ENSURING APPROPRIATE USE OF LABORATORY SERVICES

A MONOGRAPH

OFFICE OF INSPECTOR GENERAL

OFFICE OF EVALUATION AND INSPECTIONS

OCTOBER 1990

ENSURING APPROPRIATE USE OF LABORATORY SERVICES

A MONOGRAPH

OFFICE OF INSPECTOR GENERAL

OFFICE OF EVALUATION AND INSPECTIONS

OCTOBER 1990

ENSURING APPROPRIATE USE OF LABORATORY SERVICES

A MONOGRAPH

Richard P. Kusserow
INSPECTOR GENERAL

OEI-05-89-89150

OCTOBER 1990

EXECUTIVE SUMMARY

PURPOSE

This report examines forces that affect the use of diagnostic clinical laboratory services and explores alternative payment approaches.

BACKGROUND

Until recently, most Medicare legislation involving clinical laboratory services has focused on controlling the amount the program pays for services. Passage of the Omnibus Reconciliation Act of 1989 has focused attention on controlling utilization. It is in the context of this change in focus that this inspection examines the forces that encourage utilization of laboratory services and considers various solutions to control laboratory test use.

METHODOLOGY

We compiled information and data regarding clinical laboratory services from journal articles, previous government and private sector studies, Congressional testimony and from HCFA's Part B Medicare Annual Data (BMAD) files. We also obtained information on payment policies and utilization review procedures from 21 randomly selected Medicare carriers. Seven national associations, representing the medical and laboratory communities, also provided their perspectives. Additional information was obtained from the working files of previously published Office of Inspector General studies of physician office laboratories (POLs) and physician financial arrangements.

FINDINGS

The Use Of Clinical Laboratory Tests Is Rising.

- Between 1984 and 1988, Medicare Part B payments for laboratory services have more than doubled.

- The volume of clinical laboratory services has increased disproportionate to the increase in the beneficiary population, from approximately 116 million services in 1985 to nearly 148 million services in 1988.

- Testing accounts for nearly 25 percent of the line items paid by carriers.

Many Factors Influence Use Of Laboratory Tests.

- Physician ordering decisions are affected by the patient's condition and other factors such as fear of malpractice.

- Medicare's fee-for-service system financially rewards increased use.

- Researchers and our respondents confirm that many factors encourage use.

The Sheer Volume And Small Dollar Value Of Laboratory Services Render The Current Pre And Post Payment Review Systems Ineffective.

- Fragmentation, upcoding, test groupings and other billing idiosyncracies hinder accurate claim review and cause erroneous payments.

- The medical necessity of laboratory services is difficult to determine because no consensus exists on the appropriateness and intensity of laboratory services for a given medical condition or complaint.

Current Initiatives Do Not Fully Address Laboratory Use.

- Direct billing initiatives and other restrictions on who can bill for laboratory services do not alter incentives that encourage use.

- Reinstatement of the deductible and coinsurance for laboratory services may reduce Medicare laboratory payments. However, by itself, its effects on utilization are uncertain.

- Initiatives which would prevent physician ownership of any laboratory may adversely affect access to services.

- Competitive bidding initiatives focus on cost but raise questions on quality of services and may not control use.

- Practice guidelines may improve medical necessity determinations but will not alter the other problems inherent in the fee-for-service system.

- Volume performance standards may lower costs, but they may not affect individual treatment decisions.

Rolling Laboratory Reimbursement Into Office Visit Payments Is A Promising Strategy For Curbing Over Use.

- Laboratory roll ins would consolidate Medicare reimbursement for individual laboratory tests into the recognized charge for physician office visits.

- Laboratory roll ins would provide physicians with incentives to ensure appropriate use of clinical laboratory services and lower Medicare's administrative costs.

CONCLUSION

The LRI has the potential to alter the forces inherent in the current FFS system which encourage and reward excessive use of laboratory services. At the same time, it recognizes the physician's authority in determining which tests are medically necessary, does not unjustly penalize patients for decisions out of their control and leaves the marketplace and its dynamics unrestrained.

The major features of this mechanism would:

- be relatively easy to implement;

- provide appropriate incentives which allow for predictable, controlled growth of Medicare laboratory expenditures;

- reduce the number of claims line items processed by carriers by 25 percent;

- reduce the paperwork burden for billers and carriers; and,

- use deductibles and coinsurance where they can be most effective in affecting overall utilization of health care.

