

INDEPENDENT DIAGNOSTIC TESTING FACILITY (IDTF) PERFORMANCE STANDARDS

Below is a list of the performance standards that an IDTF must meet in order to obtain or maintain their Medicare billing privileges. These standards, in their entirety, can be found in 42 C.F.R section 410.33(g).

1. Operate its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.
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 calendar days.
3. 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.
 - (i) 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.
 - (ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient
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 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 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 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.
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 –
 - (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 include, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Non-physician practitioners may order tests as set forth

in §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:

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

- (i) Sharing a practice location with another Medicare enrolled individual or organization.
- (ii) Leasing or subleasing its operations or its practice location to another Medicare enrolled individual or organization.
- (iii) Sharing diagnostic testing equipment using in the initial diagnostic test with another Medicare-enrolled individual or organization.

16. Enrolls 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.

17. Bills 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.