

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Independent Physiological Laboratories:
Vulnerabilities Confronting Medicare**



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EXECUTIVE SUMMARY

PURPOSE

To identify program vulnerabilities associated with independent physiological laboratories and explore ways to safeguard the Medicare program from these vulnerabilities.

BACKGROUND

The Health Care Financing Administration (HCFA) defines an independent physiological laboratory (IPL) as an entity operating independent of a hospital, physician's office or rural health clinic. Testing modalities performed by IPLs include, but are not limited to, neurological and neuromuscular tests, echocardiograms, ultrasounds, x-rays, pulmonary function tests, cardiac monitoring and nuclear medicine testing. Initially, Medicare only covered diagnostic tests that were performed by a physician, hospital or other entity certified by the program to perform the test. Beginning January 1979, HCFA decided that diagnostic services performed by IPLs qualified for Medicare reimbursement and began assigning provider numbers to IPLs. To date, Medicare has issued approximately 5,000 unique IPL provider numbers. Nearly \$129 million was paid to IPL providers in 1996.

The data and information presented in this report was gathered from 1996 Medicare claims data, onsite visits, interviews and telephone surveys involving 191 IPLs selected at random. When available, we examined the enrollment applications and supporting enrollment documentation for the IPLs in our sample.

FINDINGS

One Out Of Five IPLs Authorized To Bill Medicare May Not Exist.

We could not find a place of business for 39 of the 191 IPLs in our sample. It is conceivable that some of these IPLs were legitimate businesses that closed during 1996 and before our visits in the spring of 1997. However, in some cases it was clear that no IPL had conducted business at the site we visited for many years. We also question whether 49 other provider numbers should have been assigned to the sites we visited that have no employees or equipment.

The 39 IPLs we could not locate were paid about \$800,000 in 1996 and 13 of them billed carriers in 1997. Projected to the universe of all IPL provider numbers, nearly 1,000 of the 5,000 provider numbers may have been assigned to entities that can no longer be located. We estimate that, in 1996, Medicare could have paid about \$11.6 million to IPLs that can no longer be located. Should a question arise as to the appropriateness of these payments, the Medicare program may not be able to locate these IPLs to resolve questionable claims information.

Many Discrepancies Exist Regarding Patient And Physician Relationships.

Discrepancies between patient and physician zip codes could be an indication that some IPLs are misusing patient or physician identifiers. Forty-three percent of the claims submitted by our sampled IPLs involved beneficiaries whose home zip codes clearly indicate that they and the referring physician resided in different States and in noncontiguous counties. We believe that the distance involved would make it unlikely that the patient and the referring physician have a patient-doctor relationship.

Our analysis also disclosed that 55 IPLs in our sample submitted claims using patient identifying information used by at least one other IPL. In fact, more than 10 percent of their patients were also patients of at least one other IPL. According to claims information, some patients were seen by 15 different IPLs doing business in at least 5 States. The number of patients being seen by multiple IPLs in different States may be demonstrative of a program vulnerability.

Provider Number Proliferation Adds To IPL Vulnerabilities.

Of the 5,000 provider numbers issued to IPLs, we estimate that about 62 percent were not in use in 1996. These inactive numbers, while dormant now, could become active in the future. The more provider numbers that exist, the greater the chances are that their misuse will go undetected. For example, IPLs may obtain multiple provider numbers and use them to evade carrier utilization controls or to "shop" carriers for the greatest Medicare payment.

A Large Number Of IPLs Appear Not To Meet HCFA's Definition Of Operating Independent.

The HCFA defines an IPL as an entity operating independent of a hospital, physician's office or rural health clinic. Seventy-seven out of the 191 IPLs in our sample are owned by, or affiliated with, a hospital, physician or rural health clinic. Three out of four physicians or hospitals that had been given an IPL provider number by the carrier claimed they were not operating an IPL. They claimed that they did not ask for an IPL provider number but were assigned a number by the carrier. We believe that very few of the 77 physician/hospital owned IPLs in our sample are engaged in a business operation independent of their medical practice.

RECOMMENDATIONS

In conducting this study, we took into consideration new regulations affecting IPLs (now designated independent diagnostic testing facilities or IDTFs) that went into effect on January 1, 1998. We believe the new regulations may not adequately address the vulnerabilities described in this report. Therefore, we offer the following options aimed at strengthening program safeguards:

Clearly define the term "operating independent."

Forty percent of the IPLs in our sample were owned by physicians and hospitals. Moreover, three out of four do not consider themselves to be an IPL. They provide diagnostic services primarily to their own patients. Only physicians and hospitals that hold themselves out as providing diagnostic services to the community and who will not be involved in ongoing decisions affecting

the care/treatment of patients referred to them should be enrolled as an IPL/IDTF.

Establish a more stringent enrollment and verification process.

All IPLs currently in the system should be re-enrolled. The HCFA could fund onsite inspections to ensure that IPLs are at the business address they give carriers and that they have the equipment, trained personnel and physician supervision needed to participate in the Medicare program. Carrier personnel should be trained to perform the enrollment, verification and onsite inspections of IPLs/IDTFs. All IPLs/IDTFs could be required to post a surety bond prior to the issuance of a Medicare provider number.

Strengthen the monitoring and control processes.

This monitoring process should require carriers to audit a random sample of claims submitted by IPL/IDTF providers whose billing numbers have been inactive for 90 days or more. The claims sample should be verified by contacting the referring physician or the patient. Providers with no billing activity for more than 12 months should be required to re-enroll before payments are resumed.

Completely reform the payment method.

