

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LOS ANGELES INDEPENDENT
DIAGNOSTIC TESTING
FACILITIES' COMPLIANCE WITH
MEDICARE STANDARDS**



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E X E C U T I V E S U M M A R Y

OBJECTIVE

To determine whether Independent Diagnostic Testing Facilities (IDTF) in the Los Angeles area complied with selected Medicare standards requiring IDTFs to be at the locations on file with the Centers for Medicare & Medicaid Services (CMS) and to be open during business hours.

BACKGROUND

IDTFs, a type of Medicare provider, offer diagnostic services and are independent of a physician's office or hospital. Medicare allowed almost \$1 billion for IDTF claims for 2.4 million beneficiaries in 2010. Of this, \$38.7 million was for claims by IDTFs in the Los Angeles area.

IDTF services have historically been vulnerable to abuse. In site visits in 1997, the Office of Inspector General (OIG) found that 20 percent of IDTFs were not at the locations on file with CMS. A 2001 OIG review of IDTF claims projected \$71.5 million in improper Medicare payments. In 2007, CMS reported that it had denied \$163 million in IDTF charges and terminated the Medicare billing privileges of 83 IDTFs in Los Angeles.

To comply with Medicare standards, IDTFs must maintain a physical facility at the location on file with CMS and be open during business hours. IDTFs that do not comply with Medicare standards are subject to a variety of administrative actions, including revocation of their billing privileges.

To determine whether IDTFs in the Los Angeles area were at the locations on file with CMS and were open during business hours, we conducted unannounced site visits to all IDTFs with fixed practice locations. We also determined the amount that Medicare allowed for noncompliant IDTFs.

FINDING

Forty-six of the one hundred thirty-two Los Angeles-area IDTFs failed to comply with selected Medicare standards. Twenty-four IDTFs were not at the locations on file with CMS. Twenty-two IDTFs were not open during business hours. Of the 46 noncompliant IDTFs,

25 submitted claims representing services performed on the same dates that site reviewers visited their locations.

RECOMMENDATIONS

Periodically conduct unannounced site visits to IDTFs. Periodically conducting nationwide unannounced site visits to IDTFs may enable CMS to identify and remove nonoperational IDTFs from the program and potentially reduce erroneous Medicare payments. CMS could focus unannounced site visits on high-risk areas or base them on fraud-risk assessments.

Impose a moratorium on new IDTF enrollments in the Los Angeles area. Given both the current and historical rates of potential fraud among IDTFs in the Los Angeles area, CMS should impose a moratorium on the enrollment of new Los Angeles-area IDTFs in Medicare. A moratorium would prevent new enrollments while CMS develops additional program safeguards for IDTFs in the Los Angeles area.

Take appropriate action against the noncompliant IDTFs identified by our report. Under separate cover, we have referred to CMS the IDTFs that our site visits identified as noncompliant. CMS should investigate these IDTFs and revoke their billing privileges if warranted.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations that it periodically conduct unannounced site visits to IDTFs and that it take appropriate action against the noncompliant IDTFs identified by our report. CMS stated that it anticipates increasing the frequency of unannounced site visits to IDTFs and that it will take appropriate administrative actions against the IDTFs identified in this report.

CMS did not concur with our recommendation to impose a moratorium on new IDTF enrollments in the Los Angeles area. However, CMS stated that it would take our recommendation under strong consideration. We did not make any changes to the report based on CMS's comments.

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OBJECTIVE

To determine whether Independent Diagnostic Testing Facilities (IDTF) in the Los Angeles area complied with selected Medicare standards requiring IDTFs to be at the locations on file with the Centers for Medicare & Medicaid Services (CMS) and to be open during business hours.

BACKGROUND

Medicare covers inpatient and outpatient clinical and diagnostic services. These services can be provided in a number of settings, including physicians' offices, hospitals, and IDTFs. IDTFs, a type of Medicare provider, offer diagnostic services and are independent of a physician's office or hospital.¹ Medicare allowed almost \$1 billion for IDTF claims for 2.4 million beneficiaries in 2010. Medicare allowed \$38.7 million for claims by Los Angeles-area IDTFs in 2010.