Implementation of the LRI would result in significant savings from increased coinsurance and lower administrative costs. We will shortly issue a report which further explores the financial implications of these features of the LRI reimbursement mechanism.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

This report examines forces that affect the use of diagnostic clinical laboratory services and explores alternative payment approaches.

BACKGROUND

By the end of 1986, Medicare and its beneficiaries were paying 45 percent more for Part B services than they had 3 years before.[1] Despite a freeze on physician payments, adoption of fee schedules, reductions in payments for certain services and other measures which should have controlled the growth of Part B expenditures, Medicare expenditures continue to grow. From 1975 to 1987 the rate of increase in Medicare payments per beneficiary for physician services was "... almost twice the compound annual rate of growth in the per capita gross national product and almost four times as much as the increase in Federal domestic spending...."[2]

A substantial portion of the growth in Medicare Part B expenditures is attributed to services ordered by physicians. In the period between 1985 and 1989, physician initiated services grew at a faster rate than overall Part B expenditures. Increases in volume and intensity of services accounted for roughly half of the increase in Medicare payments to physicians.[3] Volume increases reflect both increases in use and the fragmented billing of services that were formerly bundled and billed together.[4] Nowhere has increased use and fragmentation of services been more apparent than in the area of clinical laboratory services. Payments for laboratory services more than doubled between 1985 and 1989.

Both indigenous and exogenous influences have exacerbated the growth of clinical laboratory services. The exogenous factors most often cited include technological advances, spread of health insurance, oversupply of physicians, aging of the population, and malpractice liability,[5] as well as the implementation of the Prospective Payment System (PPS) for Medicare hospital inpatient services. Many articles have been written about how these exogenous factors have influenced the growth of Part B services including laboratory services. This report will only look at the indigenous causes and market forces unique to the laboratory environment. Only these indigenous causes can explain the inordinate growth which has occurred in the use of laboratory services.

Over the years, the Health Care Financing Administration (HCFA) made several attempts to control the growth of Medicare Part B expenditures for clinical laboratory services. The HCFA's approach relied primarily on voluntary disclosure of the actual charge incurred in securing laboratory work, on carrier scrutiny of laboratory claims, and on capping the amount paid per laboratory test. With the passage of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989), attention has now focused on controlling utilization. It includes the relative value scale (RVS) for physician payment; Medicare volume performance standards;

effectiveness and outcomes research to develop practice guidelines; prohibition of physician referrals to most laboratories in which they have ownership; and, restrictions on referrals among different clinical laboratories. It is in the context of these recent changes that this report examines factors that encourage utilization of laboratory services, and considers various solutions to control utilization.

SCOPE

This study looks at various forces which affect the use of laboratory services. It also examines the ability of the Medicare program to effectively enforce policies relating to these services and the environment in which they are secured. It does not include Medicare data on services provided to registered hospital outpatients, hospital inpatients and enrollees of health maintenance organizations. The report involves only non-hospital diagnostic clinical laboratory services.

METHODOLOGY

We compiled information and data regarding clinical laboratory services from journal articles, previous government and private sector studies, Congressional testimony and from HCFA's Part B Medicare Annual Data (BMAD) files. We also obtained information on payment policies and utilization review procedures from 21 randomly selected Medicare carriers. Seven national associations, representing the medical and laboratory communities, also provided their perspectives. Additional information was obtained from the working files of previously published Office of Inspector General studies of physician office laboratories (POLs) and physician financial arrangements.

FINDINGS

FINDING 1: The Use Of Clinical Laboratory Tests Is Rising.

Of the 19 billion diagnostic tests performed each year on Americans, a large portion are clinical laboratory services. In 1982, laboratory testing accounted for $11 billion in annual medical care costs.[6] By the end of 1986, the amount of money spent on laboratory testing had grown to $20 billion. Current estimates place the yearly laboratory market at $30 billion.[7]

Medicare annual expenditures for laboratory services parallels the growth in laboratory expenditures experienced by the nation as a whole. Medicare expenditures for Part B laboratory services have continued to escalate despite adoption of a fee schedule method of reimbursement and reductions in test payment amounts. Between 1984 and 1988, Medicare Part B payments for laboratory services (excluding hospital outpatient laboratory services) have more than doubled. In 1983, payments totalled approximately $800 million. By 1988, payments had risen to approximately $1.9 billion and are expected to exceed $2.5 billion in 1990. This growth in Medicare expenditures for laboratory services is not accounted for by increased Part B enrollment or by inflation, but is due to an increase in the volume of laboratory services and billing idiosyncracies inherent in the current fee-for-service (FFS) system.

