Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicare Payments for Clinical Laboratory Services

Vulnerabilities and Controls

Statement Before the Expert Committee
on
Medicare Payment Methodology for Clinical Laboratory Services
of the
Institute of Medicine

by

George F. Grob
Deputy Inspector General for Evaluation and Inspections
Department of Health and Human Services

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OFFICE OF INSPECTOR GENERAL

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January 20, 2000

I wish to thank the Institute of Medicine for the opportunity to present to you the concerns of the Office of Inspector General regarding Medicare payments for clinical laboratory services.

I must say at the outset that the current system used by Medicare to pay for these services is significantly vulnerable to fraud, waste, abuse, and error. One of the largest civil settlements ever to resolve disputes about incorrect Medicare payments was made with one of the nation's clinical laboratory companies. The settlement, amounting to $325 million, was not an isolated case. In fact, a series of settlements along the same lines with other laboratories, including some of the nation's largest, resulted in almost a billion dollars in recoveries, fines, and penalties in recent years. These settlements involved complaints of billings for services not performed, unbundling tests, false diagnosis codes, kickbacks to physicians for patient referrals, double-billings, and billings for unordered tests and tests not medically necessary.

Many of the large national laboratories have been cooperating in resolving disputes and improving their internal safeguards to prevent fraud and abuse. However, we cannot drop our guard. Just yesterday, the Department of Justice and the Department of Health and Human Services announced the conclusion of largest health care case ever, with fines and payments totaling $486 million. Of this, $167 million was explicitly related to laboratory tests. We have also been finding similar problems with Medicare and Medicaid payments to smaller local laboratories. And now appearing on our screen are concerns emanating from the development of new, innovative laboratory services, business practices, and the larger environment of the medical care market place.

The prevention, detection and correction of the problems cited above did not result from the effective functioning of the Medicare payment system. Rather, it was the result of investigations, audits, prosecution, negotiations, compliance agreements, and

communications all of which are adjunct to, but somewhat outside, the Medicare bill payment and adjudication process. In fact, the current payment system provides neither the incentives nor the controls needed to deal with integrity problems. Such shortcomings exist at every level of the laboratory services usage and billing cycle--including interfaces with the patients who receive the services, the physicians who order them, the laboratories that perform and bill, and the Medicare fiscal agents who review and pay for laboratory services.

For all the reasons cited above, the Office of Inspector General believes that the Institute of Medicine's study is timely and warranted, and we are hopeful that it will be able to address the serious shortcomings mentioned above. At a minimum, in its deliberations, the study panel should not forget the problems that have plagued us in the past, as they will surely re-occur if not attended to. To assist the Institute in its study, we are providing a summary of the work we have conducted over the years, along with some suggestions and reflections on options for revamping the Medicare payment system.

We particularly want to call to your attention to the need to: simplify the Medicare payment system; increase beneficiary involvement in the oversight of billings; experiment with innovative payment methods; strengthen the capacity of carriers to review bills and analyze billing patterns, and expedite the process by which coverage decisions and billing codes are reviewed and approved.

I will be happy to answer any questions you may have and our staff will gladly discuss any of our concerns with you in greater detail during the course of your study.

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INTRODUCTION

BACKGROUND

Early History and Medicare Payment System

Medicare pays physicians, hospitals, independent laboratories and other providers for clinical laboratory services they provide to patients. To receive payment, providers are required to submit itemized bills for reimbursement to Medicare fiscal agents called carriers and intermediaries. When the Medicare program began, physicians billed Medicare for laboratory services they performed in their own office and for laboratory services they purchased at a discount from hospital and independent laboratories. Many physicians routinely "marked up" the cost of the their purchased laboratory services when billing Medicare and other insurers.

In 1980, the statute was changed to eliminate markups on purchased laboratory services. The law required physicians to disclose the actual cost of the laboratory services they purchased from other laboratories. Enforcement of this law was difficult and many physicians continued to purchase laboratory services at discount prices and bill Medicare marked up prices. Some physicians expanded testing in their office, others entered into joint ventures with hospital and independent laboratories.

Fee Schedules and Caps

In 1984, Congress again addressed the problem of physician laboratory markups. The Omnibus Deficit Reduction Act of 1984 prohibited physicians from billing for laboratory work they did not perform. This legislation also changed how Medicare paid for laboratory tests by eliminating reasonable charge as a basis for payment. Congress required that the Health Care Financing Administration (HCFA) establish regional fee schedules as a first step in establishing a national fee schedule by 1990 for all laboratory test billed to Medicare. The requirement of a national fee schedule was repealed in the Omnibus Budget Reconciliation Act of 1989, but regional fee schedules remained and a "cap" per procedure code was established for laboratory payments.

The HCFA established the fee schedules on a carrier-wide basis. The fee schedule amounts vary by carrier. Currently, the caps are set at 74 percent of the national limitation or ceiling for each laboratory service. The national ceilings were limited to the median of all carrier fee schedule allowances. Claims submitted are paid the lowest of the actual charge, the fee schedule amount or the cap. Deductibles and coinsurance for laboratory services were eliminated.

Quality Assurance

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) required all entities that perform testing on human samples to be registered and certified under CLIA in accordance with the complexity of testing performed. Laboratory procedures were categorized into waived procedures, physician-performed microscopy, moderate complexity, and high complexity testing, with progressively stringent requirements for each level of testing. Physician offices, like all other providers, had to meet the standards for the testing performed.

Expenditures

Annual expenditures for laboratory tests have risen over the last decade. Between 1988 and 1998 the number of laboratory services billed to Medicare rose from 232 million services annually to nearly 652 million services. Despite reductions in the payment caps, Medicare's annual expenditures for laboratory tests have increased from $2.8 billion in 1988 to somewhere between $3.4 billion and $4.7 billion in 1998. Precise estimates are not yet available.

The Balanced Budget Act

The Balance budget Act of 1997 mandated several actions be taken regarding payment for laboratory services. It reduced Medicare payment caps to 74 percent of the mean. It required that no more than five regional carriers be established to process and pay Medicare laboratory claims. It also mandated that an entity be designated to analyze Medicare laboratory data. Further, the Act required the use of negotiated rule making to establish national coverage and administrative policies for Medicare Part B laboratory services.