Another more far reaching option would be to eliminate direct payment to IPLs/IDTFs and pay the ordering physician. The physician would then pay the IPL for services provided to his or her patients. We believe this option would make it significantly more difficult for nonexistent IPL businesses to defraud the program and would eliminate most of the vulnerabilities described in this report.

Moreover, this proposal recognizes the advantages to Medicare when services are bundled into payments to certain providers who are responsible for the overall care of patients. It is analogous to recent payment policy changes involving skilled nursing facilities (SNFs). The new policy requires SNFs to bill Medicare for all services provided to residents in their care and it prohibits payments directly to the subcontracted suppliers.

AGENCY COMMENTS

The HCFA and the Assistant Secretary for Management and Budget (ASMB) commented on this report. The HCFA concurred with three of our four recommendations and plans to strengthen procedures related to IPL/IDTF provider enrollment, verification and monitoring as suggested in this report. They did not agree with our far more reaching recommendation to change the way Medicare pays for IPL services. The Assistant Secretary for Management and Budget concurred, with comment, on all four of our recommendations.

Based on HCFA's and ASMB's comments, we made some changes and clarifications to the report. The complete text of these comments can be found in Appendix A and B, respectively. Our response to their comments begins on page 10 of this report.

We plan to re-examine this area in the future to see if HCFA's new regulations and current course of action reduces Medicare's exposure to the vulnerabilities we have identified in this report.

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INTRODUCTION

PURPOSE

To identify program vulnerabilities associated with independent physiological laboratories and explore ways to safeguard the Medicare program from these vulnerabilities.

BACKGROUND

The Health Care Financing Administration (HCFA) defines an independent physiological laboratory (IPL) as an entity operating independent of a hospital, physician's office or rural health clinic.¹ Testing modalities performed by IPLs include, but are not limited to, neurological and neuromuscular tests, echocardiograms, ultrasounds, x-rays, pulmonary function tests, cardiac monitoring and nuclear medicine testing. Medicare pays an IPL for diagnostic services if: (1) the IPL meets applicable State and local licensure laws, (2) the services are ordered by a physician, and (3) the services are reasonable and medically necessary.²

Initially, Medicare only covered diagnostic tests that were performed by a physician, hospital or other entity certified by the program to perform the test. In January 1979, HCFA determined that IPL services qualified for reimbursement and began enrolling and assigning provider numbers to IPLs.³

Since 1979, the number of IPLs in the Medicare program has steadily increased. In 1987, less than 1,700 IPL provider numbers had been issued.⁴ Today, there are approximately 5,000 numbers, of which 1,100 have been issued by the Railroad Retirement Board (RRB) carrier.⁵ In 1996, the Medicare program paid nearly \$129 million to IPL providers.

During a recent Office of Inspector General inspection of carrier fraud unit cases, we discovered that all of the IPL cases we reviewed involved potentially non-existent providers. A common problem appeared to be unverifiable or false information (e.g. non-existent business addresses) on IPL provider enrollment applications. The case file review also suggested that some IPLs obtained multiple provider numbers to avoid carrier medical necessity and utilization safeguards

¹ "Quality Assurance In Independent Physiological Laboratories," (OEI-03-88-1400), October 1990.

² Medicare Carriers Manual, Section 2070.5 and Section 1862 (a)(1)(A) of the Social Security Act.

³ The Health Care Financing Administration determined that IPL services qualified for reimbursement under Section 1861(s)(3) of Title XVIII of the Social Security Act.

⁴ "Quality Assurance In Independent Physiological Laboratories," (OEI-03-88-01400), October 1990.

⁵ Section 1842(g) of the Social Security Act, as amended, gives the Railroad Retirement Board the authority to separately contract with a carrier to process Medicare Part B claims for railroad retirement beneficiaries.

and to facilitate schemes to defraud Medicare.⁶ Based on problems discovered in our study of carrier fraud units and problems reported in a previously issued OIG report entitled, "Quality Assurance In Independent Physiological Laboratories," we decided to take a closer look at IPLs.

The HCFA and its fiscal agents, the carriers, also recognized problems with IPL providers and have taken steps to address vulnerabilities presented by them. In May 1996, prior to this study, HCFA implemented a new provider enrollment application (HCFA 855) that includes a special attachment for providers enrolling as IPLs. This new enrollment application solicits information about the IPL's actual place of business/practice, testing modalities and ownership. In addition to a new enrollment application, HCFA also formed a work group to review IPL policy and regulations.

On October 31, 1997, HCFA published regulations that may ultimately eliminate the term "IPL." A new entity, independent diagnostic testing facilities (IDTFs), was created as of January 1, 1998. Entities currently participating in the Medicare program as IPLs must meet IDTF enrollment requirements, physician supervision requirements and personnel requirements set forth in the newly published regulations.

METHODOLOGY

The data and information presented in this report was gathered from: (1) 1996 HCFA Part B claims data, (2) onsite visits, interviews and telephone surveys of IPLs, and (3) carrier IPL enrollment applications and supporting documentation.

We requested from HCFA all of the 1996 IPL claims submitted to carriers for payment. The HCFA returned a file containing approximately 1.3 million final action IPL claims and 2.3 million line items. From this file we constructed a unique list of 2,818 IPL provider numbers used to submit claims in 1996. We then selected 191 provider numbers from the 2,818 numbers using simple random sampling. This sample size provides a confidence level of 95 percent with 7 percent precision for estimates. We also accessed HCFA's databases to locate the name and address of physicians who referred patients to each IPL and to identify patient residences.

Each sampled provider number was sent to the carrier identified as having paid all, or most, of its claims. We asked the carriers, including the RRB carrier, to provide the current business address and telephone number for each of our sampled IPLs. In December 1997, we asked some carriers to provide 1997 payment data for some IPLs in our sample.