FIGURE 1
Growth in Laboratory Expenditures Despite Reductions in Payment

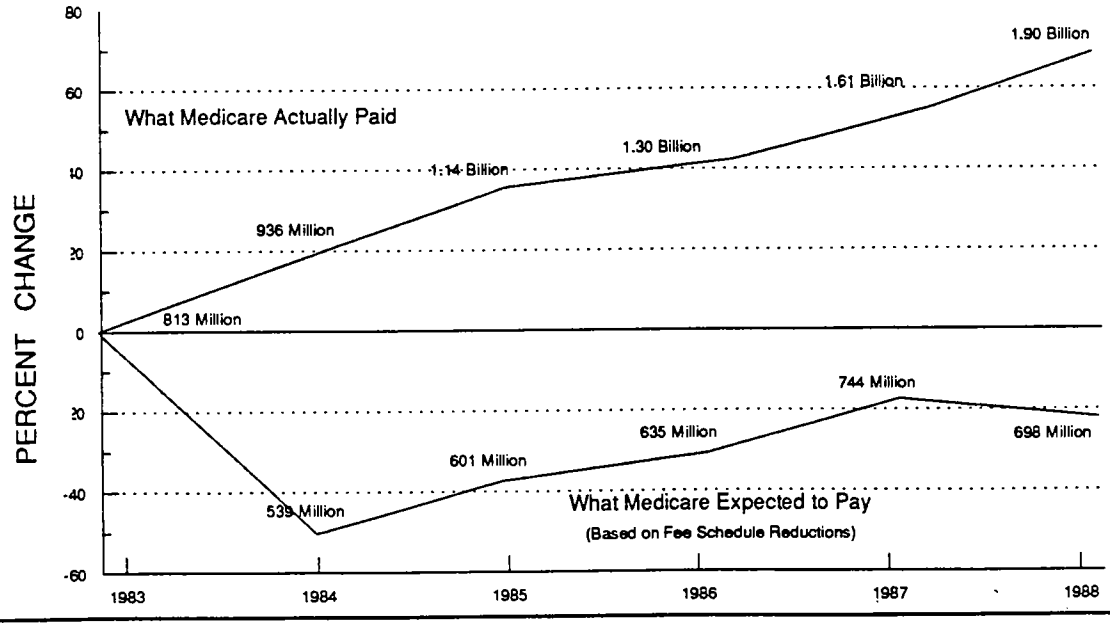

Figure 1 illustrates the escalation that has occurred in Medicare expenditures for clinical laboratory services from 1983 through 1988. The bottom line represents projected annual expenditure levels resulting from adoption of fee schedules and subsequent increases and

reductions in payment levels. The bottom line has been adjusted to reflect the growth in the beneficiary population. The top line, in Figure 1, shows what Medicare has actually paid for clinical laboratory services since adoption of the fee schedules in 1984. The graph clearly demonstrates that adoption of the fee schedule did not reduce Medicare expenditures for laboratory services or slow the rate of growth.

In addition to the growth in expenditures, the volume of laboratory services paid by the Medicare program has also increased disproportionate to the increase in the beneficiary population, from approximately 116 million services to nearly 155 million services between 1985 and 1988. This growth in the volume of laboratory services is consistent with the effects predicted in a 1982 study conducted for HCFA. That study concluded that reductions in payment levels are often offset by increased volume.[8]

FINDING 2: Many Factors Influence Use Of Laboratory Service

Physician ordering decisions are affected by the patient's condition and other factors.

Once a patient decides to seek medical care, subsequent decisions about medical services are almost entirely in the hands of the physician. The kinds and intensity of services that the patient receives are usually out of the patient's control.[9]

Medicare and other insurers reinforce the control of the physician in procuring clinical laboratory services by paying only for tests which are ordered by a physician and which the physician has determined are medically necessary.[10] Medicare and most other insurers will not pay for patient initiated tests, routine testing and tests which are not medically indicated.

