Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MIAMI INDEPENDENT DIAGNOSTIC TESTING FACILITIES' COMPLIANCE WITH MEDICARE STANDARDS

Daniel R. Levinson
Inspector General

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EXECUTIVE SUMMARY

OBJECTIVES

1. To determine whether Independent Diagnostic Testing Facilities (IDTF) in the Miami 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.
2. To describe CMS actions against IDTFs that did not comply with these standards.

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, $23.4 million was for claims by IDTFs in the Miami 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.

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 Miami 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 and reviewed documentation about CMS actions against noncompliant IDTFs.

FINDINGS

Twenty-seven of the ninety-two Miami-area IDTFs failed to comply with selected Medicare standards. Twenty-three IDTFs were not at the locations on file with CMS. Four IDTFs were not open during business hours. Of the 27 noncompliant IDTFs, 14 submitted claims representing services performed on the same dates that site reviewers visited their locations.

CMS took action against most of the noncompliant IDTFs as a result of a special enrollment project and routine oversight. CMS took action against 23 of the 27 noncompliant IDTFs in the months after we completed our site visits. A special enrollment project resulted in 13 actions against noncompliant IDTFs, and routine oversight resulted in 10 actions against noncompliant IDTFs.

Three IDTFs against which CMS took action received Medicare payments while CMS was revoking their billing privileges. Medicare continued to pay 3 of the 12 noncompliant IDTFs while the revocations of their billing privileges were being finalized. CMS took an average of 17 weeks to remove these three IDTFs from Medicare. Between the time when CMS determined that they were noncompliant and the time when the revocations were finalized, Medicare allowed $146,000 for claims submitted by these IDTFs.

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.

Immediately stop payments to noncompliant IDTFs whose billing privileges are being revoked. CMS should immediately stop payments to noncompliant IDTFs as soon as there is enough evidence to begin the revocation process. Currently, CMS may continue to pay providers between the time when they are determined to be noncompliant and the time when their revocations are finalized. These payments should be retroactively recouped; however, previous OIG work demonstrates that many Medicare overpayments are not recovered. If CMS immediately stops payments while concurrently pursuing appropriate action against noncompliant IDTFs, it will help avoid loss of Medicare funds.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations. CMS stated that it anticipates increasing the frequency of unannounced site visits to IDTFs. CMS also stated that it is exploring options to use payment suspensions in conjunction with revocation actions for providers and suppliers that are found to be nonoperational. We did not make any changes to the report based on CMS's comments.

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OBJECTIVES

1. To determine whether Independent Diagnostic Testing Facilities (IDTF) in the Miami 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.
2. To describe CMS actions against IDTFs that did not comply with these standards.

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 $23.4 million for claims by Miami-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]

[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).

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 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 and 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

[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 Oct. 5, 2009.

- report any change in location to CMS within 30 days of the change.[9]

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*

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

[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).

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 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 of a provider's revocation. 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.

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[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).

South Florida High Risk Enrollment Project

Concurrently with our review, CMS conducted a special project—the South Florida High Risk Enrollment Project—that targeted fraud among specific provider types that are vulnerable to abuse. As part of the project, CMS conducted site visits to all IDTFs in South Florida to verify their existence.

CMS used the results of these site visits, along with other information, to create a fraud-risk score for each IDTF. IDTFs with high fraud-risk scores could be subject to a variety of administrative actions. In some cases, CMS used evidence from the site visits to take action against noncompliant IDTFs.

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 Los Angeles area, *Los Angeles Independent Diagnostic Testing Facilities' Compliance With Medicare Standards* (OEI-05-09-00561).

METHODOLOGY

We performed unannounced site visits in May 2010 to all IDTFs with fixed practice locations in the Miami–Miami Beach–Kendall, FL Core Based Statistical Area (Miami 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. We also reviewed documentation about CMS actions against noncompliant IDTFs. 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 Miami area because this area was highlighted by concurrent OIG work as having–in comparison to other

areas in the country–both a high concentration of IDTFs and a high proportion of IDTFs with unusual billing patterns.

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.[20] We focused on these standards to limit our interaction with IDTF staff and reduce the risk of alerting staff at potentially fraudulent IDTFs to our presence.

