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# **Independent Diagnostic Testing Facility (IDTF)**



This Medicare Learning Network® (MLN) booklet explains the requirements for an Independent Diagnostic Testing Facility (IDTF) to enroll in the Medicare program. This booklet will also tell you of IDTFs key billing issues.





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# What's Changed?

Deleted section on IDTFs and COVID-19 Public Health Emergency

#### **Definition**

An IDTF is a facility independent of both 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)).

Medicare Administrative Contractors (MACs) pay for diagnostic procedures under the Medicare Physician Fee Schedule (MPFS) when an IDTF performs them. An IDTF may be a fixed location or a mobile entity.

With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF doesn't:

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

# **Medicare Enrollment Requirements**

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

## One Enrollment per Practice Location

An IDTF must separately enroll each of its practice locations (except for locations they use solely as warehouses or repair facilities). This means that an enrolling IDTF can have only 1 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 undergo a separate site visit for that location. The MAC receives the application, begins processing it, and then CMS or its agent will conduct an unannounced site visit. Each IDTF mobile unit must enroll separately. 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. Medicare will revoke billing privileges from any location that fails to comply with any of these enrollment requirements.

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

The filing date of an IDTF Medicare enrollment application is the date the MAC gets a signed application that it's 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 MAC-approved Medicare enrollment application
- The date the IDTF first started providing services at its new practice location. A newly enrolled IDTF, therefore, may not get payment for services provided before the effective date of billing privileges.

**Note:** If the MAC rejects an IDTF application and the IDTF sends a new application, the date of filing is the date the MAC gets the new enrollment application.

**Leasing and Staffing** 

A mobile IDTF doesn't 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 410.33(c)
- Diagnostic testing equipment and non-physician personnel described in 42 CFR 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 IDTFs**

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
- Operate in compliance with all applicable federal, state, and local licensure and regulatory requirements regarding patient health and safety

Together we can advance health equity and help eliminate health disparities for all minority and underserved groups. Find resources and more from the CMS Office of Minority Health:

- Health Equity Technical Assistance Program
- Disparities Impact Statement



Place of Service (POS) is defined on the claim form as the point of the actual delivery of service. When the IDTF performs or administers an entire diagnostic test at the patient's location, the patient's location is the POS. When an IDTF performs 1 or more aspects of the diagnostic testing at the IDTF, the IDTF is the POS. (See 42 CFR 410.33(e)(1).) See Place of Service Issues section below for more information about coding for POS.

### **Requirements for an IDTF Supervising Physician**

An IDTF must have 1 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
- 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 the IDTF must meet all supervisory physician functions at each location, regardless of the number of physicians involved. This is particularly applicable to mobile IDTF units that can use different supervisory physicians at different locations. They may have a different physician supervise the test at each location. The physicians only have to meet the proficiency standards for the tests they are supervising. Each supervising physician can provide general supervision at no more than 3 IDTF sites. This applies to both fixed sites and mobile units where 3 concurrent operations are capable of performing tests.

Supervising physicians must meet the following criteria:

- 1. Have a license to practice in the state(s) where the diagnostic tests they supervise take place
- 2. Be Medicare-enrolled. But they don't need to be Medicare-enrolled in the same state as the IDTF's enrollment.
- 3. Meet the proficiency tests for any tests they supervise
- 4. The Office of the Inspector General (OIG) hasn't currently excluded or barred the physician from participation in any Federal Executive Branch procurement or non-procurement program
- 5. Provide general supervision for no more than 3 IDTF sites

### Requirements for an IDTF Interpreting Physician

IDTFs don't need to have interpreting physicians. If the IDTF does have such physicians, the IDTF interpreting physician must:

- 1. Have a license to practice in the state(s) where the diagnostic tests they supervise take place
- 2. Be Medicare-enrolled
- 3. The OIG hasn't currently excluded or barred the physician from participation in any Federal Executive Branch procurement or non-procurement program
- 4. Be qualified to interpret the types of tests (codes) the IDTF listed in the enrollment application



### **Requirements for an IDTF Technician**

An IDTF technician must:

- 1. Meet the certification and license standards of the state in which they perform tests at the time of the IDTF enrollment and at the time they perform any tests
- 2. Be qualified to perform the types of tests (codes) the IDTF 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 <u>Form CMS-855B</u>. This attachment lists the Independent Diagnostic Testing Facilities Performance Standards, which are in <u>42 CFR 410.33(g)</u>. In completing the enrollment application, including Attachment 2, the IDTF certifies that it meets the following standards and all other requirements consistent with <u>42 CFR 410.33(g)</u>.