Services that may be provided by an IDTF include, but are not limited to, magnetic resonance imaging, ultrasound, x-rays, and sleep studies. Although some IDTF services can be performed remotely, such as pacemaker monitoring, most IDTF services require a patient to be present at a facility.

Historical Vulnerabilities

IDTF services have historically been vulnerable to fraud, waste, and abuse. IDTFs were originally known as Independent Physiological Laboratories (IPL). In 1997, after becoming concerned that IPL services were vulnerable to abuse—in particular, citing a lack of certification requirements and confusion about the type of services that IPLs should provide—CMS issued new standards to address these vulnerabilities.^{2, 3} The new standards modified staffing, certification, and documentation requirements for IPLs. IPLs were also renamed IDTFs to help clarify their function.⁴

Also in 1997, the Office of Inspector General (OIG) conducted site visits to IPLs. In an August 1998 report based on these visits, OIG reported

¹ 42 CFR § 410.33(a)(1).

² 62 Fed. Reg. 59048, 59071–72 (Oct. 31, 1997).

³ 62 Fed. Reg. 59048, 59100–01 (Oct. 31, 1997) (adding 42 CFR § 410.33).

⁴ 62 Fed. Reg. 59048, 59071–72 (Oct. 31, 1997).

that 20 percent of IPLs were not at the locations on file with CMS.⁵ In the report, OIG also projected \$11.6 million in improper payments for IPL services and expressed concerns that the new standards that CMS had issued would not be sufficient to reduce the vulnerabilities that OIG had identified.⁶

Despite the new standards, problems with IDTF services persisted. In a 2001 review of IDTF services, OIG identified claims that were not reasonable, necessary, ordered by a physician, or sufficiently documented and projected \$71.5 million in improper payments.⁷ In 2007, CMS reported that it had denied \$163 million in IDTF charges and terminated Medicare billing privileges for 83 IDTFs in Los Angeles.⁸

In May 2009, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative was launched to increase efforts to reduce Medicare fraud. A collaboration between officials from the Department of Health & Human Services and the Department of Justice, the HEAT initiative builds upon existing programs that combat fraud and identifies new methods to prevent fraud.

Medicare Standards

CMS designed the IDTF standards—most recently updated in 2008—to ensure that IDTFs and their staffs operate in accordance with appropriate business practices. Among other things, these standards require IDTFs to:

- maintain a physical facility,
- be accessible during regular business hours, and
- report any change in location to CMS within 30 days of the change.⁹

⁵ OIG, *Independent Physiological Laboratories: Vulnerabilities Confronting Medicare*, OEI-05-97-00240, August 1998.

⁶ *Ibid.*

⁷ OIG, *Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001*, A-03-03-00002, June 2006.

⁸ CMS testimony before the House Budget Committee, July 17, 2007. Accessed at <http://www.cms.hhs.gov> on October 5, 2009.

⁹ 42 CFR §§ 410.33(g)(2), (g)(3), and (g)(14)(i).

See Appendix A for the 17 Medicare standards for IDTFs.

IDTF Enrollments

An IDTF that wishes to enroll in Medicare must submit an application. The application collects various types of information, including the address at which the IDTF will provide services and the services that it will provide.¹⁰

An applicant must indicate whether it will provide services at a fixed location or whether it will be mobile or portable. A mobile or portable IDTF does not provide services at one fixed location. An applicant must submit a separate application for each IDTF practice location and for each mobile or portable unit.¹¹

Before approving an IDTF's enrollment, CMS reviews the application and conducts an initial site visit. These processes may help to ensure that information on the application is correct and that the applicant complies with all 17 Medicare standards.

Postenrollment Site Visits

According to the *Medicare Program Integrity Manual*, if an existing IDTF requests an expansion of services and if the new services are sufficiently different from those already provided, CMS must conduct a postenrollment site visit.¹² For example, if an IDTF that provides sleep studies submits a request to start providing ultrasound tests, CMS is required to conduct a postenrollment site visit.