We analyzed claim payment data and information on all 191 IPLs in our sample. Interviews were conducted with 149 IPLs.⁷ While we analyzed data on all of the IPLs in our sample, we did not visit or contact IPLs under investigation. Carriers were unable to provide identifying information

⁶ "Carrier Fraud Units," (OEI-05-94-00470), November 1996.

⁷ We were unable to interview 42 IPLs (39 could not be located and 3 refused to cooperate). This does not impact the statistical validity of our sample. It is, in itself, considered a finding of this report.

on four providers in the sample. As with IPLs under investigation, we analyzed data on these IPLs but were unable to visit them.

We reviewed all of the claims submitted in 1996 by the 191 IPLs in our random sample. Our claims review looked at the number of claims submitted, distribution of referring physicians, whether the referring physician and patient resided close enough to have a patient-doctor relationship, the types of services billed, number of patients shared with other IPLs, service volume for time in business and nature of procedures being billed to Medicare.

Between July 14, 1997 and September 30, 1997, we visited 139 IPL sites, in 25 States, indicated in the carriers' records as the principle place of business. If the IPL was at the site we conducted an interview. If the IPL was not at the site we left a letter asking them to call us to complete the interview. We attempted to contact by telephone the IPLs we were unable to visit. We also tried to reach, by telephone, all of the IPLs that were not at the place of business we visited. During our interviews, we obtained information regarding: practice locations, ownership structure, business arrangements, testing modalities, licensure, technician credentials, physician supervision and billing arrangements.

Carriers that had assigned the provider numbers to our sample IPLs were also asked to provide copies of the provider enrollment applications. We received copies of 134 provider enrollment applications and supporting documentation. Carriers were unable to furnish the remaining applications for a variety of reasons.

We conducted our inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

One Out Of Five IPLs Authorized To Bill Medicare May Not Exist.

We could not find a place of business for 39 of the 191 IPLs in our sample. Twenty-seven were not at the site indicated in carrier records and we were unable to contact them by telephone. Another 12, not at the site we visited, told us that they had ceased operations or were no longer billing Medicare. It is conceivable that some of these IPLs were legitimate businesses that closed during 1996 and before our visits in the spring of 1997. However, in some cases (including some of the businesses that claimed they recently closed) it was clear that no IPL had conducted business at the site we visited for many years. Our inability to locate these IPLs at the address Medicare has as their place of business may be an indication that they may not exist.

The 39 IPLs we were unable to locate were paid about \$800,000 in 1996. At least 13 of these IPLs billed Medicare in 1997. Projected to the universe of all IPL provider numbers, nearly 1,000 of the 5,000 IPL provider numbers may have been assigned to entities that can no longer be located. Based on our finding, we estimate that, in 1996, Medicare could have paid about \$11.6 million to IPLs that can no longer be located.⁸ Should a question arise as to the appropriateness of these payments, the Medicare program may not be able to locate these IPLs to resolve questionable claims information.

In addition to not being at the site of record, one out of four IPLs could not be reached by telephone. Telephone numbers in carrier files were incorrect, disconnected or not listed with directory assistance. Our inability to reach the IPL or its principals may be an indication that they are not operating businesses.

Some of the IPLs we talked to on the telephone may also not exist. Unaware that we had visited their place of business, a few IPLs in our sample claimed they were doing business at the empty site we had recently visited. Others, aware of our visit, claimed that the sites existed merely to meet Medicare requirements and that no business was actually transacted at the location.

In addition to the 39 IPLs that may no longer exist, we found 49 other IPLs whose business address led us to a physician office, hospital or other medical establishment. At some of these sites, they claimed that our sampled IPL was a truck, van or technician that would come to the site periodically to perform diagnostic services for their patients. They claimed that on the day diagnostic services were being performed, the site was an IPL. In some of these cases, the "IPL" had no equipment or personnel whatsoever, but subcontracted with another IPL to

⁸ At the 90 percent confidence interval the actual amount might lie between \$4.5 million and \$18.7 million.

provide equipment or personnel. We have concerns about the Medicare practice of issuing provider numbers to businesses that have no permanent address or personnel or equipment.

In at least 12 other cases, it was inconclusive as to whether or not we had actually reached, or conducted our survey with, the IPL identified in our sample. In these instances, we believe that we were in contact with the IPL's billing service, a physician's office or another medical establishment. While these entities had knowledge of the IPL, they did not appear to be the principles who completed the enrollment application. At some physician offices, hospitals and other medical establishments, they claimed they were not an IPL and had no knowledge of the IPL in our sample. Some of these sites appear to have been given an IPL provider number for carrier administrative purposes and both the IPL and carrier acknowledge the site is not an IPL. A serious program vulnerability exists when the Medicare program pays entities that cannot be located. The inability to locate IPLs is not necessarily proof of intent to commit fraud, since it may indicate a problem with timely reporting or recording of change of address information. However, the extent of this problem documented in this study raises questions as to the legitimacy of many IPLs.

Many Discrepancies Exist Regarding Patient And Physician Relationships.

We examined the potential misuse of patient health insurance claim numbers by comparing zip codes of our sampled IPLs, their patients and referring physicians. We found that 43 percent of the IPLs submitted claims involving beneficiaries whose home zip codes clearly indicated that they and the referring physician resided in different States. Zip codes that bordered State lines were excluded to accommodate those areas in the country where people might regularly cross State lines to procure goods and services.

