



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 30 2006

TO: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson *Daniel R. Levinson*
Inspector General

SUBJECT: Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001 (A-03-03-00002)

The attached final report provides the results of our review of claims billed by independent diagnostic testing facilities (IDTFs) for services provided to Medicare beneficiaries during calendar year (CY) 2001. This review was requested by the Centers for Medicare & Medicaid Services (CMS) Miami satellite division of the Atlanta regional office.

Our objectives were to determine whether:

- services that IDTFs provided to Medicare beneficiaries with 100 or fewer services during CY 2001 were (1) reasonable and necessary; (2) ordered by a physician; and (3) sufficiently documented in accordance with Federal laws, regulations, and guidelines and
- IDTFs operated in accordance with their initial enrollment applications and subsequent updates filed with the carriers.

Services that IDTFs provided to Medicare beneficiaries were not always reasonable and necessary, ordered by a physician, or sufficiently documented. Of the 230 sampled beneficiaries, who received 1,804 IDTF services, 80 beneficiaries received 1,231 services that did not comply with applicable Federal laws, regulations, and guidelines. Ninety-four IDTFs received \$164,839 in improper payments for these services.

We found a marked pattern of repetitive use of services. Fifty-five of the sampled beneficiaries accounted for 1,095 of the 1,231 questioned services. These beneficiaries received their services from IDTFs in California and Florida.

Based on our sample, we estimate that IDTFs enrolled with 10 selected carriers received \$71.5 million in Medicare payments during CY 2001 for services that did not comply with Federal laws, regulations, and guidelines.

IDTFs also did not always comply with initial enrollment application and subsequent update requirements. Of the 219 IDTFs that provided services to the sampled beneficiaries, 191 did not comply with these requirements. IDTFs did not report operational changes such as the identity and number of technicians, supervising and interpreting physicians, type and model number of equipment, and tests performed. IDTFs also failed to report changes in their ownership and location.

We recommend that CMS require its carriers to:

- recover the \$164,839 in overpayments that we identified;
- perform follow-up reviews to identify and recover a potential \$71.5 million in improper payments made to IDTFs by the 10 selected carriers, in particular those in California and Florida; and
- consider performing site visits to monitor compliance with IDTFs' initial enrollment applications and subsequent updates should funding become available.

In its comments on our draft report, CMS agreed with the first two recommendations subject to verification of the overpayments by the Medicare contractors and other conditions. Specifically, CMS stated that it would recover Medicare overpayments if the overpayment amount is greater than the cost to Medicare of making the recovery and if the recovery can be made within the applicable statute of limitations. CMS requested that we furnish the data necessary to initiate its review and recovery of the potential \$71.5 million in improper payments. With respect to the third recommendation, CMS stated that, because of funding limitations, it was not able to require Medicare carriers to conduct site visits to monitor IDTF compliance.

We will provide CMS with the data necessary to initiate its review and recovery effort. While we continue to believe that onsite visits are a useful tool to ensure that only legitimate IDTFs are enrolled in the Medicare program, we recognize that funding limitations may preclude the carriers from performing such visits. Accordingly, we have modified our third recommendation to acknowledge those funding limitations.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at george.reeb@oig.hhs.gov. Please refer to report number A-03-03-00002 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF CLAIMS BILLED BY
INDEPENDENT DIAGNOSTIC
TESTING FACILITIES FOR
SERVICES PROVIDED TO
MEDICARE BENEFICIARIES
DURING CALENDAR YEAR 2001**



Daniel R. Levinson
Inspector General

June 2006
A-03-03-00002

Office of Inspector General

<http://oig.hhs.gov>

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EXECUTIVE SUMMARY

BACKGROUND

This review was requested by the Centers for Medicare & Medicaid Services (CMS) Miami satellite division of the Atlanta regional office. A program safeguard contractor reviewed the services in the sample.

Medicare

Title XVIII of the Social Security Act, as amended, established Medicare as a national health insurance program for people age 65 or older, certain people under age 65 with disabilities, and people with end-stage renal disease. CMS administers the Medicare program.

Independent Diagnostic Testing Facilities

An independent diagnostic testing facility (IDTF) is an entity independent of a hospital or physician's office in which licensed or certified nonphysician personnel (technicians) perform diagnostic tests under physician supervision. Medicare requires that IDTF services be reasonable and necessary, ordered by a physician, and sufficiently documented. During the audit period, calendar year (CY) 2001, Medicare also required enrolled IDTFs to report any change in personnel, equipment, tests performed, ownership, or location to the Medicare carrier within 30 days of the change.