The law also requires that the Secretary of Health and Human Services request the Institute of Medicine to conduct a study of Medicare Part B payments for clinical laboratory tests and that it include recommendations regarding alternative payment systems and a discussion of access to high quality laboratory services.

Office of Inspector General Work

Laboratory services have been of major concern to the Office of Inspector General. Over the years, we have carried out nation-wide investigations of inappropriate payments; assisted the Department of Justice in prosecuting wrongdoers and negotiating settlements to resolve payment disputes; and, imposed corporate integrity agreements. We have conducted audits of Medicare and Medicaid providers; completed evaluations and audits dealing with subjects like quality of services, physician ownership arrangements and self-referral, physician office laboratories, cholesterol screening, utilization trends, bundling

and unbundling of procedures, and discounts. We have issued fraud alerts, advisory opinions, and compliance guidelines to the clinical laboratory industry; and more generally opened up communications with industry representatives to assist them in preventing fraud and payment errors.

SCOPE AND METHODOLOGY

This report identifies vulnerabilities, control weaknesses, and options to improve Medicare payment methods for clinical laboratory services. It was prepared at the request of the Institute of Medicine to support its study effort on this topic.

Information contained in this report was derived primarily from past work of the Office of Inspector General involving laboratories and laboratory testing. Additional data and other information was obtained from HCFA, Internet sites and literature reviews.

VULNERABILITIES

FRAUD, WASTE, ABUSE, ERROR

Fraud, waste, abuse, and error with respect to payments for clinical laboratory services have been significant problems in the Medicare and Medicaid program. Over the last decade, approximately one billion dollars has been recovered from laboratory companies, including many of the largest such companies in the nation, to resolve disputes connected with false or erroneous bills paid through the Medicare program. While most of these large disputes have been resolved, we continue to find the same billing problems in smaller local laboratories and other providers.

Because of the size of the problem (as measured in dollars lost to the Medicare program), its pervasiveness throughout the lab industry in past years, and the continuing vulnerability of the Medicare payment system to such improper billings, it is important to gain a clear understanding of the nature of the improper practices that led to these losses.

Fraud cases involving laboratory services span a broad spectrum, from blatant actions intended to defraud Medicare to more subtle efforts that mix legitimate claim information with false information. The most common types of fraud involve the filing of false claims. The chart below summarizes the type of billing that results in false claims.

FRAUDULENT BILLING
♦ Billing for Services Not Performed
♦ Billing for Services Not Ordered
♦ Billing for Services Not Needed
♦ Up-coding
♦ Unbundling
♦ Duplicate Billing
♦ Falsifying Diagnoses

These concepts are fairly straightforward, but there are subtle variations of them which make abusive billings hard to detect. One such example relates to unbundling. Unbundling occurs when a laboratory bills separately for some, or all tests, analyzed

simultaneously by a single piece of equipment on a single patient specimen. There are sophisticated versions of this type of false billing. In some cases, laboratories have provided an option for physicians to order customized groupings of tests (called panels and profiles) that do not exactly correspond to the coding principles used by Medicare. The physicians are led to believe that the additional tests included in the panels and profiles they order are either performed free (as part of the panel/profile) or at very low cost. The laboratories then billed Medicare for the Medicare covered panel *plus* the additional tests. Many physicians said they were not aware that the extra tests would be separately billed and would not have authorized them if they had known.

Most laboratory fraud cases do not go to a criminal trial. The vast majority of laboratories referred to the Justice Department for criminal or civil action are settled outside of court. The settlements represent agreements between a laboratory and Medicare to repay financial damages stemming from fraudulent or abusive activity. In some cases, laboratories have agreed to repay Medicare losses plus penalties and fines for engaging in fraudulent or abusive practices.

Law Enforcement Projects

All of the problems mentioned above were revealed in Project LabScam, the first systematic nation-wide law enforcement project in the medical field. Project LabScam stemmed from the December 1992 guilty plea of National Health Laboratory and its agreement to repay $111 million. Information, developed during the course of the investigation, made it appear likely that the improper billing techniques used by this company were commonly practiced by other large, national laboratory companies.

Project LabScam was a joint law enforcement task force that followed up on these leads and focused on the billing practice of all the major independent clinical diagnostic laboratories in the country. It initially resulted in settlements against several laboratories --SmithKline Beecham, MetPath/MetWest, Damon, Roche and Allied. Some of these companies were acquired or merged into other companies, but we were able to pursue the recoveries from the new companies. These companies subsequently agreed to make payments to resolve charges of false claims by their own or predecessor companies. They also entered into detailed corporate integrity agreements to prevent improper activities. Some enhanced their existing compliance programs.

Among the largest settlement were those involving Laboratory Corporation of America Holdings (LabCorp), which in November 1996 agreed to pay $187 million to resolve charges of false claims to government programs; and Smith Kline Beecham Clinical laboratories, which in February 1997 agreed to a $325 million civil suit settlement. The latter case was one of the largest civil settlements ever in the medical care area. The settlement covered civil liability stemming from: unbundling clinical laboratory tests; billing for tests not performed; inserting false diagnosis codes to obtain payment; paying

kickbacks to physicians for patient referrals; double-billing for laboratory tests provided to patients with end stage renal disease; and billing for tests that were unordered and medically unnecessary.

Because of the importance of the Project LabScam and other similar cases in revealing the nature and extent of fraud, waste, abuse, and error with respect to Medicare payments for laboratory services, we have provided a more detailed summary of this project in the Appendix.

Many of the large national laboratories have been cooperating in resolving disputes and improving their internal safeguards to prevent fraud and abuse. However, we cannot drop our guard. Project LabScam is not the totality of all situations involving improper payments for laboratory services.

In fact, on January 19, 2000, the Department of Justice and the Department of Health and Human Services announced the conclusion of the largest health care case to date with Fresenius Medical Care North America, the world's largest provider of kidney dialysis goods and services. The case involved $468 million in fines and payments, of which $167 million is directly related to laboratory services--$36.6 million in criminal fines for false claims; $15.2 million in criminal fines for kickbacks to induce referrals of claims to the company; and civil settlement payments of $112.2 for unnecessary tests and $2.8 million for tests which were part of clinical trials. The criminal conduct uncovered during this investigation started prior to October, 1996 when Fresenius acquired National Medical Care and its subsidiaries. Fresenius has cooperated with the investigation and has taken steps designed to prevent similar misconduct in the future.