The extent of patient-physician zip code discrepancies cannot be attributed entirely to patients who change their residence seasonally. The distance involved would make it unlikely that the patient and the referring physician have a patient-doctor relationship. It appears that, at a minimum, many of these claims would not meet HCFA's current requirement that the ordering physician be the physician who treated the patient.⁹

Our analysis of zip codes also disclosed that 29 percent of IPLs in our sample submitted claims using patient identifying information used by at least one other IPL.¹⁰ In fact, more than 10 percent of their patients were also patients of at least one other IPL. According to claims information, some patients were seen by 15 different IPLs doing business in at least 5 States.

⁹ The November 22, 1996 final rule for the 1997 Physician's Fee Schedule (61 CFR 59490), revised §410.32 to state that, to be covered, diagnostic tests had to be ordered by the physician who treats the patient.

¹⁰ We modeled our analysis after the methodology proposed by Malcolm K. Sparrow in: "License To Steal: Why Fraud Plagues America's Health Care System," Westview Press, 1996.

There are plausible explanations as to why different IPLs provide service to the same beneficiaries, and to explain how the referring physician's practice and the patient's home are hundreds of miles apart. For example, patients may need multiple diagnostic services that can not be provided by a single IPL. In other cases, the billing for the diagnostic service may have been split with one IPL billing for the technical component (the performance of the test) while another bills for the professional component (the interpretation of the test results). The data may also reflect, to some degree, the mobility of today's elderly patients.

However, discrepancies between patient and physician zip codes could also be an indication that Medicare might be vulnerable to IPLs that misuse patient or unique physician identifiers called UPINs that are readily available to the public. The apparent lack of a clear patient-doctor relationship and the extent of patient sharing, particularly across State lines, clearly deserves closer scrutiny.

Provider Number Proliferation Adds To IPL Vulnerabilities.

Another vulnerability is created by the sheer number of provider numbers issued by Medicare carriers. There are at least 5,000 provider numbers assigned to IPLs. Our analysis indicates that 62 percent of these numbers are not being used to bill Medicare. These inactivate provider numbers can be activated at any time. In most cases, an IPL simply has to submit a claim.

The more provider numbers that exist, the greater the chances are that their misuse will go undetected and the easier it becomes to evade carrier utilization controls and program safeguards. For example, it is impossible to compile a complete billing history for an IPL when claims are submitted under a variety of provider numbers to carriers in different States. We found that carriers are often unable to associate or cross-reference numbers being used by the same IPL provider.

The 191 IPLs in our sample hold at least 500 provider numbers in different program specialties used for billing. When IPLs offer portable x-ray services, clinical laboratory services or medical supplies, they are issued a separate provider number for each type of services. Each carrier, including the RRB carrier, issues its own provider numbers; therefore, IPLs doing business in several States have different provider numbers for each State. Physicians who own IPLs also have separate provider numbers for their individual and group medical practice sites. It also appears that separate IPL numbers have been assigned to some physicians billing for the professional component of a diagnostic test performed by an IPL. Virtually all of the problems and vulnerabilities discussed in previous OIG work on provider numbers were found to apply to IPLs.¹¹

¹¹ "Carrier Maintenance of Medicare Provider Numbers," (OEI-06-89-00870), May 1991, and "Carriers Still Need To Purge Unused Provider Numbers," (OEI-01-94-00231), December 1995.

Contributing to potential vulnerabilities associated with excessive provider numbers are the provider numbers generated by the RRB carrier. In the universe of IPL provider numbers in 1996, 23 percent of the numbers were duplicate RRB numbers. While the RRB enrollment application requires the IPL to first obtain and then furnish the RRB with the local Medicare provider number, the RRB does not cross-reference this number in any database. The RRB also does not verify this number with the local carrier other than to check it against the list of providers and persons barred from participating in the Medicare program. Therefore, the number is only retrievable directly from the RRB's enrollment application. To retrieve this information would require an extensive manual search of boxed files. Likewise, the other carriers do not cross-reference their numbers with RRB numbers nor with other local carrier numbers.

A Large Number Of IPLs Appear Not To Meet HCFA's Definition Of Operating Independent.

The HCFA defines an IPL as an entity operating independent of a hospital, physician's office or rural health clinic. In our sample, 77 IPLs (40 percent) indicated that they were owned by physicians, hospitals or rural health clinics. Fifty-nine IPLs are owned, wholly or in part, by a physician or a group of physicians. Eleven are owned wholly, or in part, by a hospital and five are joint ventures involving both hospitals and physicians. Two IPLs appeared to be affiliated with a rural health clinic. The number of IPLs owned wholly, or in part, by physicians represents a 7 percent increase over previous estimates.¹²

Neither regulation or policy defines the meaning of operating independent. Therefore, we could not determine whether ownership, in itself, violates the intent, if not the spirit, of HCFA's policy. Three out of four IPLs owned by physicians or hospitals claimed they were not an IPL. Most of these IPLs provided diagnostic services primarily to their own patients. They do not hold themselves out as providing diagnostic services to the community. They have active medical practices and seemed perplexed as to why their Medicare carrier assigned them another provider number to bill for diagnostic services they provide primarily to their own patients.

Overall, at least 123 of the 187 identifiable IPLs in our sample are affiliated with some other health care provider billing Medicare. These businesses include: durable medical equipment companies, clinical laboratories, pharmacies, hospitals, physician office practices and home health agencies.

¹² "Financial Arrangements Between Physicians and Health Care Businesses, Report to Congress," (OA-12-88-01410), May 1, 1989.