OBJECTIVES

Our objectives were to determine whether:

- services that IDTFs provided to Medicare beneficiaries with 100 or fewer services during CY 2001 were (1) reasonable and necessary; (2) ordered by a physician; and (3) sufficiently documented in accordance with Federal laws, regulations, and guidelines and
- IDTFs operated in accordance with their initial enrollment applications and subsequent updates filed with the carriers.

SUMMARY OF FINDINGS

Services Did Not Comply With Applicable Federal Reimbursement Requirements

Services that IDTFs provided to Medicare beneficiaries were not always reasonable and necessary, ordered by a physician, or sufficiently documented. Of the 230 sampled beneficiaries, who received 1,804 IDTF services, 80 beneficiaries received 1,231 services that did not comply with applicable Federal laws, regulations, and guidelines. Ninety-four IDTFs received \$164,839 in improper payments for these services.

The questioned services included:

- 546 services, totaling \$75,720, that were not reasonable and necessary;
- 544 services, totaling \$69,717, that were not sufficiently documented;
- 102 services, totaling \$12,137, that were provided pursuant to orders identifying physicians who denied knowing the beneficiaries or ordering the services; and
- 39 services, totaling \$7,265, that were unallowable for other reasons.

We also found a marked pattern of repetitive use of services. Fifty-five of the sampled beneficiaries accounted for 1,095 of the 1,231 questioned services. These beneficiaries received their services from IDTFs in California and Florida.

Based on our sample, we estimate that IDTFs enrolled with 10 selected carriers received \$71.5 million in Medicare payments during CY 2001 for services that did not comply with Federal laws, regulations, and guidelines.

Facilities Did Not Report Operational Changes

Of the 219 IDTFs that provided services to the sampled beneficiaries, 191 did not comply with initial enrollment application and subsequent update requirements. IDTFs did not report operational changes such as the identity and number of technicians, supervising and interpreting physicians, type and model number of equipment, and tests performed. IDTFs also failed to report changes in their ownership and location.

CMS required carriers to perform site visits and verify information included in the IDTFs' applications before issuing a provider number. However, CMS did not require carriers to conduct periodic follow-up visits to determine whether IDTFs were continuing to operate in accordance with Federal regulations. IDTFs may have taken advantage of the lack of monitoring to modify their operations without the knowledge or approval of the carriers and contrary to Federal regulations and guidance.

RECOMMENDATIONS

We recommend that CMS require its carriers to:

- recover the \$164,839 in overpayments that we identified;
- perform follow-up reviews to identify and recover a potential \$71.5 million in improper payments made to IDTFs by the 10 selected carriers, in particular those in California and Florida; and
- consider performing site visits to monitor compliance with IDTFs' initial enrollment applications and subsequent updates should funding become available.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its comments on our draft report, CMS agreed with the first two recommendations subject to verification of the overpayments by the Medicare contractors and other conditions. Specifically, CMS stated that it would recover Medicare overpayments if the overpayment amount is greater than the cost to Medicare of making the recovery and if the recovery can be made within the applicable statute of limitations. CMS requested that we furnish the data necessary to initiate its review and recovery of the potential \$71.5 million in improper payments. With respect to the third recommendation, CMS stated that, because of funding limitations, it was not able to require Medicare carriers to conduct site visits to monitor IDTF compliance.

CMS's comments are included as Appendix C.

OFFICE OF INSPECTOR GENERAL RESPONSE

We will provide CMS with the data necessary to initiate its review and recovery effort. While we continue to believe that onsite visits are a useful tool to ensure that only legitimate IDTFs are enrolled in the Medicare program, we recognize that funding limitations may preclude carriers from performing such visits. Accordingly, we have modified our third recommendation to acknowledge those funding limitations.

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INTRODUCTION

BACKGROUND

This review was requested by the Centers for Medicare & Medicaid Services (CMS) Miami satellite division of the Atlanta regional office.

Medicare

Title XVIII of the Social Security Act (the Act), as amended, established Medicare as a national health insurance program for people age 65 or older, certain people under age 65 with disabilities, and people with end-stage renal disease. CMS administers the Medicare program.

Independent Diagnostic Testing Facilities

The independent physiological laboratory (IPL) program existed prior to the establishment of independent diagnostic testing facilities (IDTFs). In August 1998, the Office of Inspector General issued two reports about vulnerabilities in the IPL program that the new IDTF category was intended to address. The first report, “Independent Physiological Laboratories: Vulnerabilities Confronting Medicare” (OEI-05-97-00240), stated that:

- One out of five IPLs may not have existed.
- Discrepancies existed regarding reported patient-doctor relationships.
- IPLs did not appear to meet the definition of operating independently.

The second report, “Independent Physiological Laboratories: Carrier Perspectives” (OEI-05-97-00241), identified carrier concerns about IPL vulnerabilities, including:

- billing for services not rendered,
- falsifying physician orders or providing no physician orders for testing performed,
- misrepresenting patient diagnoses to obtain improper coverage of services,
- offering kickbacks to physicians for the referral of patients, and
- overutilization.