There are indications that problems similar to those uncovered through Project LabScam are occurring with smaller laboratories and certain providers billing Medicare and Medicaid.

Hospital Outpatient Laboratory Project

The Hospital Outpatient Laboratory Project conduct by our office has documented hospital laboratory abuses stemming from unbundling and double billing of laboratory tests and, in some cases, the improper billing of medically unnecessary laboratory tests. The 241 hospitals audited thus far have agreed to repay more than $54.6 million in overpayments and False Claims Act damages.

Duplicate Part A and Part B Payments

Medicare incorporates laboratory payments into institutional and provider payments for hospital inpatients and end stage renal disease (ESRD) patients. These Part A payments are made by intermediaries. For other types of patients, laboratory tests are paid

separately to the laboratory provider. These payments are made under Part B of the program and can be paid by either intermediaries and carriers depending on the type of facility billing for the laboratory tests.

We have found that Medicare paid twice for diagnostic services, including laboratory tests, performed within 72 hours of a patient's admission to a hospital. Diagnostic tests performed within 72 hours of a hospital admission are considered pre-admission tests and payment for them is included in Medicare hospital payment.

We have also found that Medicare has made duplicate payments to laboratories providing services to ESRD patients. Investigations have found laboratories billing Medicare Part B for tests Medicare Part A had already paid under the dialysis center ESRD composite rate.

Medicaid

Reviews of 28 State Medicaid programs through partnership audits conducted by State and Federal Government auditors found problems similar to those discovered in Medicare--laboratory services not properly grouped together (bundled into a panel) or duplicated for payment purposes. In addition, Medicaid payments sometimes exceeded Medicare payment rates, contrary to Federal rules.

Remedies and Prevention

The descriptions above, particularly those regarding Project LabScam, indicate that many serious laboratory payment problems are resolved through audit and law enforcement, including convictions, settlements, and corporate integrity agreements. In addition to these measures, we have undertaken a variety of preventive measures designed to reduce Medicare and Medicaid's exposure to fraud and abuse. Program exclusions, and new approaches such as compliance guidelines and fraud alerts are some of the preventive measures in use today.

Exclusions. One indication of the extent of the problem connected with laboratory billings is the number of individuals and companies excluded from participation in Federal Government medical care programs as a result their improper activities. To date, more than 125 laboratories and individuals associated with them have been excluded from participating in government health insurance programs.

Compliance Guidelines. The Office of Inspector General has developed model compliance plans designed to assist clinical laboratories in developing effective internal controls that help prevent fraud, abuse and waste. These have been prepared with considerable input from medical care industries. The compliance guidelines for laboratories were one of the first developed. They have been subsequently modified based on new developments in this field and further consultation with the laboratory industry.

A complete copy of the compliance guidelines can be found on the Office of Inspector General website (www.dhhs.gov/oig). Key elements of the plan include:

--written standards of conduct,
--policies and procedures that address potential fraud,
--designation of a chief compliance officer,
--education and training of employees,
--a hotline or other means to receive complaints,
--adoption of procedures to protect complainants,
--a system to respond to allegations of improper or illegal activities,
--audits and evaluations to monitor compliance,
--appropriate disciplinary action of errant employees, and
--investigation and remediation of systematic problems.

Some laboratories have agreed to mandatory compliance agreements as part of their settlement with the Federal Government. But the broader guidelines are being voluntarily adopted by many large corporations to develop a culture of integrity within their businesses and to avoid future integrity problems.

Fraud Alerts. A fraud alert regarding inappropriate arrangements for the provision of clinical laboratory services has also been issued by the Office of Inspector General. This fraud alert was designed to educate the laboratory community and Medicare subcontractors about potential violations of Medicare and Medicaid anti-kickback laws. By describing practices that appear to violate the law, it is hoped that laboratories and their customers will cease and desist from such illegal practices.

LABORATORY MARKETPLACE

The market for laboratory services can be characterized by intense competition for a finite number of patients. Laboratories need a certain minimum volume of tests to succeed financially. To achieve this minimum test volume, a laboratory needs a predictable volume of patient referrals. Because referrals are a function of tests ordered by physicians, laboratories try to find ways to ensure that physicians will refer patients and test specimens to their laboratory and not another.

Self Referral

Several studies conducted in the 1980s, including a 1989 Office of Inspector General report to Congress, showed that physicians with ownership interest ordered many more tests than their peers who had no financial interest in a laboratory. This report, "Financial Arrangements Between Physicians and Health care Businesses" (OAI-12-88-01410) found

that 12 percent of physicians who bill Medicare have ownership or investment interests in entities to which they make patient referrals and that at least 25 percent of independent clinical laboratories were owned in whole or part by referring physicians. Patients of referring physicians who owned or invested in independent clinical laboratories received 45 percent more clinical laboratory services than all Medicare patients in general, regardless of place of service (including physician office labs) and 34 percent more services directly from independent clinical laboratories than all Medicare patients in general.

In 1989, serious concerns about the referral patterns of physicians who had ownership interests in clinical laboratories led Congress to pass Section 1877 of the Social Security Act, commonly referred to as "Stark I." Under Section 1877, a physician having a proscribed financial relationship with a clinical laboratory may not make a referral to that laboratory for a service paid by Medicare and the laboratory may not bill Medicare for that referred service. Physicians who operate their own office laboratories, licensed under CLIA, are exempt from this prohibition.

Discounts

In vying for referrals, laboratories may offer volume discounts to gain a competitive edge. Discounts are based upon expected volume of referrals and other costs and competitive factors presented by each client. They often may have little or no relationship to the actual cost incurred in performing a test. Laboratories may grant a discount on one or more tests to a client if it believes that the client will also order enough higher margin tests to make an overall account sufficiently profitable. Such discounts are possible because the discount price of a laboratory test is often significantly lower than the amount paid by Medicare and third party insurers.