In addition, CMS may conduct postenrollment site visits at its discretion.¹³ CMS cites unannounced postenrollment site visits as a successful way to determine whether IDTFs are operational and are at the locations on file with CMS.¹⁴ According to the *Medicare Program Integrity Manual*, when CMS conducts a site visit to verify the operational status of an IDTF, CMS should attempt to make its determination using only an external review of the IDTF. CMS requires

¹⁰ Form CMS-855B. Accessed at <http://www.cms.hhs.gov> on October 13, 2009.

¹¹ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 10, § 4.19.1(C). Accessed at <http://www.cms.hhs.gov> on February 3, 2011.

¹² CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 10, § 4.19.6(C). Accessed at <http://www.cms.hhs.gov> on February 3, 2011.

¹³ 42 CFR § 410.33(g)(14).

¹⁴ Preamble to final rule implementing sections of the Patient Protection and Affordable Care Act of 2010. 76 Fed. Reg. 5862, 5869 (Feb. 2, 2011).

that reviewers document their visits using written observations of the facilities and photographs as appropriate.¹⁵

CMS Administrative Actions

CMS may take the following administrative actions against noncompliant or inactive providers, including IDTFs:

- *Investigation.* CMS investigations may include site visits and interviews with IDTF staff and Medicare beneficiaries, as well as analysis of claims data.
- *Prepayment review.* CMS reviews documentation from providers before deciding whether to pay claims.
- *Payment suspensions.* CMS may immediately suspend some or all payments to an IDTF if there is a credible allegation of fraud against that IDTF.¹⁶
- *Revocation.* CMS may revoke Medicare billing privileges for an IDTF that does not comply with Medicare standards.¹⁷ Medicare should not pay for services provided after the date that a provider's billing privileges are revoked. If CMS determines that a provider is no longer operational, the date of revocation is the date of this determination.¹⁸
- *Deactivation.* CMS may deactivate a provider's billing privileges when an IDTF has not submitted claims for 12 consecutive months.¹⁹ This reduces the risk that the billing privileges associated with that provider's identification number will be used for fraudulent purposes.

Temporary Moratoria

CMS may also reduce the potential for fraud, waste, or abuse among IDTFs by imposing a moratorium on IDTF enrollment. CMS's authority to impose moratoria on specific provider types, specific geographic

¹⁵ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 15, § 20.1. Accessed at <http://www.cms.hhs.gov> on February 22, 2011.

¹⁶ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 8, § 8.3.1.1. Accessed at <http://www.cms.hhs.gov> on August 16, 2011.

¹⁷ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 15, § 15.27.2(A). Accessed at <http://www.cms.hhs.gov> on January 31, 2011. See also 42 CFR § 424.535(a)(1).

¹⁸ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 15, § 15.27.2(B). Accessed at <http://www.cms.hhs.gov> on January 31, 2011. See also 42 CFR § 424.535(g).

¹⁹ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 15, § 15.27.1. Accessed at <http://www.cms.hhs.gov> on January 31, 2011. See also 42 CFR § 424.540(a).

areas, or both was established by the Patient Protection and Affordable Care Act and implemented in 2011.²⁰

Related Work

OIG is conducting a concurrent analysis of national IDTF claims data. This analysis identifies areas with high utilization of services provided by IDTFs, compares the patterns of IDTFs in these areas with the patterns of IDTFs nationally, and identifies IDTF claims with unusual characteristics.

OIG also completed a companion report assessing IDTFs in the Miami area, *Miami Independent Diagnostic Testing Facilities' Compliance With Medicare Standards* (OEI-05-09-00560).

METHODOLOGY

We performed unannounced site visits in May and June 2010 to all IDTFs with fixed practice locations in the Los Angeles–Long Beach–Glendale, CA Core Based Statistical Area (Los Angeles area). We determined whether these IDTFs complied with selected Medicare standards requiring IDTFs to be at the locations on file with CMS and to be open during business hours. See Appendix B for a detailed description of our methodology.