In 1997, to address problems with IPLs, CMS established a new provider category, IDTFs, which replaced the IPL program by 1999. Specifically, CMS defined an IDTF as a “new entity independent of a hospital or physician’s office in which diagnostic tests are performed by licensed, certified, non-physician personnel under appropriate physician supervision . . . a fixed location, a mobile entity, or an individual non-physician practitioner” (62 Federal Register 59071, October 31, 1997). Regulations (42 CFR § 410.33) established the requirements for IDTF participation in Federal health care programs.

During our audit period, calendar year (CY) 2001, prospective IDTF providers submitted enrollment applications (Form HCFA 855) that required detailed information, including personnel, equipment, tests performed, ownership, and location. Once enrolled, IDTFs were approved only for the operations described on their applications. Applicants were required to report all operational changes to the carrier within 30 days. (See application, pages 1 and 10 (certification statement), and Program Memorandum B-98-45.) Regarding supervising physicians, the program memorandum stated that “The basic requirement is that all the supervisory physician functions be properly met at each location, regardless of the number of physicians involved.”

Medicare Carrier and Program Safeguard Contractor Responsibilities

According to Chapter 10, section 5, of the “Medicare Program Integrity Manual,” the Medicare carriers’ monitoring functions for IDTFs include:

- receiving the enrollment application,
- verifying and validating the information on the application,
- performing site visits prior to approving the application, and
- processing claims for IDTF services.

The carriers also perform medical reviews of IDTFs, and the program safeguard contractors (PSCs) perform certain program integrity functions, such as medical reviews for benefit integrity purposes and fraud detection and prevention.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether:

- services that IDTFs provided to Medicare beneficiaries with 100 or fewer services during CY 2001 were (1) reasonable and necessary; (2) ordered by a physician; and (3) sufficiently documented in accordance with Federal laws, regulations, and guidelines and
- IDTFs operated in accordance with their initial enrollment applications and subsequent updates filed with the carriers.

Scope

We audited a stratified random sample drawn from a population of 682,950 beneficiaries who received 1,742,984 IDTF services paid by 10 Medicare carriers. (See Appendix A.) We selected the 10 carriers that paid the highest amount for IDTF claims during the audit period. The 10 carriers paid \$274,799,317 for IDTF claims during CY 2001, 63 percent of total Medicare payments to IDTFs.

We divided the population of 682,950 beneficiaries with 100 or fewer services into 2 strata:¹

- stratum 1: beneficiaries with 25 or fewer services and
- stratum 2: beneficiaries with 26 to 100 services.

We reviewed all services that IDTFs provided during CY 2001 to each sampled beneficiary in strata 1 and 2 to determine whether the services were reasonable, necessary, and allowable in accordance with applicable Federal laws, regulations, and guidelines. The sample for the 2 strata consisted of 230 Medicare beneficiaries who received 1,804 paid services totaling \$254,659. A total of 303 physicians ordered the services, and 219 IDTFs provided them.

We did not perform a detailed review of the internal controls at the carrier or IDTF level. We limited our review of internal controls to obtaining an understanding of how IDTFs operated.

Because we did not randomly select carriers, we cannot project our findings to the larger universe of carriers. We did, however, project the results of our review to the universe of IDTF payments that the 10 selected carriers made during CY 2001.

We conducted fieldwork at certain IDTFs and at the offices of certain physicians who ordered services for beneficiaries reviewed. We requested information from the IDTFs and ordering physicians that we did not visit. We also requested information from the 10 carriers.

Methodology

To accomplish our objectives, we:

- reviewed applicable Federal laws, regulations, and guidelines, including carrier program memorandums and local medical review policies;
- obtained detailed claims information for CY 2001 IDTF services in our sample and each sampled beneficiary's Common Working File history for Medicare-paid service(s) 6 months before and 6 months after the date(s) of service;
- requested a copy of each beneficiary's medical record from the ordering physician for the period 6 months before and 6 months after the date(s) of service;
- requested the medical records from IDTFs for the services included in the sample;
- developed, with the assistance of CMS and the PSC, an error matrix to catalog findings and improper payments;

¹Beneficiaries with more than 100 services during CY 2001 are the subject of another audit.

- used the PSC to perform medical reviews of the services in the sample;
- extrapolated to our sampling frame the improper payments for services that were not reasonable and necessary, not ordered by a physician, or not sufficiently documented, but did not include in the extrapolation services related to operational changes;
- interviewed IDTF officials, supervising physicians, and ordering physicians;
- obtained from the 10 selected carriers copies of IDTFs' initial enrollment applications and subsequent updates; and
- compared the information that IDTFs submitted to the carriers on their initial enrollment applications and subsequent updates with IDTFs' current operational information obtained from the 10 selected carriers.