Office of Inspector General reports document that Medicare pays more money for laboratory tests than the laboratories charge to physicians for the same test. Our work in this area has contributed to the enactment of legislation that has substantially reduced the payment caps for laboratory services.

Customized Test Packages

A laboratory will also offer customized test packages as a way of attracting patient referrals by giving them "personalized" service, tailored to the needs of that physician's practice. These customized groupings of tests are often discounted when sold to physicians, hospitals and other laboratories. With the exception of services provided to patients enrolled in Federal health programs such as Medicare and Medicaid, many providers who purchase laboratory work bill their patients and insurers for more money than they actually paid. Federal law requires that the laboratory that actually performed the test bill Medicare for them. No such provision exists with regard to private pay

patients. Anecdotal evidence suggests that the discount rates offered to physicians by some independent laboratories may be related to the number of Medicare patients referred to the laboratory.

Laboratories routinely offer customized profiles and panels to physicians. Physicians often order the profile/panel containing the test they need rather than specifying just the needed test(s). Profiles and panels desensitize physician concerns about the medical necessity of the laboratory tests they are ordering. Moreover, panels and profiles contribute to unbundling billing schemes and contributes to the ordering of medically unnecessary laboratory tests.

Customized Services

In addition to discounts and customized laboratory panels and profiles, business practices which streamline day-to-day operations, facilitate rapid turn around time, enable better service and provide convenience to the patient are often used to gain a competitive edge. Physicians and laboratories have been known to share telephones, computer hardware and software, laboratory and other medical equipment, office supplies, management services and personnel. Like other businesses, the sellers and purchasers of laboratory services engage in activities designed to promote goodwill. Under existing Medicare law, these business practices may be considered inducements for patient referrals, and therefore construed as illegal.

QUALITY OF LABORATORY TESTING

The Office of Inspector General has been concerned about the quality of laboratory services provided to Medicare beneficiaries. One of the first areas we examined in the mid 1980s was unregulated laboratory testing in physician office laboratories. In particular, mistakes made in pap smear tests caused great concern to Congress and others in the laboratory community.

Quality

We released reports addressing the physician office laboratories issue as well as the quality of testing in certain facilities. Subsequently, the Clinical Laboratory Improvement Amendments of 1988 (CLIA of 1988) were enacted. These amendments addressed recommendations in our report by mandating that: 1) all laboratories be regulated based on complexity of testing, regardless of volume or testing site; 2) all physician office laboratories register and meet certain standards and inspection requirements, and 3) a registration fee be imposed on all laboratories. The ultimate goal of these amendments is to assure that all types of laboratories consistently produce highly reliable results.

Another area of concern was the prevalence of public cholesterol screening conducted by all types of providers in drug stores, shopping malls and other public places. In May, 1990, we found that the accuracy and usefulness of public cholesterol screening were compromised by poor quality assurance, inadequate on-site counseling, and lack of referral to a physician when appropriate. Shortly after our report was released, public cholesterol screening dropped dramatically.

Access

The passage of CLIA raised concerns by the medical and laboratory community that laboratory sites, especially physician office labs, might cease operations and thus restrict patient access to certain types of laboratory services. Aware of this possibility, HCFA requested that we conduct a study. In a report issued in June, 1995 we found that CLIA did not affect physician ability to secure laboratory services for their patients. Physicians who changed their in-office laboratory operations were influenced by factors broader than CLIA; these influences included other government regulations, such as the Stark amendments and Occupational, Safety and Health Administration requirements, and non-government factors, such as sales, mergers and managed care.

The HCFA has recently reported that due to CLIA, the overall quality of laboratory services has improved. We have not conducted any recent studies examining the implementation and impact of CLIA, but are again beginning studies in this area.

EMERGING AND FUTURE ISSUES

Home Test Kits

During the next decade, the number of laboratory tests approved for home testing will increase significantly. New technology will spawn new home test kits capable of providing laboratory information comparable to traditional and more complex laboratory methods. Home tests kits allow people to obtain a sample for laboratory analysis in the comfort of their own home. Some kits produce results very rapidly while other kits only provide a method for collecting a specimen. The specimen is then sent to a laboratory where the actual testing is performed.

Patient initiated testing is not reimbursed by Medicare. Medicare does pay for glucose monitors and glucose testing strips. To be covered, a laboratory test must be ordered by a physician, performed in a CLIA certified laboratory and medically necessary in the diagnosis and treatment of a patient. In recent months, Medicare has seen significant increase in billings from nursing facilities for blood glucose monitoring performed with equipment approved for patient use at home. Testing performed in the home is not paid by Medicare.

Medicare policy does not adequately address the use of laboratory test kits approved for home testing. The number of tests for home use will continue to rise and current Medicare policies may be inadequate to address the coverage problems that will accompany this increase. Medicare needs to evaluate its coverage polices for home test kits, bed side testing and new technology. What constitutes routine testing? When, if ever, is it payable? How, if at all, will Medicare pay for HIV tests, pap smears and other home tests order by a physician, collected by a patient and analyzed at a laboratory?

Nursing Homes

Many elderly patients confined to nursing homes have standing physician orders to monitor a patient's glucose levels. In many cases, patients have their blood sugar checked three or more times each day and records of the results are kept for physician review.

Historically, nursing facilities have not billed Medicare for glucose screening. Recently, they began billing for each glucose test they perform on a patient. They obtain a CLIA certificate of waiver that permits them to bill for laboratory tests approved for home use. Policy on coverage is unclear and some Medicare fiscal agents pay nursing homes for glucose testing while others do not. The HCFA is working on clarifying policy in this area. We have urged them not to pay for glucose monitoring in nursing facilities because it is a routine service and should be covered in the nursing facilities' per diem rate.

Alternative Medicine

Patient interest in alternative medicine has increased during the last decade. Accompanying the increased interest in alternative medicine are new laboratory technologies purported to provide information about a patient's medical status. Live Blood Analysis (LBA) and Biological Terrain Analysis (BTA) are two tests widely marketed over the Internet. The tests are ordered and used primarily by nutritionists, chiropractors and naturopaths. The efficacy of these tests and their ability to produce consistent results has not been established using scientific methods. Evidence suggests that different providers obtain different results and interpret the results differently.