RECOMMENDATIONS

When conducting this inspection, we took into consideration new regulations affecting IPLs (now designated independent diagnostic testing facilities or IDTFs) that went into effect on January 1, 1998. We believe the new regulations may not adequately address the vulnerabilities described in this report; therefore, we offer the following options aimed at strengthening program safeguards:

Clearly define the term "operating independent."

The HCFA should clearly define the term operating independent. Forty percent of the IPLs in our sample were owned by physicians and hospitals. Moreover, three out of four do not consider themselves to be an IPL. They provide diagnostic services primarily to their own patients. Only physicians and hospitals that hold themselves out as providing diagnostic services to the community and who will not be involved in ongoing decisions affecting the care/treatment of patients referred to them should be enrolled as an IPL/IDTF.

Establish a more stringent enrollment and verification process for IPLs/IDTFs this could include the following:

- ▶ an unannounced visit to the IPL/IDTF business site(s) prior to issuing a provider number;
- ▶ provide adequate funding for enrollment and verification processes by either setting aside operating funds or collecting application fees;
- ▶ periodically re-enroll all IPLs/IDTFs in the system using the same procedures used to enroll new providers;
- ▶ verify documentation and information furnished by IPLs/IDTFs through third-party sources;
- ▶ train carrier personnel performing the enrollment, verification and onsite inspections; and,
- ▶ require all IPLs/IDTFs to post a surety bond prior to the issuance of a Medicare provider number.

Strengthen the monitoring and control processes.

- ▶ Require carriers to audit new IPL/IDTF claims before an initial payment is made. A random selection of claims should be validated by contacting the referring physician or the patient. The existence of a patient-physician relationship should also be established during this initial audit;
- ▶ Provide adequate funding for ongoing monitoring activities;
- ▶ Conduct periodic unannounced revisits to IPL/IDTF businesses;
- ▶ Require carriers to flag for claim review IPL/IDTF provider numbers that have not been used for 90 days. Numbers not used for 12 months should be removed from the system and canceled. Those IPLs/IDTFs whose billing numbers have been canceled should be required to re-enroll; and,
- ▶ Take steps to ensure that the carrier servicing the jurisdiction where the beneficiary receives services processes all IPL/IDTF claims.

We recognize that establishing more stringent enrollment and verification processes and strengthening monitoring processes may be resource intensive. We did examine other options that might address the vulnerabilities we found. We believe that the most cost-effective option and administratively simple approach would be to:

Completely reform the payment method.

This option would eliminate direct payment to IPLs/IDTFs and pay only the ordering physician. The physician would be responsible for paying the IPL and any other subcontractors for diagnostic services provided to his or her patients. We believe this option would make it significantly more difficult for nonexistent IPL businesses to defraud the program and would eliminate most of the vulnerabilities described in this report.

Moreover, this proposal recognizes the advantages to Medicare when services are bundled into payments to certain providers who are responsible for the overall care of patients. It is analogous to recent payment policy changes involving skilled nursing facilities (SNFs). This new policy requires SNFs to bill Medicare for all services provided to residents in their care and it prohibits payments directly to the subcontracted suppliers. Our recommended change in IPL/IDTF payment policy would also eliminate vulnerabilities inherent in the split billing option that enables multiple providers to bill for different parts of the same service.

AGENCY COMMENTS

We would like to thank HCFA and the Assistant Secretary for Management and Budget (ASMB) for commenting on the draft of this report. The full text of each agency's comments can be found in Appendix A and B, respectively.

The HCFA concurred with three of our four recommendations and plans to strengthen procedures related to IPL/IDTF provider enrollment, verification and monitoring as suggested in this report. They did not agree with our more far reaching recommendation to change the way Medicare pays for IPL services.

Based on HCFA's comments, we have made changes and clarifications to the report. We simplified our recommendation that HCFA clearly define "operating independent." We recognize that HCFA plans to address this issue but felt that further clarification was needed.

Most of the physicians and hospitals we visited claimed they were not an IPL. We did find some physicians and hospitals that do, in fact, hold themselves out as providing diagnostic services to the community and agree with HCFA that these businesses rightfully should be enrolled as IDTFs.

However, we do oppose assigning IPL provider numbers to physicians, hospitals and rural health clinics that do not hold themselves out to other physicians as an IPL/IDTF. Physicians and hospitals that own their equipment, provide staff (or subcontract for staff) and provide most of their services to their own patients should not be given an IPL/IDTF provider number. Assigning multiple numbers to providers who perform services within the scope of their license or certification greatly increases the risk of inappropriate payments and is administratively burdensome.

Based on HCFA's comments, we eliminated three options and changed the wording of another concerning how to strengthen the monitoring and control processes. Our initial suggestion was that HCFA mandate that the carrier servicing the jurisdiction where the beneficiary resides process all IPL/IDTF claims. We have changed this option to reflect HCFA's position that, "...the locality in which the service is furnished determines carrier jurisdiction...."

The HCFA did not agree with our far more reaching recommendation to reform the IPL payment method. They believe it would make more sense to implement our other recommendations before attempting to reform the payment method.

In response to HCFA's comment we would like to point out that our proposed payment reform does not create a new payment method or a new fee schedule but relies on the physician fee schedule that currently exists to determine Medicare's payment amount for the diagnostic services billed by physicians. While we are not changing our recommendation, we recognize that there may be other payment mechanisms that may be useful in controlling the vulnerabilities described in this report.

The ASMB concurred with our recommendations but expressed concern about the cost effectiveness of establishing more stringent enrollment and verification procedures and strengthening the monitoring processes. The ASMB also wanted to know how our proposal to completely modify the payment method for IPL services would address the potential for physicians to mark-up prices and engage in inappropriate referrals and kickback activities.