See Appendix A for details of the sampling methodology and Appendix B for the sample results and projections.

We performed our review in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Eighty sampled beneficiaries received 1,231 services totaling \$164,839 from IDTFs that did not comply with applicable Federal laws, regulations, and guidelines. Based on these sample results, we estimate that the 10 selected carriers made improper Medicare payments of \$71.5 million to IDTFs in CY 2001.

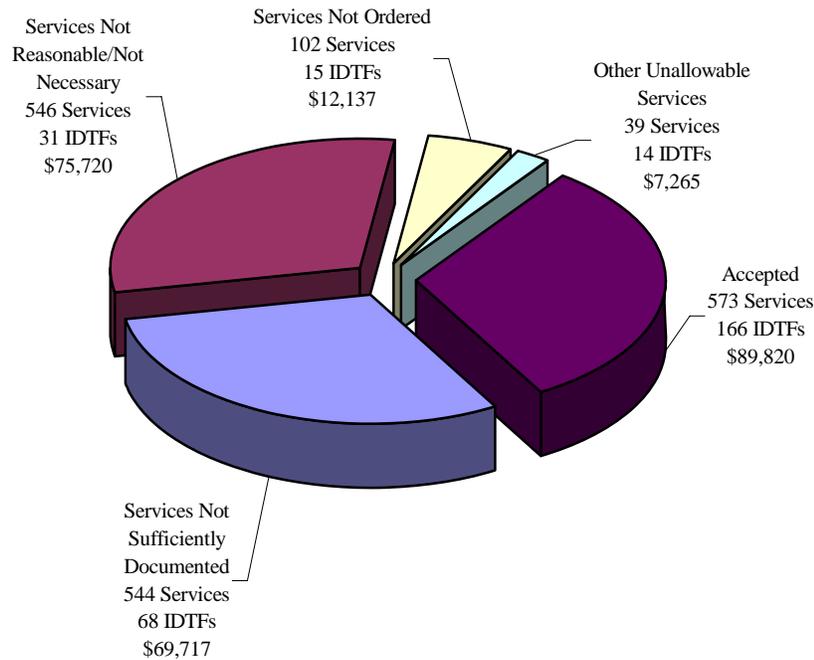
In addition, 191 IDTFs did not comply with Federal regulations or with CMS program memorandums covering the setup, enrollment, and physician supervision requirements of the initial enrollment applications and subsequent updates.

NONCOMPLIANCE WITH APPLICABLE FEDERAL REIMBURSEMENT REQUIREMENTS

Of the 230 sampled beneficiaries, who received 1,804 IDTF services totaling \$254,659, 80 beneficiaries received 1,231 services that did not comply with Federal laws, regulations, and guidelines. Ninety-four IDTFs received \$164,839 in improper payments for these services.

Chart 1 shows that IDTFs received improper payments for services that were not reasonable and necessary, services performed without sufficient documentation, services performed without the knowledge of treating physicians, and services that were unallowable for various other reasons.

Chart 1: Results of Review²



We also found a marked pattern of repetitive use of services. Fifty-five of the sampled beneficiaries accounted for 1,095 of the 1,231 questioned services. These beneficiaries received their services from IDTFs located in California and Florida.

Services Not Reasonable and Necessary

Sampled beneficiaries received 546 IDTF services, totaling \$75,720, that were not reasonable and necessary. IDTFs that provided these services did not comply with section 1862(a)(1)(A) of the Act, which states that no payment may be made for items or services “which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

For example, 1 beneficiary in southern California received 96 services comprising 27 different diagnostic tests ordered by 18 physicians and billed by 16 separate IDTFs. Medicare paid a total of \$12,068 for the 96 services. We questioned 84 of these services, including 50 services as not reasonable and necessary because they were performed at a higher than expected frequency and because the medical record contained no indication of management or coordination of care, such as followup by the ordering physician.

²Some IDTFs in our sample provided multiple services determined to be unallowable for multiple reasons. Therefore, the chart reflects more IDTFs than the number reviewed.

Services Not Sufficiently Documented

Sampled beneficiaries received 544 IDTF services, totaling \$69,717, that lacked sufficient documentation to determine whether the services billed were reasonable and necessary, were ordered by a physician, or complied with other Federal requirements. IDTFs did not provide sufficient documentation for 58 of the 544 services, the ordering physician did not provide sufficient documentation for 437 services, and neither the IDTF nor the physician provided sufficient documentation for 49 services. Without sufficient documentation, it was impossible to determine whether the services met the requirements of the governing laws and regulations, including those for diagnosis and treatment as specified in section 1862(a)(1)(A) of the Act.