Under current law, all sites analyzing specimens derived from the human body must register and apply for a CLIA certificate. This policy was designed to ensure uniform testing, regardless of where the tests were performed.

It is unknown how many labs currently certified under CLIA perform LBA or BTA. Some laboratories performing LBA and BTA have been certified under CLIA. Others claim that they are exempt from CLIA because the tests are performed solely for research purposes and not used in patient care and treatment decisions. It is believed that the vast majority of sites performing LBA and BTA are unknown. The extent to which patients are sold nutritional supplements and natural remedies based on the results of these tests is unknown.

Electronic Medical Records and Billing

Many of the safeguards used by the Medicare program rely on the separation of responsibility. This separation allows Medicare to compare a patient's medical record to the claims submitted for payment. If the person or entity billing Medicare changes or adds a diagnosis or adds a laboratory service not ordered by the patient's physician, the patient's medical record and other records in the audit trail would show who and how information was changed.

The current processes used in patient care can be viewed as one directional. Increased use of electronic systems that generate the medical record, billing claims and most supporting documentation may change these processes to bi-directional. For example, under the linear system the billing department might add a diagnostic code to ensure payment of a particular laboratory test. To avoid detection of the added diagnostic code, the patient's medical record would need to be pulled and modified to reflect the added code. The source document completed by the physician and used to prepare bills would also need to be modified. These additions and modifications to the key records in the billing audit trail would in all likelihood be noticed during an audit.

New technology can be bi-directional or interactive. In our example, changes and additions by the billing department might interact with the patient's record, changing or adding to the original information recorded by the physician, so that it agrees with the claim submitted to Medicare for payment.

ADMINISTRATION AND CONTROLS

Evidence clearly shows that Medicare and Medicaid systems are vulnerable to laboratory claims that have been manipulated to defraud the program and to maximize reimbursement. The administrative systems for paying Medicare claims are inherently incapable of dealing with the vulnerabilities. They contain neither incentives to curtail use nor controls to prevent improper payments. The pervasive and substantial improper billings uncovered by Project LabScam were not prevented, detected, or corrected by Medicare's claims payment system. They were largely dealt with through investigations, audits, civil settlements, prosecutions, corporate integrity agreements, industry outreach initiatives, and voluntary compliance plans--all adjunct to but not integrally connected to the payment system. Similarly, the problems of self referral, quality, and access were more subjects of evaluation studies than they were of payment control systems.

In the previous sections of this report, we attempted to discuss incentives and the lack controls related to physicians and laboratories billing Medicare. We have described the role of law enforcement, audit, evaluation, legal advice, and voluntary efforts of laboratory corporations to cultivate a culture of integrity and develop internal controls of their own to prevent a re-occurrence of integrity problems. In the sections below, we will address more specifically the shortcomings of the payment system and of the role of beneficiaries in controlling laboratory use and identifying inappropriate billing.

FISCAL AGENTS AND CONTROLS

Billing Volume and Payment Controls

In 1998, clinical laboratory services represented approximately 2.2 percent of Medicare Part B expenditures, including hospital outpatient services, but accounted for considerably more of the Medicare Part B service volume. The average payment per laboratory service was $7.21. Payers have claimed that their efforts to monitor and properly pay laboratory services do not give them sufficient return to cover the expenses associated with claim monitoring.

Past audits have revealed that both Medicare carriers and intermediaries have not always had adequate controls to detect and prevent inappropriate payment for certain laboratory tests (chemistry, hematology, and urinalysis) tests. Implementing adequate safeguards is complicated and expensive for such a huge volume of claims.

Medicare often receives multiple claims for laboratory services provided to a beneficiary during a period of illness. Clinical diagnostic laboratory tests can be submitted by multiple

laboratory providers, e.g. hospitals, physician offices, independent laboratories, etc. These claims can be submitted to a number of Medicare contractors who potentially have different payment policies, different screens and edits, and different documentation policies. Serious problems have been identified when claims for the same patient are submitted to more than one fiscal agent.

Medical Necessity

Medicare fiscal agents must deny or adjust payment for claims they determine to be medically unnecessary. Unlike claims for primary care, Medicare and Medicaid fiscal agents have a difficult time determining the medical necessity of laboratory services because little consensus exists concerning the appropriateness and intensity of laboratory services for a given medical condition or complaint. Determining medical necessity can involve complex claim development with a relatively small return for the effort involved.

Moreover, when claims for medically unnecessary services are discovered, Medicare holds the billing laboratory financially responsible for any incorrect payments. Laboratories claim they have no control over the tests ordered and that they are not in a position to question the medical judgement of an ordering physician.

Procedures Codes

In 1997, more than 1,300 laboratory procedure codes were billed to Medicare. Of these 1,300 codes, over 30 percent were not eligible for payment. More than half of the codes billed were billed less than 1,000 times. Yet the processing of these claims (whether paid or denied) is administratively costly and resource intensive.

The shear number of laboratory procedure codes also contributes to overutilization. Multiple procedure codes describing similar tests and procedure codes that dissect a test into its individual components contribute to excessive payments and other abuses that harm the Medicare program financially. Excessive coding options increases the risk of coding error. They contribute to Medicare's inability to detect duplicate claims and they allow providers to up-code or unbundle laboratory services to maximize reimbursement.

Perhaps of equal importance is the difficulty that Medicare has in keeping up with advances in the laboratory industry. New equipment makes it increasingly easy to perform more and more tests with minimal additional cost. Billers of laboratory services have argued that they were unable to bill packages/profiles as a single procedure code because no approved Medicare code existed that accurately described their package. Changes and additions to the laboratory procedure codes have been evolving rapidly to accommodate new technology and the customization of panels. However, audits have revealed that the procedure codes and laboratory guidance by HCFA have not kept pace with these new developments. The process which Medicare uses to periodically review and approve new procedure codes to

accommodate advances in technology and changes in laboratory practices may be several years behind the current medical care and laboratory testing practices.

ROLE OF BENEFICIARIES

Medicare beneficiaries play little or no role in controlling laboratory utilization. This is primarily because, unlike other services Cover under Part B of the Medicare program, they do not make co-payments for these services and receive no information from Medicare about laboratory services that are billed in their names.