We believe that reforming the current payment mechanism would be the most cost-effective way to reduce abuses and resolve problems Medicare has experienced with nonexistent IPLs. The potential for kickbacks would be greatly reduced, if not eliminated, when Medicare pays the ordering physician. Physicians will have little or no incentive to offer kickbacks to subcontractors, since physicians (and not providers whose existence depends on physician referrals) would control the ordering and the funds generated from their orders. Some physicians, currently using IPLs, may increase their use of services. Having all of the claim information about a physician's use of diagnostic services on their billing history greatly enhances carrier ability to identify physicians whose use of diagnostic services differs from that of their peers.

The potential for duplicate payments would be greatly reduced because physicians would be required to bill globally. The physician would be paid for the technical and professional components of any diagnostic test. It would be more difficult to defraud the program. Since all bills would come from the ordering physician the likelihood of billing for services not rendered or misrepresenting services would be significantly reduced. Moreover, it would ensure that the patient and physician have a valid patient-physician relationship. It would enhance Medicare's ability to detect overutilization and to recover overpayments resulting from medically unnecessary services or excessive services. Unlike IPLs, it is more difficult for physicians to simply close up shop and leave Medicare with uncollectible overpayments.

In their technical comments HCFA noted that we have failed to, "... cite a single example of a test that was not actually furnished as billed by an IPL, or that was not medically necessary for the beneficiary who received the service." It is true that we did not determine the medical necessity of IPL services nor did we calculate overpayments based on inappropriate payments. That was not the purpose of our study.

We believe that carriers are already familiar with cases involving unnecessary or undelivered IPL services. The purpose of our study was to identify and better understand the program vulnerabilities associated with IPLs and explore ways to safeguard the Medicare program from these vulnerabilities.

Moreover, we believe there is ample evidence available in our reports to substantiate these problems should HCFA wish to examine the evidence.

Our report entitled *Independent Physiological Laboratories: Carrier Perspectives* (OEI-05-97-00241), provides information from the carriers about IPLs falsifying physician orders, misrepresenting patient diagnosis, double billing, unbundling services, carrier

shopping and over utilizing patient services. They also found non-existent IPLs.

Our analysis indicated that many of the IPLs in our sample might be involved in fraudulent or abusive billing activities and that some IPLs may not exist at all. We advised HCFA of potential problems involving some IPLs in our sample. We then asked our own Office of Investigations (OI) to review the information we had developed on some IPLs. Some of the information we provided to OI was subsequently forwarded to field agents for investigation. Other information will be sent to the Medicare carriers for further development. A decision will then be made whether to undertake a full-scale investigation or pursue administrative actions, such as overpayment determinations and collections.

Our work in this area is continuing. In addition to the investigative and administrative referrals mentioned above, we plan to re-examine this area in the future to see if HCFA's new regulations and current course of action reduces Medicare's exposure to the vulnerabilities we have identified in this report.

APPENDIX A

**Health Care Financing Administration
Comments on the Draft Report**



Memorandum

DATE: JUL 14 1998

TO: June Brown
Inspector General

FROM: Nancy-Ann Min DeParle *NMD*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Reports: "Independent Physiological Laboratories: Vulnerabilities Confronting Medicare" (OEI-05-97-00240) and "Independent Physiological Laboratories: Carrier Perspectives," (OEI-05-97-00241)

We reviewed the draft reports you sent us and have the following comments: The Health Care Financing Administration (HCFA) defines an independent physiological laboratory (IPL) as an entity operating independent of a hospital, physician's office, or rural health clinic. Testing modalities performed by IPLs include, but are not limited to, neurological and neuromuscular tests, echocardiograms, ultrasounds, x-rays, pulmonary function tests, cardiac monitoring, and nuclear medicine testing.

Initially, Medicare only covered diagnostic tests that were performed by a physician, hospital, or other entity certified by the program to perform the test. Beginning January 1979, HCFA decided that diagnostic services performed by IPLs qualified for Medicare reimbursement and began assigning provider numbers to IPLs. To date, Medicare has issued approximately 5,000 unique IPL provider numbers. Nearly \$129 million was paid to IPL providers in 1996. Vulnerabilities associated with this industry have been widely recognized by HCFA and its carriers. Both have taken steps to address the vulnerabilities.

We concur with many of the options presented in recommendations 1, 2, and 3. We do not concur with recommendation 4. Our detailed comments are as follows:

OIG Recommendation 1 (1 recommendation)

Clearly define the term "operating independent" and ensure that only those entities truly operating independently are certified as independent physiological laboratories/independent diagnostic testing facilities (IPLs/IDTFs).

HCFA Response

We concur. Under the new regulations, the term IPL will no longer exist and an IDTF will require an attestation statement with strict standards. Additionally, we are contemplating having an IDTF obtain a surety bond. Therefore, a potential incentive exists for IDTFs to claim that they are not independent. In that regard, a clear definition of independent for IDTFs would be of value. The self-referral prohibitions (Stark Amendments) could affect how an entity may attempt to classify itself. However, at the current time the final regulations concerning this area have not been published.

We have attached a copy of an October 1989 memorandum from the HCFA Philadelphia Regional Office that requested clarification of the term "operates independently" as used in MCM Section 2070.5 and of its application to an IPL owned by a physician. We are also attaching a copy of a January 9, 1990, response to that memorandum from the Director of the former Bureau of Policy Development. The memorandum states in pertinent part:

" . . . The meaning of the word "independent" in this section does not have the usual meaning found in other parts of Medicare manuals. . . .