Scope

We focused our review on IDTFs with fixed practice locations because it was not feasible to locate mobile or portable IDTFs for unannounced site visits. Mobile or portable IDTFs do not provide services at one fixed location.

We focused on IDTFs in the Los Angeles area because this area has a high concentration of IDTFs compared to other areas of the country.

We focused on IDTF standards 3 and 14, which require an IDTF to maintain a physical facility and to be accessible during regular posted business hours to CMS and beneficiaries.²¹ We focused on these

²⁰ The Patient Protection and Affordable Care Act, P.L. 111-148, § 6401(a)(3) (adding section 1866(j)(6) of the Social Security Act, which was redesignated as section 1866(j)(7) by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, § 1304). Implementing regulations for moratoria on newly enrolling Medicare providers and

suppliers are located at 42 CFR § 424.570.

²¹ 42 CFR §§ 410.33(g)(3) and (g)(14).

standards to limit our interaction with IDTF staff and reduce the risk of alerting staff at potentially fraudulent IDTFs to our presence.

Finally, we focused this report on the results of our site visits. In a companion report—*Miami Independent Diagnostic Testing Facilities' Compliance With Medicare Standards* (OEI-05-09-00560)—we include the results of a Miami-based special project and describe CMS actions against noncompliant IDTFs in that area. Because there was no special project in the Los Angeles area, a similar review was outside the scope of this report.

Data Sources and Data Collection

Identifying IDTF locations. To identify IDTF locations for our Los Angeles-area site visits, we first used the 2009 Part B National Claims History (NCH) file to identify IDTFs that submitted claims in 2009 for practice locations in the Los Angeles area. We then located addresses for all 149 IDTFs with fixed practice locations through the Provider Enrollment, Chain, and Ownership System and a data request to CMS.

Site visits to IDTFs. We conducted unannounced site visits in May and June 2010 to determine whether these IDTFs maintained a physical facility at the location on file with CMS and were open during business hours. We recorded all observations using a standard form.

Updates after site visits. To account for any changes in our information between the time when we identified our study population and the dates of our site visits, we requested address updates and changes in enrollment status from CMS for all IDTFs that we found to be noncompliant.

Payments to noncompliant IDTFs. We used the 2010 Part B NCH file to determine how much Medicare allowed for services reportedly provided by noncompliant IDTFs.

Analysis

Before analyzing our site visit results, we removed 17 IDTFs from our analysis. Fourteen of these were no longer enrolled in Medicare at the time of our site visits. We categorized three IDTFs as “unable to determine.” Our analysis was performed on the remaining 132 IDTFs.

Determining compliance. We determined compliance with IDTF standards 3 and 14 in the following manner:

I N T R O D U C T I O N

- We determined that an IDTF was at the location on file with CMS if it maintained a physical facility with its name clearly marked somewhere other than a building directory (e.g., a sign on or near the primary entrance to the IDTF).
- We determined that an IDTF was open if it was accessible to CMS and beneficiaries during regular business hours (i.e., the door was unlocked) during either of two visits on separate days.

IDTFs that did not meet at least one standard were considered noncompliant for the purposes of this report.

We aggregated the results of the site visits to determine the numbers of IDTFs that (1) maintained physical facilities at the locations on file with CMS and (2) were open during business hours. We also categorized site reviewers' observations about what was found (e.g., a sign with a different business name) at the locations on file with CMS.

Payments to noncompliant IDTFs. We calculated the total amount that Medicare allowed in 2010 for IDTFs that were not at the locations on file with CMS and for IDTFs that were not open. For each IDTF, we also calculated the amount that Medicare allowed in 2010 following our site visit (i.e., from the date of our last site visit through December 2010). In addition, we determined the number of noncompliant IDTFs that submitted claims representing services provided on the same dates that site reviewers visited their locations and the amount that Medicare allowed for such services.