Data Sources and Data Collection

Identifying IDTF locations. To identify IDTF locations for our Miami-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 Miami area. We then located addresses for all 107 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 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.

CMS actions against noncompliant IDTFs. To describe CMS actions against noncompliant IDTFs following our site visits, we requested the results of the special enrollment project through December 2010. Along with these results, we received data about routine actions taken by CMS through December 2010 for these noncompliant IDTFs.

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 15 IDTFs from our analysis. Eleven of these were no longer enrolled in Medicare at the

[20] 42 CFR §§ 410.33(g)(3) and (g)(14).

time of our site visits. We categorized four IDTFs as "unable to determine." Our analysis was performed on the remaining 92 IDTFs.

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

- 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 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.

Review of CMS actions against noncompliant IDTFs. We reviewed CMS actions against the noncompliant IDTFs identified by our site visits. We determined for how many IDTFs CMS took each type of action (e.g., prepayment review) and whether the actions resulted from the special enrollment project or from routine oversight. We aggregated these results to determine the number of noncompliant IDTFs that CMS took action against after our site visits, as well as the number of noncompliant IDTFs that had been subject to each type of action.

Further, we calculated the amount of time that CMS took to implement each revocation and determined whether the IDTF continued to receive

Medicare payments during the process. Revocation was the only CMS action for which we completed this analysis because it is the only one for which we had relevant data. To calculate how long CMS took to implement the revocation, we compared the date that CMS determined the IDTF was not compliant and the date that CMS finalized the revocation. We then calculated the amount that Medicare allowed for claims representing services provided by the IDTFs between these dates.

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 Miami 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.

Twenty-seven of the ninety-two Miami-area IDTFs failed to comply with selected Medicare standards

Twenty-seven of the IDTFs in the Miami area were not at the locations on file with CMS or were not open during business hours. Medicare allowed $2.6 million for services provided by these IDTFs in 2010, $1.5 million of which was allowed after our site visits. An additional two IDTFs were open only during the second visits made to their locations. We considered these IDTFs open for the purposes of this review.

Twenty-three 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 23 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."[21] Medicare allowed $2 million for these 23 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 four 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 store front 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 23 noncompliant IDTFs

What OIG Found at Location on File	
Description	**Number**
Sign with a different business name	9
No sign indicating a business name	6
Nonexistent address/suite	4
Private residence with no sign indicating an IDTF	4
Total	**23**

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

[21] 42 CFR § 410.33(g)(3).

Photo 1
No name was posted to indicate that an IDTF was operational at this location.

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

Four IDTFs were not open during business hours

Four 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."[22] Site reviewers visited three of the four IDTFs during their posted business hours. The remaining IDTF did not have posted business hours and was visited during reasonable business hours (9 a.m. to 5 p.m.). Medicare allowed almost $600,000 for these four IDTFs in 2010.

Two 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.

[22] 42 CFR § 410.33(g)(14).

Fourteen noncompliant IDTFs submitted claims representing services provided on the dates of their site visits

Fourteen of the noncompliant IDTFs submitted claims representing 138 services performed on the same dates that site reviewers visited their locations. Medicare allowed $16,000 for 102 of these services. Eleven of the fourteen IDTFs that submitted claims were not at the locations on file with CMS, and three 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 lung 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 CMS. However, IDTFs that change locations without notifying CMS within 30 days are no longer compliant with all Medicare standards.