There are many reasons which explain why physicians order laboratory tests when caring for their patients. Experts, who have studied physician behavior, report that the most common reasons to explain why physicians order laboratory tests are: to reduce uncertainty in their diagnosis and management of a patient,[11] to search for asymptomatic disease, to monitor chronic conditions and to validate previous test findings.[12] Other reasons include physician need to be complete, lack of experience, poor test interpretation, routine screening, ordering packaged clusters of tests and fear of malpractice suits.[13]

One study suggests that individual physician test-ordering behavior often becomes routinized over time.[14] This individual behavior has hindered the development of a consensus, among physicians and professional associations, over acceptable test ordering protocols.[15] This lack of consensus in test ordering behavior has been observed by researchers, who compared use of laboratory services in different practice settings and under different financial incentives.[16, 17] Other researchers have focused on the variability of tests ordered for a specific diagnosis and the absence of correlation with improved patient outcome.[18,19,20,21,22,23]

The market impinges on ordering decisions in ways that encourage increased use of tests.

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.

This competitive market impinges on two aspects of the test ordering decision: where to have the test run, and how much testing to order. Both aspects are affected by those who stand to profit from the test ordering decision, which can include the physician ordering the test as well as the laboratory that runs the test.

In vying for referrals, laboratories may offer volume discounts and customized packages of tests to gain a competitive edge. Discounts are based upon expected volume of referrals and other cost and competitive factors presented by each client. They often may have little or no relationship to the actual cost incurred in performing a test. "...[A] laboratory 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."[24] Such discounts are possible because the discount price of a laboratory test is often significantly different from the amount paid by Medicare and other third party insurers. On the average, Medicare reimbursement rates are nearly twice as much as the discount amount paid by physicians and other laboratories for tests. When groups of tests are purchased, Medicare pays even more.[25]

A laboratory will also offer customized test packages as a way of attracting patient referrals by giving the test orderer "personalized" service, tailored to the needs of that physician's practice. These customized groupings of tests are often sold to wholesale clients (physicians, hospitals and other laboratories) at considerable discount. Many wholesale clients subsequently bill their patients and insurers, such as Medicare, for more money than they actually paid. A 1988 survey found that the average mark-up on purchased laboratory work was 139 percent. The same survey found that sixteen percent of the surveyed physicians charged patients and insurers more than three times the price charged to them by the laboratories that actually conducted the tests.[26]

In addition to discounts, 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. It is not uncommon for physicians and laboratories to share telephones, computer hardware and software, laboratory and other medical equipment, office supplies, management services and personnel.[27] 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.

The market competition for test volume and patient referrals is further complicated if the test orderer stands to profit from where the test is performed. Having ownership interest in a laboratory can significantly increase a physician's revenues.[28,29] In response to this potential new source of revenue, many physicians have established laboratories in their offices or expanded their existing POL testing capabilities. Others, practicing independently of one another, have pooled their resources to establish joint venture or collaborative laboratories.[30] In some areas of the country, independent and hospital laboratories have entered into joint ventures with physicians to retain their market share. Having physicians as partners not only makes joint ventures competitive but also increases their laboratory profitability by assuring a sufficient patient base.

Having a financial interest in a laboratory which performs tests can affect a physician's decision to order tests. A recent Office of Inspector General report to Congress established that at least 25 percent of the nearly 4500 independent clinical laboratories (ICLs) are owned in whole or in part by referring physicians. The same report found that Medicare "[p]atients of referring physicians who own or invest in ICLs received 45 percent more clinical laboratory services than all Medicare patients....[And] 34 percent more services from independent clinical laboratories than all Medicare patients...."[31] Laboratory owners and participants in laboratory joint business ventures are aware that the financial success of their laboratory depends on the number of patients referred by partners in the laboratory.

Medicare's FFS reimbursement system financially rewards increased use of laboratory tests.

Under the FFS system, increased use of medical services is rewarded. The FFS reimbursement system pays for medically necessary services provided to a Medicare beneficiary. Services are provided by physicians and others who then submit bills itemizing the services they have provided to Medicare's fiscal agents for payment. This means that the more services are ordered, rendered and billed, the more Medicare pays to the biller. This reward system intensifies competition for the finite pool of referrals needed to succeed financially.