Medicare beneficiaries generally rely on the recommendations of their physicians regarding the appropriateness of medical tests. This is largely because of the complexity and sophistication of the tests ordered for them. It is worth noting, however, that beneficiaries do interact with and question their physicians about equally if not more complicated surgeries, equipment, and other treatments.

Deductibles and Co-payments

As noted in the background section, beneficiaries pay no deductibles or co-payments for laboratory tests. To some extent this may reduce their involvement in decision making about tests ordered for them, since they have no financial stake in the prescription.

It is uncertain what effect deductibles and coinsurance would have on laboratory test utilization. Most of today's Medicare beneficiaries have supplemental insurance or Medicaid coverage that pays for such expenses. Patients who do not qualify for Medicaid and who are too poor to afford supplemental insurance policies appear most likely to be hurt by deductibles and coinsurance. However, the introduction of private supplemental insurance programs does bring the added advantage of oversight by these insurers, since they do have a financial stake in the tests ordered. The medical needs of low income beneficiaries are no different for laboratory tests than for any other Medicare benefits.

Notice of Payment

Another laboratory payment vulnerability is the lack of a beneficiary notice. Generally, beneficiary notices are sent to inform patients as to what services have been billed to and paid for by Medicare. One exception is laboratory tests. No notice is sent to inform the beneficiary when a laboratory test has been paid. This was largely because of the sheer volume of tests and the cost of generating a notice each time a laboratory test was billed.

OPTIONS FOR IMPROVEMENT

Over the years, the Office of Inspector General has made a number of recommendations to Departmental policy makers and Congress regarding laboratory services. As the Institute of Medicine deliberates an alternative method for payment of clinical laboratory services we offer the following for consideration:

Reduce the Number of Procedure Codes

We believe that any discussion of an alternate laboratory payment system should focus on reducing the number of procedure codes available for billing, thus, reducing the chance of inappropriate billing and administrative costs.

Designate Regional Carriers

The Balance Budget Act of 1997 (BBA) mandated that no more than five regional carriers be designated to pay all Part B laboratory claims, excluding hospital outpatient claims. As yet these carriers have not been designated. We urge this be done soon. We believe that these specialty carriers can more effectively deal with the highly specialized nature of the vulnerabilities we have described for laboratory tests. The efficacy of the specialty regional carriers has been demonstrated for durable medical equipment which has also been subject to considerable and specialized fraud vulnerabilities.

We question why hospital outpatient departments would be excluded from the jurisdiction of a regional Medicare payer. A considerable amount of Part B laboratory testing is being performed by hospital outpatient departments. Excluding them from any kind of laboratory billing analysis does not seem prudent. Allowing hospital outpatient departments to bill a different fiscal agent other than the designated payer perpetuates a system that is vulnerable to duplicate billing.

Establish Statistical Data Analysis Unit

The Balanced Budget Act also stipulated that a "central statistical resource" be designated to perform analysis, identify billing trends, identify aberrant providers, and suggest changes in national laboratory policy. This provision has also not yet been implemented. A central statistical resource could be effective in detecting vulnerabilities, referring suspected providers for audit or investigation, and analyzing the impact of current and proposed coverage policies. It would probably work best in tandem with specialty carriers discussed above, but it could also be effective without them.

Establish National Coverage and Administrative Policies

The Balanced Budget Act of 1997 mandated that HCFA use the negotiated rule making process to develop national coverage and administrative policies for clinical diagnostic laboratory tests under Medicare Part B, excluding tests performed in hospital outpatient departments. Among issues to be negotiated are: 1) the medical condition for which a laboratory test is reasonable and necessary, 2) the appropriate procedure codes used to bill, including when laboratory tests should be bundled into one code, and 3) the medical documentation that is required by a Medicare contractor when a claim is submitted. If implemented, this process would go a long way toward addressing the shortcomings of the current process in keeping up with testing and payment practices in the laboratory arena.

We believe that any national policies regarding the billing for and documentation of laboratory services should apply to all laboratory billers, including hospital outpatient departments.

Restore Beneficiary Notices

Restoring beneficiary notices is also viewed as an opportunity for improving Medicare's program safeguards. These notices may improve patient awareness of the costs related to their laboratory services. They may also improve Medicare's ability to detect aberrant providers, but their effect on controlling use and rising costs is limited.

Now that beneficiary notices are being sent to some beneficiaries on a periodic basis instead of each time a claim is paid, it may be feasible to include laboratory payment information on them. Patient review of notices is a corner stone in the nationwide campaign to encourage and train beneficiaries to identify questionable billing and report suspected fraud. Such notices are used routinely by commercial insurance plans.

Apply Patient Deductibles and Coinsurance

Other options for addressing the rise in laboratory use and expenditures call for the restoration of patient cost sharing. These proposals would require patients share in the cost of their laboratory services by imposing the Medicare annual deductible and coinsurance on patients.

Establish A Competitive Bidding Demonstration

The Balanced Budget Act of 1997 calls for the establishment of no more than five demonstration projects concerning the use of competitive bidding in securing Medicare items and services. One of the five projects must involve the competitive bidding for oxygen and oxygen equipment. Another demonstration could involve competitive bidding for laboratory services.

The HCFA has proposed a number of different competitive bid methods. All have faced strong opposition from the medical community and the laboratory industry. Apprehension about the possible effects of sending laboratory work to the lowest bidder, and possible effects on the quality of testing has, until recently, kept competitive bidding on the back burner. Competitive bidding may save money but it may also lead to other abuses such as sink testing. It may also undermine the development of new laboratory procedures and have other consequences.

Prospective Payment

Establishing a prospective laboratory payment is an option that would control both the rise in use of laboratory services and the rise in expenditures. It would virtually eliminate the fraudulent and abusive practice mentioned previously. A prospective laboratory payment system would eliminate the current administrative burden associated with policing laboratory claims. A prospective payment system would combine a fixed amount to cover laboratory services with the amount paid for patient office visits. Studies would need to be conducted to determine what, if any, harm a prospective laboratory payment system would have on a physician's medical practice. Any such proposal would also need to establish a way for physicians potentially harmed by such a system to present evidence to justify an increase in their laboratory prospective payment. This could be accomplished by an outlier payment provision.