For example, 3 IDTFs in southern California received a total of \$3,126 for 11 services provided to 1 beneficiary, including 3 electrocardiograms, 3 ultrasounds, 2 allergy tests, 1 sleep test, and 2 neurology tests. Neither the IDTFs nor the ordering physician produced medical record documentation for the services.

Services Not Ordered

Sampled beneficiaries received 102 IDTF services, totaling \$12,137, for which the physicians whose names appeared on the orders denied knowing the beneficiaries, furnishing consultation or treatment, or ordering the services. Performing services without a valid order from a physician violates the requirements of 42 CFR § 410.33(d).

For example, an IDTF in southern California received \$1,703 in improper payments for two allergy tests provided to one beneficiary in June 2001. In response to our request for information about the services, the physician on record as ordering the tests wrote: "I have not seen this patient in my office since 02/17/2001. Furthermore, I have no recollection of referring this patient for allergy testing."

Other Unallowable Services

Sampled beneficiaries received 39 IDTF services, totaling \$7,265, that were questioned for various reasons, such as duplicate payments and noncovered transportation and screening services.

California and Florida Carriers

We found a marked pattern of repetitive use of services in California and Florida. (See the table.) IDTFs paid by carriers in California had the highest number of unallowable services in all categories. The sample included 66 beneficiaries from California served by 66 IDTFs. California had 998 services for 39 beneficiaries questioned out of a total of 1,132 services. The questioned services included 483 services that were not reasonable and necessary, 418 services that were not sufficiently documented, 71 services that were not ordered, and 26 services that were unallowable for other reasons. The 39 beneficiaries in California accounted for \$141,999 of the \$164,839 questioned.

Although the pattern was not as striking, IDTFs paid by the Florida carrier likewise indicated a repetitive use of services. The sample included 52 beneficiaries from Florida served by 61 IDTFs. Florida had 97 services for 16 beneficiaries questioned out of a total of 255 services, far fewer than California. Most of these questioned services fell within 2 categories: 54 services that were not sufficiently documented and 31 services for which the physicians whose names appeared on the orders denied knowing the beneficiaries or ordering the tests. We also questioned five services that were not reasonable and necessary and seven services for other reasons.

Repetitive Use of Services

	Beneficiaries	IDTFs	Services	Questioned Services	Questioned Costs
California (2 carriers)	66	66	1,132	998	\$141,999
Florida (1 carrier)	52	61	255	97	\$9,282
Total	118	127	1,387	1,095	\$151,281
10 carriers	230	219	1,804	1,231	\$164,839
Percent	51	58	77	89	92

IDTFs paid by carriers in California and Florida provided all 102 services in our sample for which the ordering physicians denied ordering the services. Together, the IDTFs in California and Florida accounted for roughly half of the sampled beneficiaries. Fifty-five of those beneficiaries received 89 percent of the questioned services, for which the three carriers made 92 percent of the improper payments.

Total Estimated Improper Payments

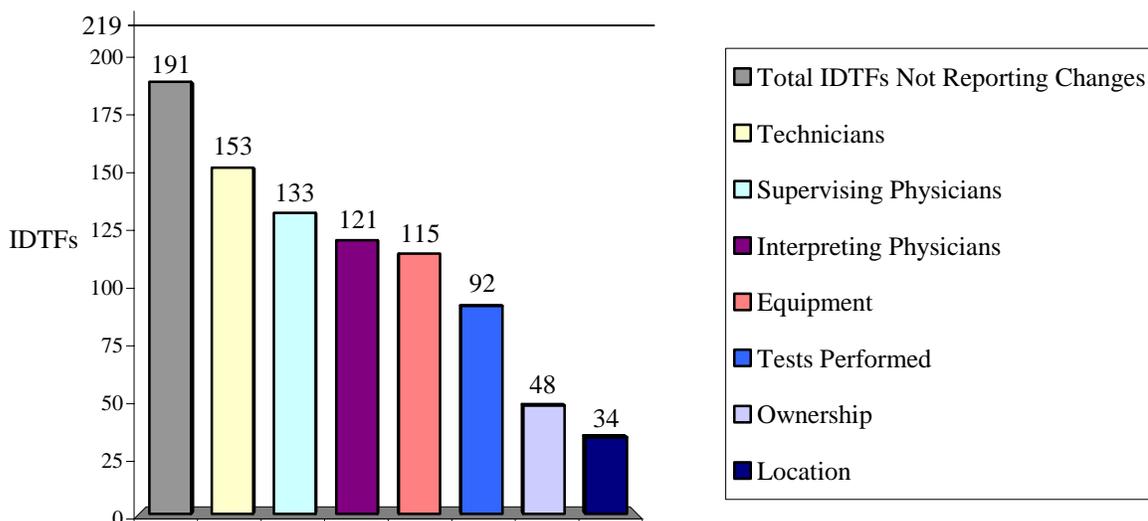
Based on our sample, we estimate that IDTFs enrolled with the 10 selected carriers received \$71.5 million in Medicare payments during CY 2001 for services that did not comply with Federal laws, regulations, and guidelines.