Limitations

Because we reviewed compliance with only 2 of the 17 Medicare IDTF standards, we may be understating the number of noncompliant IDTFs in the Los Angeles area. IDTFs must meet all 17 standards to be eligible to bill Medicare for services.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

► FINDING

Forty-six of the one hundred thirty-two Los Angeles-area IDTFs failed to comply with selected Medicare standards

Forty-six of the IDTFs in the Los Angeles area were not at the locations on file with CMS or were not open during business hours.

Medicare allowed \$6.2 million for services provided by these IDTFs in 2010, \$2.6 million of which was allowed after our site visits. An additional five IDTFs were open only during the second visits made to their locations. We considered these IDTFs open for the purposes of this review.

Twenty-four IDTFs were not at the locations on file with CMS

After taking into account the IDTFs that submitted address updates to CMS, we found that 24 of the IDTFs that we visited did not maintain a facility at the location on file with CMS. CMS requires all IDTFs to “[m]aintain a physical facility.”²² Medicare allowed \$4 million for these 24 IDTFs in 2010.

As Table 1 shows, when site reviewers visited the locations on file with CMS, they found different businesses, unmarked office suites, and private residences with no indication that IDTFs were located there. In three cases, the street addresses on file with CMS did not exist or the suite numbers on file with CMS did not exist at the given street addresses. See Photo 1 for an example of an empty suite that site reviewers found at the location CMS had on file for one IDTF.

Table 1
Description of
the locations on
file with CMS for
24 noncompliant
IDTFs

What OIG Found at Location on File	
Description	Number
Sign with a different business name	10
Private residence with no sign indicating an IDTF	7
No sign indicating a business name	4
Nonexistent address/suite	3
Total	24

Source: OIG unannounced site visits to IDTFs, May and June 2010.

²² 42 CFR § 410.33(g)(3).

F I N D I N G

Photo 1
There was no
indication that an
IDTF was
operational at this
location.



Source: OIG unannounced site visits to IDTFs, May and June 2010.

Twenty-two IDTFs were not open during business hours

Twenty-two IDTFs maintained a visible sign at the location on file with CMS but were locked during business hours on 2 separate days. CMS requires that each IDTF “[b]e accessible during regular business hours to CMS and beneficiaries” and “[m]aintain a visible sign posting its normal business hours.”²³ Site reviewers visited 15 of the 22 IDTFs during their posted business hours. The remaining seven IDTFs did not have posted business hours and were visited during reasonable business hours (9 a.m. to 5 p.m.). Medicare allowed \$2.2 million for these 22 IDTFs in 2010. See Photo 2 for an example of an IDTF that was not open during business hours.

²³ 42 CFR § 410.33(g)(14).

FINDING

Photo 2
The IDTF's name was posted (name redacted in photo), but the door was locked at each of two visits during regular business hours.



Source: OIG unannounced site visits to IDTFs, May and June 2010.

Five additional IDTFs were locked during business hours on the first day we visited and open on the second day. These IDTFs were considered open for the purposes of this report because they were open on the second visits. However, these IDTFs may have been open on our second visits because they had become aware of our review.

Twenty-five noncompliant IDTFs submitted claims representing services provided on the dates of their site visits

Twenty-five of the noncompliant IDTFs submitted claims representing 259 services performed on the same dates that site reviewers visited their locations. Medicare allowed \$45,000 for 222 of these services. Fourteen of the twenty-five IDTFs that submitted claims were not at the locations on file with CMS, and 11 were not open during business hours.

The services reportedly performed on the same dates as OIG's site visits generally would have required a beneficiary to be physically present. The most common services billed on the dates of OIG's site visit were x-ray services and vascular studies.

Submitting claims representing services provided at a noncompliant location raises suspicion that these services may not have been legitimate. These IDTFs may have changed locations without notifying

F I N D I N G

CMS. However, IDTFs that change locations without notifying CMS within 30 days are no longer compliant with all Medicare standards.



R E C O M M E N D A T I O N S

Forty-six of the one hundred thirty-two IDTFs in the Los Angeles area did not comply with selected Medicare standards. Twenty-four of these noncompliant IDTFs were not found at the locations on file with CMS and 22 were not open during business hours. Twenty-five of these noncompliant IDTFs submitted claims representing services provided on the same dates that OIG site reviewers visited their locations.

