15 | Enroll 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 | Bill 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 an 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 Form CMS-855 application.   |  |

#### **Billing Issues for IDTFs**

Consistent with 42 CFR 410.32(a), the supervisory physician for the IDTF, whether or not for 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.

If an IDTF wants to bill for an interpretation performed by a physician who does not share a practice with the IDTF, the IDTF must meet certain conditions concerning the anti-markup payment limitation. If a physician working for an IDTF (or a party related to the IDTF through common ownership or control as described in 42 CFR 413.17) does not order the technical component (TC) or the professional component (PC) of a diagnostic test (excluding clinical diagnostic laboratory tests), it would not be subject to the anti-markup payment limitation (see Chapter 1, Section 30.2.9 of the "Medicare Claims Processing Manual").

#### **Transtelephonic and Electronic Monitoring Services**

Transtelephonic and electronic monitoring services (for example, 24 hour ambulatory EKG monitoring, pacemaker monitoring and cardiac event detection) may perform some of their services without actually seeing the patient. Most but not all of these billing codes currently are 93012, 93014, 93040, 93224, 93225, 93226, 93232, 93230, 93231, 93233, 93236, 93270, 93271, 93731, 93733, 93736, 95953, and 95956. These monitoring service entities should be classified as IDTFs and must meet all IDTF requirements. CMS currently does not have specific certification standards for IDTF technicians; technician credentialing requirements for IDTFs are at the MAC's discretion. They do require a supervisory physician who performs General Supervision. Final enrollment of a transtelephonic or electronic monitoring service as an IDTF requires a site visit.

For any entity that lists and will bill codes 93012, 93014, 93268, 93270, 93271, or 93272, the MAC must make a written determination that the entity actually has a person available on a 24-hour basis to answer telephone inquiries. Use of an answering service in lieu of the actual person is not acceptable. The person performing the attended monitoring should be listed in Section 3 of Attachment 2 of Form CMS-855B. The qualifications of the person are at the MAC's discretion. The MAC shall check that the person is available by attempting to contact the applicant during non-standard business hours. In particular, at least one of the contact calls should be made between midnight and 6:00 AM. If the applicant does not meet the availability standard, they should receive a denial of enrollment.

#### **Ordering of Tests**

All procedures performed by the IDTF must be specifically ordered in writing by the physician or practitioner 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. (Non-physician practitioners may order tests as set forth in CFR 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.



#### Diagnostic Tests Subject to the Anti-Markup Payment Limitation

In most instances, physicians working for an IDTF do not order diagnostic tests because such tests are generally ordered by the patient's treating physician. If a physician working for an IDTF does not order a diagnostic test, the test is not subject to the anti-markup payment limitation. However, if a physician working for an IDTF (or a physician financially related to the IDTF through common ownership or control) orders a diagnostic test payable under the Medicare Physician Fee Schedule (MPFS), the anti-markup payment limitation may apply (depending on whether the performing physician or other supplier meets the "sharing a practice" requirements). For further information in this case, IDTFs should refer to the "Medicare Claims Processing Manual," Chapter 1, Section 30.2.9, Payment to Physician or Other Supplier for Diagnostic Tests Subject to the Anti-Mark-up Payment Limitation, available at <a href="http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf">http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf</a>.

#### **Therapeutic Procedures**

An IDTF shall not be allowed to bill for any CPT or HCPCS codes that are solely therapeutic.

#### **Place of Service Issues**

CMS released MLN Matters® Article <u>MM7631</u> on April 1, 2013, which advises physicians, providers, and suppliers of the national policy and coding instructions for Place of Service (POS). The importance of this national policy is underscored by consistent findings, in annual or biennial reports from Calendar Year (CY) 2002 through CY 2007, by the Office of the Inspector General (OIG) that physicians and other suppliers frequently incorrectly report the POS in which they furnish services.

This article advises that CMS establishes that, for all services, with two exceptions, paid under the MPFS, the POS code to be used by the physician and other supplier will be assigned as the same setting in which the beneficiary received the face-to-face service. Because a face-to-face encounter with a physician or other provider is required for nearly all services paid under the MPFS and anesthesia services, this rule will apply to the overwhelming majority of MPFS services.

In cases where the face-to-face requirement is obviated, such as those when a physician or other provider provides the professional component (PC) interpretation of a diagnostic test from a distant site, the POS code assigned by the physician or other provider will be the setting in which the beneficiary received the technical component (TC) of the service. For example, a beneficiary receives an MRI at an outpatient hospital near his/her home. The hospital submits a claim that would correspond to the TC portion of the MRI. The physician furnishes the PC portion of the beneficiary's MRI from their office location –POS code 22 will be used on the physician's claim for the PC to indicate that the beneficiary received the face-to-face portion of the MRI, the TC, at the outpatient hospital. IDTFs should review this article in order to use the correct POS code when billing for services.

For more details about this policy, you should refer to MLN Matters® Number MM7631, Revised and Clarified Place of Service (POS) Coding Instructions. The article is available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7631.pdf">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7631.pdf</a>.

Additional clarification about this policy may be found at Frequently Asked Questions Related to Change Request 7631(Revised and Clarified Place of Service Coding Instructions), dated April 25, 2013, available at <a href="http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/FAQs-CR7631-4-25-13.pdf">http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/FAQs-CR7631-4-25-13.pdf</a>.

#### Resources

The following resources will help IDTFs understand Medicare requirements:

| For More Information About                      | Resource  |
|---|---|
| "Medicare Claims Processing Manual," Chapter 35 | http://www.cms.gov/Regulations-and-Guidance/<br>Guidance/Manuals/downloads/clm104c35.pdf                                |
| 42 CFR 410.33                                   | http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec410-33.pdf                              |
| "Medicare Program Integrity Manual," Chapter 15 | http://cms.hhs.gov/Regulations-and-Guidance/<br>Guidance/Manuals/Downloads/pim83c15.pdf                                 |
| Medicare Enrollment Application CMS-Form 855B   | http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf   |
| MLN Matters® Number MM7631                      | http://www.cms.gov/Outreach-and-Education/<br>Medicare-Learning-Network-MLN/MLNMatters<br>Articles/downloads/MM7631.pdf |
| "Medicare Claims Processing Manual," Chapter 1  | http://cms.hhs.gov/Regulations-and-Guidance/<br>Guidance/Manuals/Downloads/clm104c01.pdf                                |

### **Hyperlink Table**

| Embedded Hyperlink   | Complete URL  |
|--|---|
| 42 CFR section 410.33(i))  | http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec410-33.pdf                              |
| Form CMS-855B  | http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf   |
| MM7631   | http://www.cms.gov/Outreach-and-<br>Education/Medicare-Learning-Network-MLN/<br>MLNMattersArticles/downloads/MM7631.pdf |
| "Medicare Program Integrity Manual," Chapter 3,<br>Section 3.3.2.4 | https://www.cms.gov/Regulations-and-Guidance/<br>Guidance/Manuals/downloads/pim83c03.pdf                                |







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