### **IDTF** Requirements

Operate its business in compliance with all applicable federal and state licensure and regulatory 1. requirements for the health and safety of patients. Provide complete and accurate information on its enrollment application. Report changes in ownership. changes of location, changes in general supervision, and adverse legal actions to the MAC on the 2. Medicare enrollment application within 30 calendar days of the change. Report all other changes to the enrollment application to the MAC within 90 calendar days. Maintain a physical facility on an appropriate site. For the purposes of this standard, Medicare doesn't consider a post office box, commercial mail box, hotel, or motel, to be an appropriate site. The physical location must have an address, including the suite identifier, which the United States Postal Service (USPS) recognizes. • The physical facility, including mobile units, must contain space for equipment appropriate to the 3. services the IDTF 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 don't see patients at their practice location are exempt from providing hand washing and adequate patient privacy accommodations. Have all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. You must maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers, at the physical site. Also, portable diagnostic testing equipment must be available for inspection within 2 business days of a CMS inspection request. 4. 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.



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 patients and must maintain a visible sign posting the normal business hours of the IDTF.
13.	Have proper medical record storage and be able to retrieve medical records upon request from CMS or the MAC within 2 business days.
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.
11.	Maintain and calibrate your testing equipment per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.
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.
9.	Openly post these standards for review by patients and the public.
	<ul> <li>If you didn't investigate, identify the name of the person making the decision and the reason for the decision to not investigate</li> </ul>
8.	The date you got the complaint, the name of the person getting the complaint, and a summary of actions you took to resolve the complaint
	The name, address, telephone number, and Medicare Beneficiary Identifier (MBI) of the patient
	Answer, document, and maintain documentation of a patient's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, store this documentation at their home office). This includes, but isn't limited to, the following:
7.	Agree not to directly solicit patients, which include, but aren't 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 providing a consultation or treating a patient for a specific medical problem and who uses the results in the management of the patient's specific medical problem. Non-physician practitioners may order tests as set forth in <u>42 CFR 410.32(a)(3)</u> .
	\$300,000 per incident.  • Notify the CMS-designated MAC in writing of any policy changes or cancellations.
	Ensure that the insurance policy always remains in force and provides coverage of at least
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. A non-relative owned company must carry the policy. 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:
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 can't use call forwarding or an answering service as their primary method of receiving calls from beneficiaries during posted operating hours.



- Enroll in Medicare for any diagnostic testing services that it provides to a Medicare patient, regardless of whether you perform the service in a mobile or fixed base location.
- Bill for all mobile diagnostic services that you provide to a Medicare patient, unless the mobile diagnostic service is part of a service you provide under arrangement as described in Section 1861(w) (1) of the Social Security 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's 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 <u>42 CFR 410.32(a)</u>, the IDTF supervisory physician, whether or not for a mobile unit, may not order IDTF-performed tests, unless the supervisory physician is the patient's treating physician and isn't otherwise prohibited from referring to the IDTF. The supervisory physician is the patient's treating physician if they:

- · Provide a consultation or treats the patient for a specific medical problem and
- Use 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 doesn't 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) doesn't order the technical component (TC) or the professional component (PC) of a diagnostic test (excluding clinical diagnostic laboratory tests), it wouldn't be subject to the anti-markup payment limitation. See <a href="Chapter 1">Chapter 1</a>, Section 30.2.9 of the Medicare Claims Processing Manual for more information.

<u>Section 1877 of the Social Security Act</u> places limitations on certain physician referrals. MACs will deny claims you submitted in violation of <u>Section 1877</u> and demand refunds of any payments made in violation of that statute.

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

Facilities with transtelephonic and electronic monitoring services (for example, 24-hour ambulatory Electrocardiogram (EKG) monitoring, pacemaker monitoring, and cardiac event detection):

- May perform some of their services without actually seeing the patient
- · Should be classified as IDTFs
- · Must meet all IDTF requirements



Most, but not all, of the current billing codes for these services are 93040, 93224, 93225, 93226, 93270, and 93271. CMS doesn't currently 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 93268, 93270, 93271, or 93272, the MAC must 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 instead of the actual person isn't acceptable. List the person performing the attended monitoring in Section D of Attachment 2 of Form CMS-855B. The qualifications of the person are at the MAC's discretion. The MAC will check that the person is available by attempting to contact the applicant during non-standard business hours. In particular, at least 1 of the contact calls will be between midnight and 6:00 am. If the applicant doesn't meet the availability standard, the MAC will deny their enrollment.

### **Global Billing**

Global billing is acceptable when the same entity performs both the TC and Modifier 26 and that entity provides both the TC and Modifier 26 within the same MPFS payment locality. You may provide the TC and Modifier 26 in different locations if you furnish them within the same MPFS payment locality.

**Note:** As with all services payable under the MPFS, we use the ZIP Code to determine the appropriate payment locality and corresponding fee used to price the service that's subject to the anti-markup payment limitation. When a ZIP Code crosses county lines, CMS uses the dominant locality to determine the corresponding fee.

If you bill with the global diagnostic test code, report the name, address, and National Provider Identifier (NPI) of the location where you provided the TC in Items 32 and 32a (or the 837P electronic claim equivalent).

For more information on Global Billing, see Chapter 35, Section 10.2.1 of the Medicare Claims Processing Manual.

