



## Independent Diagnostic Testing Facility



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

## Table of Contents

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<b>What's Changed?</b> .....	3
<b>Definition</b> .....	3
<b>Medicare Enrollment Requirements</b> .....	4
One Enrollment per Practice Location.....	4
Effective Date of Billing Privileges.....	4
Leasing and Staffing.....	4
Multi-State IDTFs.....	5
Requirements for an IDTF Supervising Physician.....	5
Requirements for an IDTF Interpreting Physician.....	6
Requirements for an IDTF Technician.....	6
Performance Standards for IDTFs.....	6
<b>IDTF Requirements</b> .....	7
Indirect IDTFs .....	9
Indirect IDTFs General Description, Exemptions, and Verification.....	9
<b>Billing Issues for IDTFs</b> .....	9
Transtelephonic and Electronic Monitoring Services.....	10
Global Billing.....	10
Separate TC and PC Billing.....	11
Ordering Tests.....	11
Diagnostic Tests Subject to the Anti-Markup Payment Limitation.....	11
Therapeutic Procedures.....	11
Place of Service Issues.....	12
Skilled Nursing Facility (SNF) Residents Requiring Transportation for IDTF Service.....	12
IDTF Mammography Services.....	12
IDTFs and Opioid Treatment Programs (OTPs) .....	13
<b>Resources</b> .....	13

## What's Changed?

More information on several topics, including supervising physicians, interpreting physicians, and technicians.

- Added information on supervising physicians who don't intend to perform medical services outside of their role as a supervising physician (page 6)
- Added information on adding or changing:
  - Interpreting physicians (page 6)
  - Technicians (page 6)

You'll find substantive content updates in dark red.

## 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 supplies diagnostic procedures in a physician's office (see [42 CFR 410.33\(a\)\(1\)](#)).

Medicare Administrative Contractors (MACs) pay for diagnostic procedures under the Medicare Physician Fee Schedule (PFS) when an IDTF performs them. An IDTF may be a fixed location or a mobile entity, but must be independent of a physician's office or hospital.

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

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

## Medicare Enrollment Requirements

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An IDTF should be open and operational when it submits the [Medicare Enrollment Application-Clinics/Group Practices and Other Suppliers \(CMS-855B\)](#) 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 Medicare Enrollment Application-Clinics/Group Practices and Other Suppliers (CMS-855B). If an IDTF is adding a practice location to its existing enrollment, it must submit a new complete application for that location and undergo a separate site visit for that location. The MAC gets the application, starts 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 has 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 deny the application or 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 can process to approval per 42 CFR 410.33(i). 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, won't get payment for services it provides 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)

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

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
- Proper operation and calibration of equipment used to perform tests
- 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're 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 can perform tests.

Supervising physicians must:

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

If the supervising physician is enrolling in Medicare and doesn't intend to perform medical services outside of their role as a supervising physician:

- The MAC will still send the physician an approval letter, assuming successful enrollment, and issue a Provider Transaction Access Number (PTAN)
- The physician will list the IDTF's address as a practice location
- The space-sharing prohibition in 42 CFR 410.33(g) doesn't apply in this particular scenario

## Requirements for an IDTF Interpreting Physician

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

- Have a license to practice in the state where the diagnostic tests they supervise take place
- Be enrolled in Medicare
- Not be currently excluded or barred by the OIG from participation in any FEB procurement or non-procurement program
- Be qualified to interpret the types of tests or codes the IDTF listed in the enrollment application

If you add or change an interpreting physician, you must report on a Form CMS-855B change request. A new interpreting physician must meet all the necessary credentialing requirements at the time any tests were performed.

## Requirements for an IDTF Technician

An IDTF technician must:

- 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
- Be qualified to perform the types of tests (codes) the IDTF listed in the enrollment application

If you add or change a technician, you must report this on a Form CMS-855B change request. A new technician must meet all the necessary credentialing requirements at the time any tests were performed.

## Performance Standards for IDTFs

As part of its enrollment application, an IDTF must complete Attachment 2 Independent Diagnostic Testing Facilities of [Medicare Enrollment Application-Clinics/Group Practices and Other Suppliers \(CMS-855B\)](#). This attachment lists the Independent Diagnostic Testing Facilities Performance Standards, which 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).



## IDTF Requirements

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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. Report changes in ownership, changes of location, changes in general supervision, and adverse legal actions to the MAC on the 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.
3. 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 U.S. Postal Service (USPS) recognizes.
  - The physical facility, including mobile units, must contain space for equipment appropriate to the 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.
4. 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. 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 can't use call forwarding or an answering service as their primary method of getting calls from patients 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. 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. Also, the IDTF must:
  - Make sure the insurance policy always remains in force and provides coverage of at least \$300,000 per incident
  - Notify the CMS-designated MAC in writing of any policy changes or cancellations

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's 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 [42 CFR 410.32\(a\)\(3\)](#).
8. 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:
  - The name, address, telephone number, and MBI of the patient
  - 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 of the person making the decision not to investigate and the reason for the decision to not investigate
9. Post these standards openly 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. Maintain and calibrate your testing equipment 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 people performing these services.
13. Have proper medical record storage and be able to retrieve medical records upon request from CMS or the MAC within 2 business days.
14. Permit us, including our agents, or your 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 us and patients 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 provides to a Medicare patient, regardless of whether you perform the service in a mobile or fixed base location.
16. 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](#). That section 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



a person is entitled to have payment made under this title, discharges the liability of such person or any other person to pay for the services. If the IDTF claims that it's supplying 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.