For nearly 2 decades, HCFA has sought to reduce Medicare expenditures for clinical laboratory services by bringing Medicare reimbursement more in line with the wholesale prices offered to physicians and other laboratories. The original approach to resolve the discrepancy between payment levels and wholesale prices relied on voluntary disclosure of the actual charge incurred in securing laboratory work and on carrier scrutiny of laboratory claims. When voluntary efforts proved ineffective, a series of laws (listed in appendix A) were enacted to reduce expenditures by controlling the amount Medicare paid for laboratory services. These attempts to control payment resulted in volume increases which not only offset anticipated savings by also resulted in increased expenditures.

Furthermore, in the DEFRA 1984 legislation HCFA eliminated the beneficiary deductible and coinsurance with regard to laboratory services, softening its attempts to curb laboratory expenditures by reducing the financial burden on the beneficiaries. This resulted in Medicare picking up additional costs that were once the responsibility of the beneficiary. Reinstatement

of deductibles and coinsurance for laboratory services is being considered. Further discussion about coinsurance for laboratory services are included in finding 4.

Researchers and our respondents confirm that many factors influence the increased use of laboratory tests.

Articles from newspapers and academic/professional journals and government reports have also examined the overuse of laboratory services. Recently published findings of the Blue Cross and Blue Shield Association and the American College of Physicians suggest that "20-60 percent [of clinical laboratory testing] may be unnecessary."[32] Many researchers who have studied physician use of laboratory services have noted overutilization of laboratory services as part of an overall increase in physician services. Others have analyzed the problem of excessive test ordering by looking at the incentives inherent in the medical and payment systems.[33,34,35,36,37,38,39]

In our discussions with carriers, 14 of 21 felt that physicians ordered too many tests, although they disagreed over the extent of the problem. The laboratory and medical associations we contacted acknowledged that the use of laboratory services has increased and that some of this increase might be attributable to routine screening of patients. They felt that laboratory tests are relatively inexpensive compared to other alternatives for diagnosing a patient's medical status. They strenuously objected, however, to studies which indicated that much of the laboratory work being ordered was medically unnecessary or excessive.

According to the people we interviewed and journal articles in this area, a variety of exogenous factors influence the growth in laboratory services, including the aging of the population, the oversupply of doctors, the presence of health insurance and other factors. A more specific factor cited was increasing physician dependence on "objective" measures, rather than professional judgment, in making diagnoses.[40] Growth in testing also suggests increased documentation of the diagnostic/treatment process as a part of "defensive medicine." Of the objective measures or documentation sought by physicians, low-cost, readily available items such as laboratory services contribute a greater share of health care costs than expensive items like magnetic resonance imaging, CAT scans, etc.[41]

FINDING 3: The Sheer Volume And Small Dollar Value Of Laboratory Services Render The Current Pre And Post Payment Review Systems Ineffective.

The sheer volume of laboratory services and the diversity of billers present logistical problems for carrier monitoring efforts. In 1988 carriers paid for nearly 148 million laboratory services at an average payment of $12.46 per service. All 21 carriers felt that increasing their efforts to police laboratory services would increase their administrative cost disproportionate to any savings that might be realized.

The accuracy of payments made for laboratory services depends to a great extent on the ability of Medicare carriers to identify suspect services and intervene in their payment. Carriers are authorized to pay only for covered services furnished to Medicare beneficiaries. The services must be reasonable and medically necessary, furnished in the most appropriate setting and billed accurately to reflect the services rendered.[42] Carriers claim that their efforts to police laboratory services do not give them sufficient return to cover expenses. In 1988, clinical laboratory services represented approximately 5 percent of total Medicare Part B expenditures but accounted for nearly 25 percent of the Medicare Part B service volume.

Fragmentation, upcoding, test groupings and other billing idiosyncracies hinder accurate claim review and cause erroneous payments.

Carrier systems are vulnerable to laboratory claims information which has been manipulated to maximize reimbursement. Fragmented billing, customized profiles and upcoding or procedure inflation are common methods employed to manipulate the FFS system. Although HCFA and the carriers recognize that these vulnerabilities and others exist and have attempted to safeguard their claims processing systems, we found wide variation in carriers' interpretations of the problems and in their ability to detect and intervene when claims information has been manipulated.