This finding indicates that further actions are needed to protect the integrity of the Medicare program and protect beneficiaries from potentially fraudulent IDTFs. Therefore we recommend that CMS:

Periodically conduct unannounced site visits to IDTFs

CMS advocates the use of unannounced postenrollment site visits to determine whether providers are operational. Periodically conducting nationwide unannounced site visits to IDTFs may enable CMS to identify and remove nonoperational IDTFs from the program and potentially reduce erroneous Medicare payments. CMS could focus unannounced site visits on high-risk areas or base them on fraud-risk assessments.

Impose a moratorium on new IDTF enrollments in the Los Angeles area

Given both the current and historical rates of potential fraud among IDTFs in the Los Angeles area, CMS should impose a moratorium on the enrollment of new Los Angeles-area IDTFs in Medicare. A moratorium would prevent new enrollments while CMS develops additional program safeguards for IDTFs in the Los Angeles area, such as more frequent in-depth reviews of IDTFs. Because services provided by IDTFs are also available at physicians' offices and hospitals, an enrollment moratorium on IDTFs is unlikely to have a negative impact on beneficiaries' access to these services.

Take appropriate action against the noncompliant IDTFs identified by this report

Under separate cover, we have referred to CMS the IDTFs that our site visits identified as noncompliant. CMS should investigate these IDTFs and revoke their billing privileges if warranted.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations that it periodically conduct unannounced site visits to IDTFs and that it take appropriate action against the noncompliant IDTFs identified by our report. CMS stated that it anticipates increasing the frequency of unannounced site visits to IDTFs. CMS plans to compare IDTF enrollment information with public records to identify potential changes to enrollment information that would warrant further investigation. CMS stated that it will take appropriate administrative actions against the IDTFs identified in this report.

CMS did not concur with our recommendation to impose a moratorium on new IDTF enrollments in the Los Angeles area. However, CMS stated that it would take our recommendation under strong consideration and that it will assess Medicare beneficiary access to IDTF services prior to imposing a moratorium.

We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix C.

Independent Diagnostic Testing Facility Standards²⁴

The [independent diagnostic testing facility (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. 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 days.
- (3) Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mailbox, 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 privacy accommodations.
- (4) Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—
 - (i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;
 - (ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a [Centers for Medicare & Medicaid Services (CMS)] inspection request.

²⁴ These standards are taken verbatim from 42 CFR § 410.33(g).

(iii) 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—

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) 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. 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 [...] 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[s], 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 [42 CFR] § 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—

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from 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; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

A P P E N D I X ~ A

(16) Enrolls 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 [Social Security] Act.

Detailed Methodology

We conducted unannounced site visits to all Independent Diagnostic Testing Facilities (IDTF) with fixed practice locations in the Los Angeles–Long Beach–Glendale, CA Core Based Statistical Area (Los Angeles CBSA) to determine whether they complied with selected Medicare standards. Specifically, we determined whether each IDTF was at the location on file with the Centers for Medicare & Medicaid Services (CMS) and was open during business hours. We then determined how much money Medicare allowed for services reportedly provided by these IDTFs in 2010.

Scope

We focused our review on IDTFs that submitted claims for Medicare payment in 2009 to concentrate our visits on IDTFs with recent activity in the Medicare program. At the time we developed our study population, data on claims from 2009 were the most recent available.

Data Sources and Data Collection

Identifying IDTF locations. We identified IDTFs that submitted claims in 2009 using the specialty code and provider identification numbers (provider ID) fields in the 2009 Part B National Claims History (NCH) file. We counted each provider ID that had only claims with the specialty code 47 as an IDTF. We determined the CBSA to which each IDTF belonged by matching the ZIP Code field from the NCH with the ZIP Codes corresponding to each CBSA. We then selected the IDTFs in the Los Angeles CBSA.