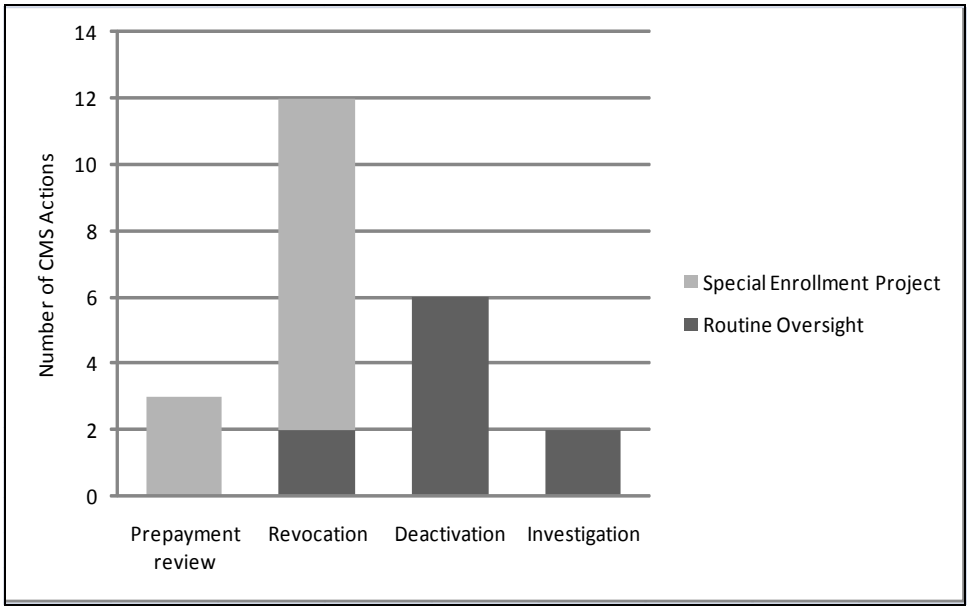
CMS took action against most of the noncompliant IDTFs as a result of a special enrollment project and routine oversight

CMS took action against 23 of the 27 noncompliant IDTFs in the months after we completed our site visits. These actions included investigation, prepayment review, revocation of billing privileges, and deactivation of billing privileges. More than half of these actions were because of the special enrollment project. The rest were because of routine oversight that applies to all Medicare providers. See Chart 1 for the actions CMS took against noncompliant IDTFs identified by this report.

The special enrollment project resulted in actions against 13 noncompliant IDTFs

As a result of the special enrollment project, CMS revoked the billing privileges of 10 noncompliant IDTFs and monitored 3 others with prepayment review. During the project, CMS conducted site visits to Medicare providers in South Florida, including IDTFs. As a result of this project, CMS took action against 13 noncompliant IDTFs that may not have been identified through routine oversight.

Chart 1
CMS actions against noncompliant IDTFs



Source: CMS actions against IDTFs, May 2010.

Routine CMS oversight resulted in 10 actions against noncompliant IDTFs

CMS revoked the billing privileges of two IDTFs, deactivated the billing privileges of six IDTFs, and investigated two others as a result of routine oversight. CMS revoked the billing privileges of two providers that submitted updated applications, but did not pass the application review. CMS deactivated the billing privileges of six IDTFs that had not submitted claims in the previous 12 months. In addition, CMS investigated two IDTFs.

CMS took no actions against four noncompliant IDTFs

CMS determined that no action was needed for the remaining four noncompliant IDTFs. After the OIG site visits, CMS visited these four IDTFs as part of the special enrollment project and found them to be operational.

Three IDTFs against which CMS took action received Medicare payments while CMS was revoking their billing privileges

Medicare continued to pay 3 of the 12 IDTFs while the revocations of their billing privileges were being finalized.[23] CMS took an average of 17 weeks to finalize these three revocations.

Between the time when CMS determined that these three IDTFs were noncompliant and the time when the revocations were finalized, Medicare allowed $146,000 for claims representing services provided by these IDTFs. Most of this amount was for a single IDTF whose billing privileges were revoked 6 months after CMS determined that the IDTF was noncompliant. Medicare allowed $145,000 for 883 services for this IDTF in that time period.

The remaining two IDTFs were allowed just over $1,000 for claims submitted while the revocations were being finalized. One of these IDTFs received frequent payments for low-cost services. This IDTF was paid for 199 services over 14 weeks while the revocation was processed. The other IDTF was paid for two services over 12 weeks while the revocation was processed.

[23] CMS revoked the billing privileges of 12 IDTFs. Ten revocations were based on special enrollment project site visits and two were based on routine oversight.

RECOMMENDATIONS

Twenty-seven of the ninety-two IDTFs in the Miami area did not comply with selected Medicare standards. Twenty-three of these noncompliant IDTFs were not found at the locations on file with CMS and four were not open during business hours. Fourteen of these noncompliant IDTFs submitted claims representing services provided on the same dates that OIG site reviewers visited their locations.

CMS also identified noncompliant IDTFs in the Miami area and was able to remove or monitor many of them. CMS actions included revocation of billing privileges, deactivation of billing privileges, prepayment review, and investigation. Three of the IDTFs continued to receive payments while their billing privileges were being revoked.