FAILURE TO REPORT OPERATIONAL CHANGES

Of the 219 IDTFs that provided services to sampled beneficiaries, 191 did not operate in accordance with their initial Medicare enrollment applications and subsequent updates filed with the carriers. Eighty-six of the noncompliant IDTFs received \$162,381 of the \$164,839 in improper payments.

Chart 2 shows the number of IDTFs that failed to comply with the requirement to report operational changes, such as the identity and number of technicians, supervising and interpreting physicians, type and model number of equipment, tests performed, ownership, and location.

Chart 2: IDTFs Not Reporting Changes³



Facilities Did Not Comply With Initial Enrollment Application and Subsequent Update Requirements

Program Memorandum B-98-45 states that IDTFs must report all operational changes to the carrier within 30 calendar days. Operational changes are defined in the enrollment application. The application in use during our review period stated: “Any changes in the information reported in this application must be reported to the Medicare or other federal health care contractor within 30 calendar days of said change.” The certification page of the application, paragraph 18.2, reiterates that the applicant must “notify the Medicare or other federal health care program contractor of any changes in this form within 30 days of the effective date of the change.” The certification page, paragraph 18.1, states: “I have read the contents of the application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare or other health care program contractor of this fact immediately.”

Of the 219 IDTFs that provided services to sampled beneficiaries, 191, including 86 IDTFs that received improper payments, failed to report operational changes:

- One hundred and fifty-three IDTFs did not report changes in the number or identity of the technicians whom they employed.
- One hundred and thirty-three IDTFs did not report changes in the identity of supervising physicians.

³Some IDTFs in our sample failed to report multiple changes to carriers. Therefore, the chart reflects more IDTFs than the number reviewed.

- One hundred and twenty-one IDTFs did not report changes in the identity of interpreting physicians.
- One hundred and fifteen IDTFs did not report changes in the equipment used to perform diagnostic tests.
- Ninety-two IDTFs did not report changes in the number and/or type of diagnostic testing services provided.
- Forty-eight IDTFs did not report changes in the number of owners with a 5 percent or greater ownership interest, including 10 that did not report changes in ownership to include an ordering physician or a provider.
- Thirty-four IDTFs did not report changes in the location of the practice or number of service sites, including six IDTFs that did not notify the carrier when they closed and an additional six that could not be located to verify their continued existence.

Facilities Did Not Comply With Requirements for Supervising Physicians

IDTFs did not comply with Program Memorandum B-98-45, which specifies the requirements for reporting changes regarding the identity of the supervising physician, or with 42 CFR § 410.33(b)(1), which states that “An IDTF must have one or more supervising physicians who are responsible for the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of non-physician personnel who use the equipment.”

Of the 133 IDTFs that did not report changes in the identity of their supervising physicians, 6 ceased to employ a supervising physician at all. Seventy IDTFs employed supervising physicians who did not perform the duties outlined in the regulations. For example, one physician claimed to have performed his supervisory duties, but his hours worked consisted of interpreting test results from his home. He claimed to have performed his responsibilities for the operation and calibration of equipment based on the quality of the films he interpreted at home. The physician did not conduct oversight or onsite inspection of the equipment but concluded that if the quality of the film was acceptable, the equipment worked properly.

Thirty-four IDTFs employed or contracted with physicians who supervised multiple IDTFs or who were employed or contracted by IDTFs that covered large geographical areas. For example, in addition to being an executive at a major pharmaceutical company, one physician was responsible for a multistate IDTF’s Mid-Atlantic area, including sites in Pennsylvania, New Jersey, Maryland, and Massachusetts.

Facilities' Failure To Report Changes Was Not Detected

CMS required carriers to perform site visits and verify information on providers' applications before issuing provider numbers. However, CMS did not require carriers to conduct periodic follow-up visits to determine whether IDTFs continued to operate in accordance with Federal regulations. IDTFs may have taken advantage of the lack of monitoring to modify their operations without the knowledge or approval of the carriers and contrary to regulations (42 CFR § 410.33) and guidelines.