It may be appropriate to experiment with a limited version of this proposal--e.g., for certain specialities or for the most common tests. One opportunity for such experimentation could present itself during the implementation of the outpatient prospective payment system currently being developed for hospitals. At one point clinical laboratory test were going to be included in the hospital payment, the current proposal is to pay for all diagnostic test separately. It might be worth while to bundle laboratory tests into certain of the outpatient payment categories, at least to test this concept..

In any prospective system, incentives to withhold services exist. Past studies have shown that physicians are not likely to withhold services they feel are in the patient's best interest. Nonetheless, controls to ensure that patient's get appropriate laboratory services would need to be established.

APPENDIX

CASE EXAMPLES

Introduction

The primary mission of the Office of Inspector General (OIG), Office of Investigations (OI), is to investigate allegations of fraud, waste and abuse in the Medicare program and to protect the integrity of the program and the well-being of program beneficiaries. Investigations conducted by the OI result in criminal prosecutions, administrative sanctions and civil actions against wrongdoers, including monetary penalties and exclusion from participation in the Medicare program. One of OI's most successful efforts in the battle against Medicare fraud was a nationally coordinated effort between the OI and other Federal and State law enforcement agencies, known as Project LabScam.

Project LabScam began in 1993 and grew out of criminal investigation of National Health Laboratories (NHL) and its fraudulent billing schemes involving the "unbundling" of clinical laboratory tests. The NHL investigation revealed that laboratories used abusive marketing practices that caused doctors to order medically unnecessary tests. After the laboratories determined which tests were profitable to perform, "profiles" were created containing these tests and the tests commonly ordered by physicians. Physicians were encouraged by the laboratories to order the new, more profitable, profile of tests as opposed to ordering only those individual components of the profile, i.e., individual tests, needed for the care of the patient. Unknown to the physicians, laboratories "unbundled" the profile tests and billed Medicare, Medicaid and other health care programs the full price for the unnecessary tests as if each test were ordered and performed separately by the laboratory. In addition to using these abusive marketing schemes, laboratories also billed Federal health care programs for services that had not been ordered. For example, Medicare was routinely billed for tests not requested by the ordering physician.

At the conclusion of the NHL investigation, several of the agencies involved in the investigation formed a task force to coordinate a nationwide investigation of these unlawful billing practices. Task force efforts culminated in Project LabScam and focused on the billing practices of all of the major independent clinical diagnostic laboratories in the country. Project LabScam also sought to promote interagency cooperation and proactive investigations, unconstrained by geographic or agency boundaries. This investigative approach enabled the Government to pursue criminal, civil and administrative actions on a national level, as well as recover millions of dollars.

To date, Project LabScam has resulted in approximately $823 million in recoveries from the major independent clinical diagnostic laboratories. In addition to the recoveries received,

the laboratory industry's awareness of the Government's efforts in this area spawned a series of qui tam lawsuits, investigations against smaller laboratories and a national project targeting hospital-based laboratories. Like Project LabScam's counterparts, these cases are significant not only because of the recovery of Medicare funds, but also because they highlight vulnerabilities that continue to put the Medicare program at risk.

Project LabScam was the first joint Federal, State and local law enforcement effort to combat Medicare fraud on a national level. Based on the success of this project, the OIG will continue these joint investigative partnerships in its effort to protect the integrity of the Medicare program.

Laboratory Cases

SmithKline Beecham Clinical Laboratories, Inc., agreed to pay $325 million and to implement stringent compliance requirements to settle its civil liability for filing false claims for reimbursement to the Medicare, Medicaid, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), and Railroad Retirement Board (RRB) health care programs. SmithKline, a target of a multi-agency laboratory initiative, engaged in many improper activities including unbundling clinical laboratory tests, billing for tests not performed, inserting false diagnosis codes to obtain reimbursement, double billing for laboratory tests for patients with end stage renal disease, and billing for calculations which were both unordered and medically unnecessary. This settlement also resolves several qui tam lawsuits alleging these violations. A separate qui tam raised allegations of test data manipulation and falsified test results, but an independent review found only minor quality problems with no adverse effort on patient care.

In Michigan, Dearborn Regional Clinical Laboratories, Inc., agreed to pay the Government $500,000 to resolve its liability under the False Claims Act. An independent clinical laboratory, Dearborn allegedly submitted improper Medicare Part B claims for additional hematological indices, calculations derived from CBC test results. The CBC testing machines were programmed to automatically calculate the additional indices results for which the laboratory billed, even though the physicians did not order them. Since the additional indices were not medically necessary, they were not covered under Medicare guidelines. Corporate integrity provisions were not required as Dearborn is no longer in business.

In Massachusetts, Brigham and Women's Hospital Pathology Foundation of Boston agreed to pay the Government $476,167 to resolve allegations of improper billing practices and to enter into a 3-year corporate integrity agreement. The settlement with Brigham, a hospital specializing in clinical laboratory services, resulted from a voluntary disclosure by Brigham under the OIG's Voluntary Disclosure Pilot Program. The investigation focused on improper billings for various pathology laboratory tests over a 6-year period. The disclosure and a subsequent verification audit determined that various billing irregularities,

primarily involving services claimed but not documented, and up coded services, resulted in an approximate overpayment of $326,000 by Medicare and Medicaid.

In Florida, Miguel Mendez, owner of Prime Laboratory, Inc., was sentenced for conspiracy to submit false claims to 3 years probation, with a special condition that he serve 4 months in a special treatment center, followed by 8 months home confinement. Mendez paid kickbacks to local doctors and clinic owners in return for their referring clinical laboratory services to Prime Laboratory. Moreover, he actively solicited clinics and encouraged them to order certain tests, with a higher Medicare reimbursement rate, for which he could bill the program. In order to have the cash necessary to pay these kickbacks, Mendez engaged in an elaborate money laundering scheme. Two other co-defendants, who participated in the money laundering scheme by cashing checks under the $10,000 Internal Revenue Service reporting requirement, were sentenced as well. Hanna Adams was sentenced to 60 days home confinement, 2 years probation, and participation in an approved outpatient mental health program.