These findings indicate 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.

Immediately stop payments to noncompliant IDTFs whose billing privileges are being revoked

CMS should stop payments for any services delivered on or after the dates that CMS identified the IDTFs as noncompliant. Currently, CMS may continue to pay providers between the time when they are determined to be noncompliant and the time when the revocations of their billing privileges are finalized. These payments should be retroactively recouped; however, previous OIG work demonstrates that many Medicare overpayments are not recovered.[24] If CMS immediately stops payments while concurrently pursuing appropriate actions against noncompliant IDTFs, it will help avoid loss of Medicare funds.

[24] OIG, *Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors*, OEI-03-08-00030, May 2010.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations. In response to our first recommendation, 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. In response to our second recommendation, CMS stated that it is exploring options to use payment suspensions in conjunction with revocation actions for providers and suppliers that are found to be nonoperational. 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 Standards[25]

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.

[25] 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.

(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.

APPENDIX ~ B

Detailed Methodology

We conducted unannounced site visits to all Independent Diagnostic Testing Facilities (IDTF) with fixed practice locations in the Miami–Miami Beach–Kendall, FL Core Based Statistical Area (Miami 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 reviewed documentation about CMS actions against the noncompliant IDTFs and 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 Miami CBSA.

We located an address for each IDTF in the Miami 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).[26] Most, but not all, IDTFs have enrollment information, such as their practice locations, stored in PECOS.[27] When an IDTF did not have an address in PECOS, we

[26] 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.

[27] 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 107 IDTFs in the Miami CBSA.[28]

Site visits to IDTFs. We conducted unannounced site visits to these 107 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 17 through May 28, 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 were looking for was operating under the name we found. First,

[28] One IDTF with claims in 2009 was not identified either by PECOS supplier type or by CMS as being an IDTF. We removed this IDTF from our analysis.

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.

CMS actions against noncompliant IDTFs. Data received from the South Florida High Risk Enrollment Project (special enrollment project) through December 2010 included:

- administrative actions taken against noncompliant IDTFs, the source of these actions (i.e., special enrollment project activity or routine oversight), the effective dates of these actions, and the dates these actions were finalized by CMS; and
- dates and results of all special enrollment project site verification visits and in-depth investigations.

Analysis

Updates after site visits. CMS indicated that nine IDTFs had their billing privileges deactivated and two IDTFs had their billing privileges revoked before the dates of our site visits. We removed these 11 IDTFs from our analysis.

IDTFs categorized as "unable to determine." We removed four 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.

APPENDIX - C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 2 6 2011

TO: Daniel R. Levinson
Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: "Miami Independent Diagnostic Testing Facilities' Compliance with Medicare Standards" (OEI-05-09-00560)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled, "Miami Independent Diagnostic Testing Facilities' Compliance with Medicare Standards." The purpose of this report is two-fold. First, it seeks to determine whether Independent Diagnostic Testing Facilities (IDTFs) in the Miami area complied with selected Medicare standards requiring IDTFs to be at the location on file with CMS and open during business hours. Secondly, it describes CMS actions against IDTFs that did not comply with these selected Medicare standards.

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, $23.4 million was for claims by IDTFs in the Miami 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

screening provisions of CMS 6028-FC[1] all IDTFs are considered a moderate risk provider/supplier and are therefore subject to unannounced site visits. CMS is also exploring options to use payment suspensions in conjunction with revocation actions for providers/suppliers determined to be non-operational. 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. This process will continue under new screening provisions of CMS 6028-FC[2] as IDTFs are considered a moderate risk provider/supplier.

The CMS anticipates increasing the frequency of unannounced, out-of-cycle site visits of IDTFs. These types of site visits were historically completed based upon focused 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 immediately stop payments to noncompliant IDTFs whose billing privileges are being revoked.

CMS Response

The CMS concurs with this recommendation. CMS stops payment based upon the effective date of the revocation action. The effective date of the revocation is determined by the reason(s) for which the revocation action is initiated as outlined in Title 42 § 424.535. In addition, CMS is currently exploring options to use payment suspensions in conjunction with revocation actions for providers/suppliers determined to be non-operational.

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[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.

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

ACKNOWLEDGMENTS

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

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