RECOMMENDATIONS

We recommend that CMS require its carriers to:

- recover the \$164,839 in overpayments that we identified;
- perform follow-up reviews to identify and recover a potential \$71.5 million in improper payments made to IDTFs by the 10 selected carriers, in particular those in California and Florida; and
- consider performing site visits to monitor compliance with IDTFs' initial enrollment applications and subsequent updates should funding become available.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its comments on our draft report, CMS agreed with the first two recommendations subject to verification of the overpayments by the Medicare contractors and other conditions. Specifically, CMS stated that it would recover Medicare overpayments if the overpayment amount is greater than the cost to Medicare of making the recovery and if the recovery can be made within the applicable statute of limitations. CMS requested that we furnish the data necessary to initiate its review and recovery of the potential \$71.5 million in improper payments.

With respect to the third recommendation, CMS agreed that onsite visits were a useful tool to ensure that only legitimate providers and suppliers are enrolled in the Medicare program. However, CMS stated that, because of funding limitations, it was not able to require Medicare carriers to conduct site visits to monitor IDTF compliance. Instead, CMS proposed to establish business standards to help ensure that only qualified, scrupulous IDTFs are enrolled in the Medicare program. CMS also noted several actions taken since the time of our review to address program vulnerabilities, especially related to IDTFs in California and Florida.

CMS's comments are included as Appendix C.

OFFICE OF INSPECTOR GENERAL RESPONSE

We will provide CMS with the data necessary to initiate its review and recovery effort.

We believe that the actions taken or proposed by CMS should help reduce program vulnerabilities and improper payments. While we continue to believe that onsite visits are a useful tool to ensure that only legitimate IDTFs are enrolled in the Medicare program, we recognize that funding limitations may preclude carriers from performing such visits. Accordingly, we have modified our third recommendation to acknowledge those funding limitations.

OTHER MATTER

Although beyond the scope of our audit, we noted that technicians who did not have required licenses or certifications performed 226 services. Federal regulations (42 CFR § 410.33(c)) state that any nonphysician personnel used to perform tests:

. . . must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

APPENDIXES

SAMPLING METHODOLOGY

SAMPLING FRAME

We extracted from the Centers for Medicare & Medicaid Services National Claims History file all independent diagnostic testing facility (IDTF) Medicare services provided in calendar year (CY) 2001. We identified services allowed by the 10 carriers representing the highest allowed amounts for IDTF services:

- Alabama Blue Cross/Blue Shield—Alabama claims,
- Arkansas Blue Cross/Blue Shield—Louisiana claims,
- Empire Blue Shield—New Jersey claims,
- Florida Blue Shield—Florida claims,
- HGSA Administrators—Pennsylvania claims,
- National Heritage—Massachusetts claims,
- National Heritage—northern California claims,
- National Heritage—southern California claims,
- Texas Blue Cross/Blue Shield—Texas claims, and
- Wisconsin Physician Services—Illinois claims.

From this file, we created a file of unique Health Insurance Claim Numbers (i.e., Medicare beneficiaries). The file included the lines of service, allowed amount, and paid amount for each beneficiary. We eliminated those unique beneficiaries with total paid amounts of zero and with more than 100 services.

POPULATION

For the top 10 carriers identified for IDTF services in CY 2001, the sample population consisted of 682,950 beneficiaries with 100 or fewer services. We divided the population into two strata:

- stratum 1: beneficiaries with 25 or fewer lines of service and
- stratum 2: beneficiaries with 26 to 100 lines of service.

SAMPLING UNIT

The sampling unit was an individual beneficiary.

SAMPLE DESIGN

We used a stratified random sample.

SAMPLE SIZE

The populations and sample sizes for the two strata were as follows:

Stratum	Population	Sample Size
1	681,490	200
2	1,460	30

SOURCE OF RANDOM NUMBERS

We used the Office of Inspector General, Office of Audit Services RAT-STATS statistical software package to generate random numbers for each stratum.

METHOD OF SELECTING SAMPLE ITEMS

We numbered the units in each stratum and generated a list of random numbers for each stratum. For each stratum, we selected a unit for review when the random number value equaled the assigned number of the unit.

SAMPLE RESULTS AND PROJECTIONS

SAMPLE RESULTS

The sample results of our review of 230 beneficiaries were as follows:

Stratum	Sample Size	Number of Beneficiaries With Errors	Improper Payments
1	200	51	\$18,905
2	30	29	145,934
Total	230	80	\$164,839

STRATIFIED VARIABLE APPRAISAL PROJECTIONS

- Number of beneficiaries with errors identified in the sample 80
- Value of errors identified in the sample \$164,839
- Point estimate of questioned services \$71,522,525
- Upper limit of questioned services (90-percent confidence level) \$92,808,492
- Lower limit of questioned services (90-percent confidence level) \$50,236,557