Fragmentation is a common problem carriers encounter when reviewing claims for clinical laboratory services. It is common practice for physicians to order the tests they use most often in the form of packages which have been customized and tailored for their individual needs. Medicare would like to see these packages billed and paid the way they were purchased - as a single item.

Billers of laboratory services argue that they are unable to bill packages as a single procedure code because no single code exists which accurately describes the package.[43] Their assessment is correct. Few Medicare procedure codes exist which accurately describe the packages being ordered. This situation exists because the packages being ordered have been customized for individual physician needs. It is unlikely that Medicare could ever develop enough procedure codes to accurately describe all of these customized packages of laboratory services.

When the OIG looked at laboratory procedures, 37 percent of the line items billed to Medicare were found to have been ordered by physicians as packaged tests defined by Medicare as profiles.[44] Yet, HCFA's BMAD files do not list a single profile procedure code (codes 80050 through 80099) in the top 60 procedures billed to Medicare from 1985 to 1987. In 1987, only 2 million laboratory services billed to Medicare were identified as profiles. Using data from this previous study, we project that more than 55 million laboratory services should have been billed and paid as profiles.

Another billing practice which results in erroneous laboratory payments is upcoding or "procedure inflation."[45] Upcoding involves billing for a more complex service or procedure than was actually performed.[46] The Medicare program is vulnerable to laboratory service

upcoding because as many respondents told us, multiple procedure codes exist which define essentially the same laboratory procedures. As new methods are introduced, more procedure codes are added often with higher reimbursement rates than the older methods. The number of billing codes available to describe a test enables physicians and laboratories to select codes which will result in the highest payment. Upcoding is not easily detected by screens and often requires in-depth review of records by a trained laboratory technician.

The medical necessity of laboratory services is difficult to determine.

The Medicare carriers must deny or adjust payment for claims they determine to be medically unnecessary.[47] Unlike claims for primary care, carriers have a difficult time determining the medical necessity of laboratory services because no consensus exists concerning the appropriateness and intensity of laboratory services for a given medical condition or complaint.[48] Individual physician test ordering behavior has continued for so long that carrier data analysis no longer provides meaningful insight into acceptable test ordering protocols, but merely shows the lack of consensus which exists among physicians concerning the medical necessity of laboratory tests.

Determining medical necessity is further complicated by the complex claim development which carriers must undertake to arrive at many medical necessity decisions. It is not uncommon for a carrier to receive bills for laboratory services from several different laboratories for a single patient's episode of illness. For a single episode of patient care a carrier could receive a bill for services from a POL and from one or more ICLs and/or hospital operated laboratories (HOLs). The cost of ensuring that each individual test provided was medically necessary and not in excess of the patient's needs is a tremendous burden on the carriers which, given the volume of services, appears unrealistic.

When carriers question the medical necessity of laboratory services provided to a patient, they not only must validate that each laboratory involved performed the work they billed, but also that the patient's medical record establishes that the laboratory tests performed were medically necessary. If a laboratory service is determined to be unnecessary, the carrier must recover the payment made. Under the current system, payment is made to the entity (physician or laboratory) which performed the actual tests. When the carrier determines that a laboratory service was not medically indicated or that the services were in excess of the patient's need, recovery is made from the biller(s). The ICLs and HOLs argue that they should not be penalized for following physician orders. They argue that Medicare's recovery of payments often leaves them without any means to collect payment for work they have performed.

Carrier reviews of laboratory claims are often reversed on appeal.

All of the carriers we spoke to expressed a sense of futility concerning the effectiveness of much of the work they have done in policing laboratory claims. Even when they deny claims for payment, an increasing number are appealed, reprocessed and paid.[49] Carriers claim that the reprocessing of claims lost on appeal further increases administrative costs associated with laboratory services. Some carriers feel that had they paid the original claim, the overall cost

to the Medicare program would have been less than the expenses they incurred in developing a service for denial, preparing for the appeal, and reprocessing cases lost on appeal.