Thus, it was not our intention to prohibit a physician from owning and operating an IPL. Rather, we were providing Medicare coverage for laboratory services in a setting where coverage would otherwise not be available. Also, the word "independent" in this context means that the service is of a type that can be furnished without physician or hospital supervision.

Therefore, it is possible for a physician to own and operate an IPL that is an adjunct to his or her office practice as long as the IPL meets the coverage criteria found in 2070.5 of the MCM. . . ."

Thus, the term "independent" seems to have been used to describe IPLs as a basis for paying an entity other than a hospital or physician's office for testing other than clinical laboratory testing. Based on the above, we believe it is a questionable finding that IPLs may not be owned by physicians. Since the test involved would be payable under the physician fee schedule in either case, the alleged abuse is unclear. With regard to unclear situations involving hospitals and IPLs, there is unquestionably a possibility of abuse if an intermediary and a carrier may be billed for the same tests. HCFA's Center for Health Plans and Providers is currently developing a Provider Reimbursement Manual section setting forth clear criteria for distinguishing provider-based entities from others, and we believe this issuance will be a great help in sorting out these types of problems. The actual problem involved with the failure of an IPL to operate independent of a rural health clinic is not clear to us since all technical component payments in rural health clinic settings would be payable under the physician fee schedule.

OIG Recommendation 2 (6 recommendations)

Establish a more stringent enrollment and verification process for IPLs/IDTFs.

HCFA Response

1. An unannounced visit to the IPL/IDTF business site(s) prior to issuing a provider number.

We concur. Consistent with monetary constraints, we recommend that a significant percentage of new IDTFs be given an onsite review prior to enrollment.

2. Provide adequate funding for enrollment and verification processes by either setting aside operating funds or collecting operating fees.

We concur on the need for adequate funding for enrollment and verification processes for all provider types, including IPL/IDTFs. With respect to user fees, the Administration is seeking the legislative authority to collect such fees, including fees for enrollment and enumeration purposes, as part of the fiscal year (FY) 1999 budget process.

3. Periodically re-enroll all IPLs in the system using the same procedures used to enroll new providers.

We concur. We are currently developing a proposed regulation to require periodic re-enrollment of all provider types, including IPLs/IDTFs.

4. Verify documentation and information furnished by IPLs/IDTFs through third party sources.

We concur with this recommendation and have encouraged the Medicare contractors to use independent verification sources to the extent that funding allows. Examples of such independent sources are ChoicePoint, Information America, and Dun & Bradstreet. Furthermore, licenses of IPL personnel are required to be reported on attachment 2 of the revised Supplier/Provider Enrollment Form, HCFA-855. Carriers routinely check the required licenses of applicant personnel against state licensing records.

5. Train personnel performing the enrollment, verification and onsite inspection.

We concur. Our carriers ensure that their personnel are trained in these areas, and we monitor their efforts. In the past we have also provided training to the carriers. If carriers are allowed to use contractors to assist them in onsite inspections, we ensure that they are properly trained.

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6. Require all IPL/IDTFs to post a surety bond (just as home health agencies now do) prior to the issuance of a Medicare provider number.

We are considering the feasibility of having IPL/IDTFs post surety bonds for new applicants and current applicants. However, defining the term independent and allowing for the considerable exceptions for providers who perform IDTF services but are exempt from being called an IDTF could be problematic. For example, group practices, multi-specialty clinics, and entities who are not independent of a hospital or physician's office will not be classified as an IDTF. Other provider types such as an ambulatory surgical center which provides some IDTF type services also would not be classified as an IDTF.

OIG Recommendation 3 (8 recommendations)
Strengthen the monitoring and control processes.

HCFA Response

We concur. We did, however, note conflicting information in the report concerning the time period for requiring IPLs/IDTFs to re-enroll. Page 9 indicates that carriers should flag provider numbers that have not been used for 90 days. It then states that numbers that have not been used for 12 months should be canceled and that IPLs/IDTFs with canceled numbers should be required to re-enroll. Paragraph 3 on page iii, however, states that "providers with no billing activity for more than 90 days could also be required to re-enroll before payments are resumed." Cancellation of provider numbers that have not been used for one year seems more reasonable than using a 90-day time frame for this purpose.

1. Require carriers to audit new IPL/IDTF claims before an initial payment is made. A random selection of claims should be validated by contacting the referring physician and/or the patient. The existence of a patient-physician relationship should also be established during the initial audit.

We concur with this recommendation to the extent that the budget allows.

2. Provide adequate funding for ongoing monitoring activities.

We concur.

3. Conduct periodic unannounced re-visits to IPL/IDTF businesses.

We concur.

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4. **Require carriers to flag for claim review IPL/IDTF provider numbers that have not been used for 90 days. Numbers not used for 12 months should be removed from the system and canceled. Those IPLs/IDTFs whose billing numbers have been canceled should be required to re-enroll.**

We concur. HCFA will consider the feasibility of having IPL/IDTF claims flagged and reviewed, if a prior claim has not been submitted within 90 days. We are developing a general Medicare provider enrollment regulation which we expect to provide for the termination of inactive billing numbers for all Medicare providers. The proposed regulation under development will also describe the need for a new enrollment application for IPLs/IDTFs and other providers whose billing numbers are terminated due to inactivity.

5. **Mandate that the carrier servicing the jurisdiction where the beneficiary resides process all IPL/IDTF claims for the services to the beneficiary.**

We do not concur. We believe it is not possible to implement this recommendation without a change in the law. HCFA has consistently taken the position that law and regulations require that physician fee schedule payments be based on the area where the service is provided. Subsection 1848(b)(1) of the Social Security Act states that "the Secretary shall establish . . . payment amounts for all physicians' services furnished in all fee schedule areas. . ." (emphasis added). It is clearly the locality in which the service is furnished that determines carrier jurisdiction and locality fee schedule variations.

