

Independent Diagnostic Testing Facility Standards Do Not Remove – Posted for Patient and Public Review

This facility – called an “independent diagnostic testing facility” or “IDTF” under the Medicare rules – participates in the Medicare program. As such, it is required to post a copy of the Medicare IDTF standards for your review. The language below is quoted directly from the federal regulation 42 C.F.R. § 410.33(g).

The IDTF must certify in its enrollment application that it meets the following standards and related requirements:

1. Operates 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. Any change in enrollment information must be reported to the designated fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change.
3. Maintains a physical facility on an appropriate site. For the purposes of this standard, a post office box or commercial mail box is not considered a physical facility. 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.
4. Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must--
 - (a) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;
 - (b) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request.
 - (c) 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--
 - (a) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.
 - (b) Telephone or toll free telephone numbers 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 nonrelative-owned company and list the serial numbers of any and all diagnostic equipment used by the IDTF, whether the equipment is stationary, in a mobile unit, or at the beneficiary's residence.
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. Nonphysician practitioners may order tests as set forth in Sec. 410.32(a)(3).
8. Answer beneficiaries' questions and respond to their complaints.
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—
 - (a) Be accessible during regular business hours to CMS and beneficiaries; and
 - (b) Maintain a visible sign posting its normal business hours.

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