All of the carriers with whom we spoke agreed that the costs associated with policing laboratory claims exceed the money that would be recovered or saved if payment was denied. At a time when carrier budgets are being restrained, it appears unrealistic to expect them to police and correct the problems associated with laboratory services, especially in an environment where entrepreneurs identify vulnerabilities in carrier systems and openly market strategies to take advantage of those vulnerabilities to maximize reimbursement.[50] In the case of laboratory services, the cost of policing the industry and the claims it produces is unrealistic and probably would cost more than the value of the services billed.

FINDING 4: Current Initiatives Do Not Fully Address Laboratory Use.

Current Medicare initiatives to control use would prohibit physician referrals to most laboratories in which they have ownership, restrict referrals among different clinical laboratories and establish volume performance standards. Other proposals would reinstate coinsurance for laboratory services, ban physician ownership of laboratories entirely, require that laboratory services be procured through competitive bidding or use practice guidelines to control use. These approaches may not be adequate because the FFS system which promotes increased use remains in effect. Even the competitive bid proposals allow some aspect of the FFS system to remain.

Direct billing initiatives and other restrictions on who can bill for laboratory services do not alter incentives that encourage use.

Direct billing initiatives place restrictions on who can bill Medicare for a clinical laboratory service. Since 1984 and the passage of the Deficit Reduction Act (DEFRA 1984), physicians and laboratories can bill only for work they actually perform. The DEFRA 1984 banned physicians from billing Medicare for work they purchased from independent and hospital laboratories. The DEFRA 1984 did not prohibit laboratories from referring work to other laboratories and billing for the referred work.

The DEFRA 1984 clearly affected laboratory services. Some physicians responded by opening their own laboratories or entering into joint ventures with established ICLs and HOLs. Some of the new laboratories were merely "shells" and performed little or no actual testing. Some arrangements between ICLs/HOLs and physicians circumvented the intent of the law by simply exchanging regulated Medicare and Medicaid patient testing for nonregulated private pay patient testing. Some physicians received reduced prices from ICLs/HOLs on their nonregulated private pay patients if they referred their regulated Medicare/Medicaid patients to the ICL/HOL.

The exact number of laboratories, joint ventures and other creative arrangements established in response to DEFRA 1984 is unknown. The number of POLs established following the enactment of DEFRA 1984 is unknown, because POLs are not subject to regulation until

1992. The number of physician/HOL joint ventures is also unknown. The only available data shows that by 1988 physicians owned, or were involved in joint ventures with nearly 25 percent of the 4500 ICLs certified by Medicare. "Patients of referring physicians who own or invest in ICLs received 45 percent more clinical laboratory services than all Medicare patients...." [51]

In 1989, Congress passed OBRA 1989 which placed further restrictions on who can bill for laboratory services. The OBRA 1989 legislation bans most physicians from referring their Medicare patients to laboratories that they own, or in which they have a financial interest. Laboratories are no longer permitted to bill for work they have purchased from other laboratories unless they perform in-house 70 percent or more of the work they bill.

Four major difficulties remain with direct billing initiatives. The utilization review problems inherent in the FFS system are unchanged. Creative arrangements to secure a predictable volume of patient referrals will continue to flourish and may even be encouraged as they were by earlier legislation. Policing these arrangements will continue to be difficult and time consuming. Finally, basic incentives affecting physician ordering decisions and which result in increased use of laboratory services will still exist.

Reinstatement of the deductible and coinsurance for laboratory services may reduce Medicare laboratory payments. However, by itself its effects on utilization are uncertain

As mentioned in finding 2, reinstatement of deductibles and coinsurance for laboratory services has been proposed. Such a move may reduce the Medicare outlays by shifting a portion of expenditures back to the beneficiary. If utilization can be controlled, savings in Federal outlays could exceed several billion dollars over a 5-year period.

Deductibles and coinsurance would also place an increased administrative burden on those billing laboratory services. Additional paperwork and personnel time would be required for patient billing and collection. The average laboratory charge is relatively inexpensive (less than $12.50 based on 1988 Medicare data), yielding an average coinsurance amount of about $2.50. The cost of collecting the coinsurance could conceivably equal or exceed this amount, but in any case could be considered disproportionately large compared to the amounts to be collected.