6. **Resubmit the legislative proposal to discontinue the use of a separate carrier to process Medicare claims for railroad retirement beneficiaries.**

We do not concur. Dealing with IPL/IDTF claims is only one part of claims processing for a railroad retirement beneficiary. Whether there should be a separate carrier for railroad retirees should be based upon all factors related to processing of their claims.

7. **Create a national clearing house for IPL/IDTF provider numbers.**

We do not concur at this time. Using this method would involve considerable time, cost, and money to obtain contracts and systems changes. We would prefer to wait until we can assess the effects of the other recommended changes before considering this action.

8. **Restrict access to unique physician identifying numbers (UPINs). Confidentiality guidelines used for Social Security numbers should also apply to UPINs. It should be the responsibility of the ordering physician to disclose their UPIN.**

We do not concur. A change of this type would place an additional administrative burden on IDTFs and other providers. Also, its effectiveness would be limited by the fact that UPINs are already widely known. This will be especially impractical when we convert to the National Provider Identifier (NPI) system where it will be hard to control access to NPI numbers.

OIG Recommendation 4 (1 recommendation)
Completely reform the payment method.

HCFA Response

We do not concur at this time. We note that in order for HCFA to take such action, it would be necessary to work with the Congress to develop an appropriate new payment methodology. Given the size of this industry, this would be a challenging prospect. Further, we believe that the proposal, as stated, is insufficiently developed as to how it reduces abuse and that the problem of "nonexistent" IPLs could be addressed in a less disruptive way, such as when they are re-enrolled as IDTFs. Finally, in the example given, we question why split billing of separate components of the procedure is a bad thing as long as each component is only billed once. We believe it makes sense first to implement the OIG's other recommendations, which we believe will go a long way toward addressing this problem, before attempting to reform the payment method.

Technical Comments

The report contains carrier complaints to the effect that the way to address the "IPL problem" is to establish lists of procedures IPLs are forbidden to perform based on vague feelings of carrier medical directors and others that these procedures are being abused by IPLs. The statutory basis for establishing such lists (for other than medical reasons) directed against an entity that otherwise meets all program requirements is unclear. This position ignores the fact that HCFA pays carriers to deny claims on the basis that the services furnished are not reasonable and necessary to the diagnosis and treatment of illness or injury, but such situations are, apparently, too difficult to identify.

HCFA recognizes the vulnerabilities associated with this industry and its carriers and has taken steps to address these vulnerabilities. Based on the recommendations of a team of very experienced regional office personnel, HCFA proposed to eliminate the IPL designation and to begin anew with a new type of diagnostic testing entity known as an independent diagnostic testing facility (IDTF). This proposal was adopted as a new policy set forth in 42 CFR 410.33 and was published in the Medicare physician fee schedule final rule of October 31, 1997. When this policy is fully implemented, all

diagnostic tests (technical components) payable under the physician schedule (with a few specific exceptions cited in the regulations) must be furnished by a physician's office or an IDTF. The OIG reports recognize this action on HCFA's part and indicates that many of the problems that currently exist with IPLs--many related to fraudulent billings--will continue to exist under IDTFs. Meanwhile, the OIG has produced two reports with similar allegations, neither of which cited a single example of a test that was not actually furnished as billed by an IPL or that was not medically necessary for the beneficiary who received the service.

On page 2 of the report OEI-05-97-00240, it is noted that currently enrolled IPLs must now meet IDTF enrollment requirements. We recommend that you emphasize this so that it is clear that currently enrolled IPLs must meet all new requirements in order to continue billing Medicare and will not automatically be re-enrolled as IDTFs.

Attachment

A P P E N D I X B

**Assistant Secretary for Management and Budget
Comments on the Draft Report**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MAY 29 1998

MEMORANDUM TO: June Gibbs Brown
Office of Inspector General

FROM: John J. Callahan *John J. Callahan*
Assistant Secretary for Management and Budget

SUBJECT: **Concur with Comment: OIG Draft Reports on Medicare
Independent Physiological Laboratories (IPLs)**

ASMB agrees that the findings of the two Office of Inspector General (OIG) reports on Medicare payment and coverage of Independent Physiological Laboratory (IPL) services demonstrate the potential for fraud and abuse of this benefit. We would like to share the following questions and comments regarding the following OIG recommendations contained in the draft report:

- ▶ Strengthen monitoring and control process: Has OIG estimated the return on investment expected from increasing the number of IPL claims that are audited? Although many of OIG's proposals in the area of improved monitoring and control are sensible, resources to carry out these activities are limited. Relative to other providers, Medicare spending on IPLs is a small fraction of total Part B spending, for example, \$126 million (based on an estimate in this report) out of a total \$67.2 billion (or less than one percent) of 1996 spending. If the OIG had estimates of the total amount of money being improperly paid to IPLs each year, as well as the level of return that might be expected from increased IPL claims audits, this information would be useful in assessing what HCFA's response should be to the findings in this report.
- ▶ Completely reform the payment method for IPL services: Rethinking how Medicare pays for IPL services is a useful exercise. The OIG recommends allowing physicians to bill Medicare directly for IPL services and then reimburse the IPL for its share. On the face of it, this proposal raises concerns about the potential for physicians to mark-up prices and engage in inappropriate referral and kickback activities. Could the OIG respond to the extent it believes these are valid problems. Also, did the OIG consider offering a range of alternative mechanisms for HCFA to consider in addition to direct physician billing, e.g., competitive bidding or others?