Mediscope Diagnostic Laboratories, Inc., a clinical laboratory in New Jersey, was excluded for an indefinite period after the State suspended the laboratory from Medicaid participation. Because of the laboratory's high earnings the previous year, the State Medicaid agency conducted a prepayment review of all claims which the laboratory submitted to Medicaid for payment. The review showed over 70 percent of the claims to be fraudulent. In addition, a number of claims reviewed lacked physician's signatures on the requisition forms.

In Florida, AGL Laboratory Corp and its president Ileana Reinoso agreed to settle their civil liability under the False Claims Act for submitting false Medicare claims. The defendants agreed to be permanently excluded from participation in Federal health care programs and to release claim to approximately $103,675 in funds administratively suspended by their Medicare carrier. Although the defendants documented an inability to pay the judgements against them, both the laboratory and Reinoso agreed to the entry of judgements against them in the amount of $2.8 million and $27,000 respectively. They further agreed that about $215,300 in bank accounts frozen by the United States will be transferred to the Government. Over a ten-week period, this clinical laboratory submitted Medicare claims for diagnostic testing and received approximately $952,000 in payments. Interviews of the referring physicians listed on the laboratory's Medicare claims, however, disclosed they had not referred patients to the laboratory for testing. Moreover, most of the physicians had never seen the beneficiaries they supposedly referred.

Quest Diagnostics Incorporated agreed to pay the Government $15 million to resolve its civil liability under the False Claims Act and the Civil Monetary Penalties Law. Quest, formerly known as Corning Clinical Laboratories, Inc., entered into a joint venture agreement with Vivra Renal Care, Inc., to operate a clinical laboratory and perform laboratory tests for end stage renal disease (ESRD) patients. Between 1987 and 1996, the clinical laboratory allegedly billed Medicare and unbundled laboratory and medically

unnecessary tests and submitted claims with "boiler plate" diagnoses, without regard to the ESRD patient's true diagnosis, to facilitate payment of claims by Medicare. As a result, the clinical laboratory received approximately $5.8 million in Medicare overpayments.

Laboratory Corporation of American (LabCorp), the country's largest independent clinical laboratory, agreed to pay the Government $187 million to resolve civil and criminal liabilities for defrauding Medicare, Medicaid and various health care programs. LabCorp also agreed to enhance its existing compliance program by adopting a corporate integrity plan approved by the OIG. LabCorp allegedly submitted false claims for medically unnecessary laboratory tests. In addition to the civil settlement, Allied Clinical Laboratories, a subsidiary of LabCorp, pled guilty to a criminal charge relating to the submission of a false claim to the Medicare program. Allied will be excluded from participating in all Medicare and State health care programs.

In Ohio, Allied Clinical Laboratories signed a settlement and corporate integrity agreement in response to a qui tam action alleging false billing to Medicare, the Railroad Retirement Board (RRB) and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). Allied agreed to pay $4.9 million after investigation showed it used false diagnosis codes, lied about patient waivers, gave wrong addresses for nursing home patients, used blanket physician diagnosis letters to justify billing for limited-coverage tests, and used inaccurate provider numbers. Allied also agreed to train its employees, conduct annual reviews, establish standards of conduct, make certain annual disclosures to the Department for 5 years, and reimburse beneficiaries it had claimed executed waivers.

Damon Clinical Laboratories, formerly headquartered in Massachusetts, agreed in a global settlement to pled guilty to submitting false laboratory test billings to Medicare. Damon agreed to pay $119 million to the Government, more than $35.2 million as a criminal fine and over $83.7 million to resolve related civil liabilities. The $119 million represents recovery of three dollars for every dollar stolen from Medicare, Medicaid, the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and the Federal Employees Health Benefits Program. Damon bundled three extra tests in blood panels commonly requested by physicians, even though they did not request the extra tests. It then billed Medicare for the panel, and charged separately for the three tests. The global settlement was reached with Corning, Inc., which earlier had purchased Damon and stopped the illegal billing.

Two national clinical laboratories agreed to pay $11 million to settle allegations of submitting false claims to Medicare and other federally funded insurance programs by billing for certain blood profiles neither ordered by doctors nor medically necessary. The settlement by Corning Clinical Laboratories, Inc. - - formerly know as MetPath, Inc., and headquartered in New Jersey - - and Unilab Corporation, headquartered in California, resolves a civil fraud qui tam filed in New Jersey and covers laboratories in California, Colorado, Connecticut, Florida, Michigan, Missouri and Georgia. Whenever a doctor

ordered a complete blood count test, the laboratories billed Federal insurers for additional hemogram indices even though they were not requested or needed. Corning and Unilab denied any wrongdoing but wanted to settle the dispute.

In California, Spectra Laboratories, Inc., agreed to pay over $10 million to settle its civil liability for making false claims and paying kickbacks. Spectra is a clinical laboratory specializing in tests of end-stage renal disease patients. It submitted separate claims for tests to Medicare, the Railroad Retirement Board, the Civilian Health and Medical Program of the Uniformed Services, and the Federal Employees Health Benefits Program, when those programs had already paid the patient's dialysis centers for the tests under the composite rate. Spectra also devised schemes to induce payment for unnecessary laboratory tests such as a test-ordering system that permitted physicians to order all of the same tests for all of their patients, and paying salespersons commissions based on the Medicare reimbursements obtained from their accounts. As part of the settlement Spectra agreed to enter into a comprehensive compliance program. The compliance program requires, among other things, that Spectra implement a patient-specific test-ordering system and a tracking system that ensures proper billing of Parts A and B of the Medicare program.

Bioran Research Laboratory, based in Massachusetts, agreed to pay $6.7 million to settle civil allegations that it overcharged the Medicare program. An Office of Inspector General (OIG) investigation showed that between 1989 and 1992 Bioran routinely billed Medicare for a serum iron test whenever a physician requested a standard panel of tests. Physicians did not knowingly request the serum iron tests; rather, they assumed they were part of the standard panel. A computer analysis program development by the OIG investigator showed that Bioran, which was purchased by Corning Clinical Laboratories in 1994, improperly collected more than $3.352 million from Medicare for the serum iron tests. The computer program is readily adaptable to similar cases throughout the country.