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

 Administrator
 Washington, DC 20201

 2006 APR 21 11:09
 OFFICE OF INSPECTOR
 GENERAL

DATE: APR 20 2006

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D., Ph.D. 
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Claims Billed by Independent Diagnostic Testing Facilities For Services Provided to Medicare Beneficiaries During Calendar Year 2001" (A-03-03-00002)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the subject audit report. We would like to thank OIG for its efforts in identifying Independent Diagnostic Testing Facility (IDTF) payment vulnerabilities and improper payments. Since the time of your analysis in California and Florida, we have taken many major actions to address the types of program vulnerabilities identified in this report, especially related to IDTFs in California and Florida where Medicare fraud, waste, and abuse is more prevalent. In particular, the CMS Los Angeles Program Integrity Office has been successful in denying approximately \$69 million in Medicare improper payments to California IDTFs within a 9-month period (April 2005 - December 2005). Further, this initiative contributed to the deactivation/revocation of 77 IDTF billing numbers, the suspension of 2 IDTFs, and the sentinel effect of stopping the billings of 64 IDTFs. We are now taking further steps through business standards to build on the substantial progress in payment accuracy for IDTFs. Such business standards already exist for some Medicare providers like durable medical equipment suppliers. CMS plans to assess those standards already in existence and develop an applicable set of business standards for IDTFs. Establishing these standards on the front-end will help CMS ensure that it is doing business with qualified, scrupulous IDTFs.

By way of background, prior to the establishment of IDTFs, Independent Physiological Laboratory (IPL) programs existed. In 1998, the OIG issued two reports that identified vulnerabilities in the IPL program. In order to address the problems identified with IPLs, CMS established a new provider category, IDTFs. The requirements for IDTF participation in Federal health care programs are outlined in Federal regulations at 42 CFR 410.33.

During this review, OIG audited a stratified random sample drawn from a population of beneficiaries who received IDTF services processed through 10 Medicare carriers. OIG determined that Medicare services to Medicare beneficiaries were not always reasonable and necessary, ordered by a physician, or sufficiently documented. In addition, OIG found a marked pattern of repetitive use of services. These beneficiaries received their services primarily from IDTFs in California and Florida.

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Based on the sample, OIG estimates that IDTFs enrolled with the 10 selected carriers received \$71.5 million in Medicare payments during calendar year 2001 for services that did not comply with Federal laws, regulations, and guidelines. Additionally, OIG found that IDTFs did not always comply with initial enrollment application requirements and subsequent update requirements.

We appreciate the effort that went into this report and the opportunity to review and comment on the issues it raises. CMS looks forward to continued collaboration with OIG to continue to reduce the risk of improper billing. Our response to the recommendations and technical comments on the report follow.

OIG Recommendation

The CMS should require its carriers to recover the \$164,839 in overpayments that OIG identified.

CMS Response

The CMS agrees with the OIG's recommendation that the overpayments (subject to verification by the Medicare contractors) should be recovered as soon as possible. CMS will recover these verified overpayments if the Medicare overpayment amount is greater than the cost to Medicare of making the recovery and if the recovery is able to be made within the applicable statute of limitations.

OIG Recommendation

The CMS should require its carriers to perform follow-up reviews to identify and recover a potential \$71.5 million in improper payments made to IDTFs by the 10 selected carriers, in particular those in California and Florida.

CMS Response

The CMS agrees with the OIG's recommendation that the overpayments (subject to verification) should be recovered. Since the \$71.5 million represents the sum of several recoveries, there may be instances where the cost of recovery would be greater than the amount of the overpayment. Based on CMS' review of this OIG data, CMS will recover identified Medicare overpayments if the overpayment amount is greater than the cost to Medicare of making the recovery and if the recovery is able to be made within the applicable statute of limitations.

The CMS requests that the OIG furnish the data necessary (provider numbers, claims information - including the paid date, HIC numbers, etc.) to initiate this review and recovery effort. In addition, if possible, Medicare contractor-specific data should be written to separate floppy disks or CDs in order to better facilitate the transfer of information to the appropriate Medicare carriers.

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OIG Recommendation

The CMS should require its carriers to perform site visits to monitor compliance with IDTFs' initial enrollment applications and subsequent updates.

CMS Response

The CMS agrees that on-site visits are a useful tool to ensure that only legitimate providers and suppliers are enrolled in the Medicare program. However, given CMS' funding limitations, we are not able to require Medicare carriers to conduct site visits to monitor IDTF compliance.

Given these budget constraints and the risks presented to the Medicare program by fraudulent and/or abusive IDTFs, CMS is instead planning to propose, as discussed above, business standards for IDTFs. These business standards will be based on those standards currently required for other types of Medicare providers, such as durable medical equipment suppliers, and will help ensure that only qualified, scrupulous IDTFs are enrolled in the Medicare program.