### Separate TC and PC Billing

When you bill the TC and Modifier 26 separately (not billed globally), report the name, address, and NPI of the location where you performed each component. If the billing provider has an enrolled practice location at the address where the service took place, the billing provider or supplier may report their own name, address, and NPI in Items 32 and 32a (or the 837P electronic claim equivalent).

The NPI in Item 32a must correspond to the entity identified in Item 32 (no matter if it's the group, hospital, IDTF, or individual physician). The only exception for Medicare claims is when a provider performs a service out of jurisdiction and is subject to the anti-markup or a reference lab service. See <a href="Chapter 1">Chapter 1</a>, Section 40.1 of the Medicare Claims Processing Manual for instructions specific to anti-markup and reference lab, respectively.



### **Ordering Tests**

All IDTF-performed procedures must be specifically ordered in writing by the physician or practitioner who is treating the patient, that's, the physician who's furnishing a consultation or treating a patient for a specific medical problem and who uses the results in the management of the patient's specific medical problem. (Non-physician practitioners may order tests as set forth in 42 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 IDTF-performed tests, unless the IDTF's supervising physician is in fact the patient's treating physician. That means the physician in question had a relationship with the patient prior to the performance of the testing and is treating the patient 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 don't order diagnostic tests because the patient's treating physician typically orders such tests. If a physician working for an IDTF doesn't order a diagnostic test, the test isn't 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 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 <a href="Chapter 1">Chapter 1</a>, Section 30.2.9 of the Medicare Claims Processing Manual.

### **Therapeutic Procedures**

An IDTF isn't allowed to bill for any CPT or HCPCS codes that are solely therapeutic.

#### Place of Service Issues

CMS released <u>Change Request (CR) 7631</u> on March 29, 2013, which advises physicians, providers, and suppliers of the national policy and coding instructions for POS. Consistent Office of the Inspector General (OIG) findings stress the importance of this national policy. In annual or biennial reports from Calendar Year (CY) 2002 - CY 2007, the OIG reported that physicians and other suppliers frequently incorrectly report the POS where they provide services.

This CR advises that CMS establishes that, for all services, with 2 exceptions, paid under the MPFS, the POS code the physician and other supplier uses will be assigned as the same setting in which the patient got the face-to-face service. Because Medicare requires a face-to-face encounter with a physician or other provider for nearly all services we pay under the MPFS and anesthesia services, this rule will apply to the overwhelming majority of MPFS services.



Where the face-to-face requirement isn't needed, such as those when a physician or other provider provides the PC interpretation of a diagnostic test from a distant site, the POS code the physician or other provider uses will be the setting in which the patient got the TC of the service. For example, a patient gets an MRI at an outpatient hospital near their home. The hospital submits a claim that would correspond to the TC portion of the MRI. The physician furnishes the PC portion of the patient's MRI from their office location. So physician's claim uses POS code 22 for the PC to indicate that the patient had the face-to-face portion of the MRI, the TC, at the outpatient hospital. IDTFs should review CR 7631 to use the correct POS code when billing for services.

Get additional policy clarification in the <u>Frequently Asked Questions Related to Change Request 7631</u> (Revised and Clarified Place of Service Coding Instructions).

### **SNF Residents Requiring Transportation for IDTF Service**

In 2018, MM10550 advised providers that CMS revised both the Medicare Benefit Policy Manual and the Medicare Claims Processing Manual to clarify that a medically necessary ambulance transport from an SNF to the nearest supplier of medically necessary services not available at the SNF where the patient is the resident, including the return trip (including an IDTF), may be covered under Part B. This applies to patients in an SNF stay uncovered by Part A, but who have Part B benefits.

For SNF residents receiving Part A benefits, such ambulance trips to IDTFs for medically necessary services are subject to SNF consolidated billing.

### **IDTF Mammography Services**

<u>Chapter 18</u>, Section 20.3.1.4 of the Medicare Claims Processing Manual regulates that if an IDTF furnishes any type of mammography service (screening or diagnostic), it must have an FDA certification to perform such services. However, if you only perform diagnostic mammography services, you shouldn't enroll as an IDTF. Medicare does pay for screening mammographies (including those that are self-referred) when an IDTF performs them at the IDTF facility.

# **IDTFs and Opioid Treatment Programs (OTPs)**

The <u>Opioid Treatment Programs (OTPs) Medicare Enrollment</u> fact sheet details information on how IDTFs can enroll as Medicare providers within the OTP initiative, including examples of the CMS-855B enrollment form.

IDTFs should be aware that to be eligible to enroll as an OTP service provider with Medicare, your program must have current, valid, and full certification by the Substance Abuse and Mental Health Services Administration (SAMHSA), and meet all of SAMHSA's criteria, including but not limited to:

- Drug Enforcement Administration (DEA) registration
- State licensure
- Accreditation



### Resources

- 42 CFR 410.33(a)(1)
- 42 CFR 413.17
- Chapter 1, Section 30.2.9 of the Medicare Claims Processing Manual
- CLIA Quick Start Guide
- CMS-855B
- CR 7631
- OTP Medicare Enrollment fact sheet

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