## Indirect IDTFs

Some health care entities have diagnostic tests that don't require patient interaction, which we call "indirect IDTFs," per Section 10.2.2.4 of the [Medicare Program Integrity Manual, Chapter 10](#). Certain IDTFs perform diagnostic services via computer modeling and analytics, or other forms of testing not involving direct patient interaction. The service is often done by a technician who undertakes a computer analysis offsite or at another location where the patient isn't present. The physician then reviews the image to decide the appropriate course of action. These entities generally, though not exclusively, have 2 overriding characteristics:

- The tests don't involve direct patient interaction
- The test involves off-site computer modeling and analytics

## Indirect IDTFs General Description, Exemptions, and Verification

To account for such technological advances in diagnostic testing, we revised 42 CFR 410.33 in the [CY 2022 Physician Fee Schedule final rule](#) so IDTFs that have no patient interaction, treatment, or testing whatsoever at their practice location are wholly **exempt** from the following requirements in 42 CFR 410.33(g):

- The IDTF must have a comprehensive liability insurance policy of at least \$300,000
- The IDTF must answer, document, and maintain documentation of a patient's written clinical complaint at the physical site of the IDTF
- The IDTF must openly post the standards outlined in [42 CFR 410.33\(g\)\(9\)](#) for review by patients and the public

## Billing Issues for IDTFs

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Consistent with 42 CFR 410.32(a), the IDTF supervisory physician, whether or not for a mobile unit, can't 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 do both of the following:

- Provide a consultation or treats the patient for a specific medical problem
- 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 Section 30.2.9 of the [Medicare Claims Processing Manual, Chapter 1](#) for more information.

Section 1877 of the [Social Security Act](#) places limitations on certain physician referrals. MACs will deny claims you submit in violation of Section 1877 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

**Note:** See Indirect IDTF Exemption Section above if you perform all your services without seeing the patient.

Most, but not all, of the current billing codes for these services are 93040, 93224, 93225, 93226, 93270, and 93271. We don'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 decision 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 [Medicare Enrollment Application-Clinics/Group Practices and Other Suppliers \(CMS-855B\)](#). 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

Medicare accepts global billing when the same entity performs both the TC and Modifier 26 and that entity provides both the TC and Modifier 26 within the same PFS payment locality. You may provide the TC and Modifier 26 in different locations if you supply them within the same PFS payment locality.

**Note:** As with all services payable under the PFS, we use the ZIP Code to decide 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, we use the dominant locality to decide the corresponding fee.

If you bill with the global diagnostic test code, report the name, address, and 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 Section 10.2.1 of the [Medicare Claims Processing Manual, Chapter 35](#).

### 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 Section 30.2.9 and Section 40.1 of the Medicare Claims Processing Manual, [Chapter 1](#), and [Chapter 16](#), 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's treating the patient: in other words, the physician who's supplying 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 can't 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 before the performance of the testing and is treating the patient for a specific medical problem. The IDTF can't 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 PFS, the anti-markup payment limitation may apply, depending on whether the performing physician or other supplier meets the sharing practice requirements. For further information in this case, see Section 30.2.9 of the [Medicare Claims Processing Manual, Chapter 1](#).

### Therapeutic Procedures

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

## Place of Service Issues

In [Change Request \(CR\) 7631](#), we advised physicians, providers, and suppliers of the national policy and coding instructions for POS. Consistent OIG findings stress the importance of this national policy. In annual or biennial reports from 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 we establish that, for all services paid under the PFS, with 2 exceptions, 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 for under the PFS and anesthesia services, this rule will apply to the overwhelming majority of PFS services.

Where the face-to-face requirement isn't needed, like 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 supplies the PC portion of the patient's MRI from their office location. So, the physician's claim uses POS code 22 for the PC to show 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 [FAQs Related to Change Request 7631 \(Revised and Clarified Place of Service Coding Instructions\)](#).

## Skilled Nursing Facility (SNF) Residents Requiring Transportation for IDTF Service

We revised both Section 10.3.3 of the [Medicare Benefit Policy Manual, Chapter 10](#) and the Section 30.2.2 of the [Medicare Claims Processing Manual, Chapter 15](#) to clarify that a medically necessary ambulance transport from a 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 Medicare Part B. This applies to patients in a SNF stay not covered by Medicare 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

Section 20.3.1.4 of the [Medicare Claims Processing Manual, Chapter 18](#), regulates that if an IDTF supplies 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 pays for screening mammography, including those that are self-referred, when an IDTF performs them at the IDTF facility.

## IDTFs and Opioid Treatment Programs (OTPs)

The [Opioid Treatment Programs \(OTPs\) Medicare Enrollment](#) page details information on how IDTFs can enroll as Medicare providers within the OTP initiative, including examples of [Medicare Enrollment Application-Clinics/Group Practices and Other Suppliers \(CMS-855B\)](#).

IDTFs should know that to be eligible to enroll as an OTP service provider with Medicare, your program must have current, valid, and full certification by the SAMHSA, and meet all of SAMHSA's criteria, including but not limited to:

- DEA registration
- State licensure
- Accreditation

## Resources

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- [CLIA](#)
- [CLIA Quick Start Guide](#)
- [CLIA Regulations and Federal Register Documents](#)

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