We located an address for each IDTF in the Los Angeles CBSA with a fixed practice location using a combination of two sources. Our primary source was the practice location field from the Provider Enrollment, Chain, and Ownership System (PECOS).²⁵ Most, but not all, IDTFs have enrollment information, such as their practice location, stored in PECOS.²⁶ When an IDTF did not have an address in PECOS, we

²⁵ PECOS is the system of record for Medicare provider enrollment information. PECOS is populated based on the initial provider enrollment application and updated any time a provider submits an updated application to CMS.

²⁶ An IDTF that enrolled before 2004 and has not submitted an updated application may not have an enrollment record in PECOS.

requested this information from CMS. This process resulted in addresses for 149 IDTFs in the Los Angeles CBSA.²⁷

Site visits to IDTFs. We conducted unannounced site visits to these 149 IDTFs to determine whether they were at the locations on file with CMS and were open during business hours. We recorded all observations using a standard form. We conducted all site visits from May 3 through May 11 and on June 4, 2010.

We designed our site visit protocol to ensure that we gave providers the benefit of the doubt when determining whether they complied with Medicare standards. For example:

- All visits to IDTFs were made during posted business hours if hours were posted or during reasonable business hours (9 a.m. to 5 p.m.) if none were posted.
- If an IDTF was locked, we made a second visit to that location on a different day. We considered IDTFs to be open if they were open on either the first visit or (if applicable) the second visit.
- When the building at an IDTF's location on file with CMS was a multisuite office building, site reviewers searched for the IDTF by name as well as by suite number. We considered the IDTF to be at the location on file with CMS if site reviewers could find it in any suite or office space in the building.
- If an IDTF had a sign posted indicating that visitors should ring a buzzer or doorbell to enter the facility, site reviewers did so. If the door was opened (e.g., someone came to the door or the lock was released), we considered the IDTF to be open.
- If an IDTF had a sign posted indicating that services were available by appointment only, a site reviewer attempted to make an appointment for services with that IDTF (e.g., called the phone number listed on the sign). If the site reviewer was able to make an appointment, we considered the IDTF to be open.
- If we found a different business name at the IDTF location on file with CMS, we attempted to determine whether the IDTF we

²⁷ Two IDTFs submitted claims in 2009 using more than one provider ID. We have collapsed claims for these provider IDs, reporting on each of these as unique locations rather than as unique provider IDs.

were looking for was operating under the name we found. First, we requested from CMS all names for IDTFs that we did not find and reviewed this information to ensure that we captured all possible aliases. Second, as a final check, we reviewed public Web sites, including the National Provider Identifier registry, to determine whether the IDTF we were looking for could be operating under the name we found. If we were able to connect the two names, we categorized the IDTF as being at the location on file with CMS.

Analysis

Updates after site visits. CMS indicated that seven IDTFs had their billing privileges deactivated and seven IDTFs had their billing privileges revoked before the dates of our site visits. We removed these 14 IDTFs from our analysis.

IDTFs categorized as “unable to determine.” We removed three IDTFs from our analysis because we were unable to complete the full site visit protocol or were unable to access the door of the reported practice location.

▶ A P P E N D I X ~ C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 26 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D. /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Los Angeles Independent Diagnostic Testing Facilities' Compliance with Medicare Standards" (OEI-05-09-00561)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled, "Los Angeles Independent Diagnostic Testing Facilities' Compliance with Medicare Standards." The purpose of this report is to determine whether Independent Diagnostic Testing Facilities (IDTFs) in the Los Angeles area complied with selected Medicare standards requiring IDTFs to be at the location on file with CMS and open during business hours.

IDTFs offer diagnostic services and are independent of a physician's office or hospital. According to OIG's report, Medicare paid almost \$1 billion for IDTF claims for 2.4 million beneficiaries in 2010. Of this, \$38.7 million was for claims by IDTFs in the Los Angeles area. Medicare standards indicate that IDTFs must maintain a physical facility at the location on file with CMS and be open during business hours. IDTFs that do not comply with Medicare standards are subject to a variety of administrative actions, including revocation of their billing privileges.

The Affordable Care Act strengthens the focus on the integrity of the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) programs and provides important new tools to combat fraud and abuse, including enhanced provider and supplier screening requirements; authority to suspend payments pending investigations of credible allegations of fraud; and, when necessary, authority to impose moratoria on new providers and suppliers.

IDTF services have historically been vulnerable to abuse. As such, CMS is taking additional steps to address potential vulnerabilities in the enrollment and claims payment process for this supplier group using the authorities granted under the Affordable Care Act. Under the new

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screening provisions of CMS 6028-FC¹ all IDTFs are considered a moderate risk provider/supplier and are therefore subject to unannounced site visits. CMS will also consider imposing a moratorium in the Los Angeles area for new IDTF enrollments. We appreciate OIG's efforts in working with CMS to help ensure that IDTFs do not continue to be vulnerable to abuse. Our response to each of the OIG recommendations follows.

OIG Recommendation

The CMS should periodically conduct unannounced site visits to IDTFs.

CMS Response

The CMS concurs with this recommendation. CMS and its contractors currently conduct unannounced site visits to IDTFs during the initial enrollment and revalidation process. These site visits will continue under the new screening provisions of CMS 6028-FC² as IDTFs are considered a moderate risk provider/supplier.

The CMS anticipates increasing the frequency of unannounced, out-of-cycle site visits of IDTFs. Historically, these types of site visits focused on projects confined to certain small geographical areas. Although not specifically required by CMS-6028-FC, CMS will soon begin to systematically screen enrollment data with public source data on a quarterly basis to identify potential changes to enrollment information that would warrant further investigation. CMS anticipates that this automated screening may indicate whether a site visit is warranted to determine if the IDTF remains operational. To assist in this effort, CMS is currently soliciting a contractor to conduct site verifications (other than durable medical equipment, prosthetics, orthotics, and supplies) on a national scale.

OIG Recommendation

The CMS should impose a moratorium on new IDTF enrollments in the Los Angeles area.

CMS Response

The CMS does not concur with this recommendation at this time; however, CMS will take OIG's recommendation under strong consideration. CMS is considering appropriate criteria for potential enrollment moratoria for a number of locations, including Los Angeles. CMS is required to publish a fully-developed rationale for any moratorium in the *Federal Register*. However, CMS is willing to work with OIG on developing the underlying detailed data to support a possible moratorium or moratoria.

¹ CMS 6028-FC entitled, "Medicare, Medicaid and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers" was published in the *Federal Register* on February 2, 2011.

² CMS 6028-FC entitled, "Medicare, Medicaid and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers" was published in the *Federal Register* on February 2, 2011.

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Prior to imposing a moratorium, CMS will assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium will apply. In addition, CMS is also developing a communication network whereby states can demonstrate their compliance with a recommended moratorium or their need for a waiver due to access to care issues.

OIG Recommendation

The CMS should take appropriate action against the noncompliant IDTFs identified by our report.

CMS Response

The CMS concurs with this recommendation. Upon receiving a listing of the IDTFs identified by OIG, CMS will take the appropriate administrative action. Please note that CMS and its contractors regularly review enrollment information and will take the steps necessary to address the issues brought forth by OIG.

Again, we appreciate the opportunity to comment on this draft report and look forward to working with OIG on this and other issues.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

Laura Kordish served as the team leader for this study, and Lisa Minich and Mara Werner served as lead analysts.

We would also like to acknowledge the contributions of Office of Evaluation and Inspections central and regional offices. Contributing staff from these offices include Loul Alvarez, Melissa Baker, Jenell Clarke, Berivan Demir Neubert, Ben Dieterich, Kevin Farber, Anne Gavin, Robert Gibbons, Veronica Gonzalez, Michael Henry, Nicole Hrycyk, Pat Jackson, Christina Lester, Abby Lopez, Kevin Manley, Kevin McAloon, Beth McDowell, Linda Min, Brian Pattison, Megan Ruhnke, Talisha Searcy, Alicia Simon, Mark Stiglitz, Roman Strakovsky, China Tantameng, Jesse Valente, and Marcia Wong.

Office of Inspector General

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