Some believe that giving the beneficiary a greater financial stake in laboratory expenditures may encourage them to more actively participate in test ordering decisions, thus affecting utilization. Cost sharing may motivate beneficiaries to discuss the potential costs and benefits of certain laboratory tests with their physicians. On the other hand, it is the physician, not the patient or the laboratory, who is most influential on the number and kinds of tests to order.

The effectiveness of deductibles and coinsurance in controlling utilization is most evident in those areas where the patient has more control over the decision, such as whether to visit the physician in the first place. We believe there is a strategy which uses deductibles and

coinsurance where they will be most effective, in the beneficiary's decision to access the health care system. It is described in finding 5.

Initiatives which would prevent physician ownership of any laboratory may adversely affect access to laboratory services.

Some laboratorians suggest that Medicare could control escalating laboratory use by banning physician ownership of any laboratory. These initiatives would either ban physician laboratory ownership entirely or prevent payments for laboratory work performed by physicians and businesses with physician ownership interest. To be effective, initiatives which prohibit physician ownership would need to extend to all laboratory work and not simply apply to tests performed for Medicare and Medicaid patients. Any initiative which does not apply to all patients would, in all likelihood, exacerbate arrangements between ICLs, HOLs and physicians. The complexities of an almost infinite number of arrangements would make it difficult, if not impossible, to determine the legality of each specific arrangement.

The only viable solution would be to remove the financial incentive from the physician decision. Removing the financial incentive could only be done by prohibiting physician ownership and financial interest in any laboratory, including POLs. This initiative could hurt patient access to laboratory services in rural areas where POLs and physician owned ICLs may be the main or only source of services.

Competitive bidding initiatives focus on cost but raise questions on quality of services and may not control use.

The HCFA has considered using competitive bid to procure laboratory tests for Medicare patients. The HCFA competitive bid initiatives stem from the reported success of competitive bidding in the State of Nevada.

The State of Nevada established a sole source competitive bid project to secure laboratory testing for Medicaid patients in that State. Two laboratories perform all the testing ordered for Medicaid patients. All other laboratories (ICLs, POLs and HOLs) are foreclosed from providing covered laboratory services for Medicaid patients. According to HCFA, the Nevada sole source competitive bid project succeeded in reducing the number of laboratory tests conducted on Medicaid patients by nearly 50 percent.

The HCFA competitive bidding initiatives differ considerably from that used by Nevada. The number of laboratories allowed to perform tests on Medicare patients is not restricted as severely as in the Nevada program. Increasing the number of laboratory testing sites greatly reduces the economies brought about by increased volume. The Medicare models also allow physicians to get paid for tests they perform in-house. This de facto exemption of POLs puts roughly half of all Medicare Part B laboratory services outside the constraints of the competitive bid proposals. Any proposal which does not apply to about half of the relevant services is unlikely to achieve substantial savings for Medicare.

Both the laboratory and physician community expressed concern that competitive bidding might compromise laboratory test quality and harm patients. They felt competitive bidding might encourage laboratories to cut corners and consequently compromise patient care.

Practice guidelines may improve medical necessity determinations but will not alter the other problems inherent in the FFS system.

The medical associations with whom we spoke suggested that Medicare control laboratory use by using clinical practice guidelines. They suggest that clinical practice guidelines being developed be used by Medicare to determine the medical necessity of laboratory services. Practice guidelines should be developed because they could improve the quality of treatment provided to patients by reducing physician uncertainty. Used as a baseline, the agreed upon parameters for medical treatment may also help to reduce the risk and costs associated with malpractice suits against physicians.

Unless practice guidelines are combined with additional safeguards, they will do little to correct overuse. We support establishing practice guidelines because they will be useful in identifying under-treatment. However, most guidelines set a floor but not a ceiling, and consequently, have little or no effect on the incentives in the FFS system which lead to excessive use of services.

Volume Performance Standards (VPS) may lower costs, but they may not affect individual treatment decisions.

The VPS establish aggregate payment and volume targets for Medicare Part B physician services and payments including clinical laboratory services. Future growth in Medicare Part B payments to physicians will be related to past expenditures for physician services and to the volume of physician services provided to patients. If physicians, as a whole, exceed the targets they would get little or no update in their fees the following year. If physicians meet the target, they would get a full fee update.

Critics of VPS claim that VPS aggregate targets do not provide incentives which will alter individual physician behavior. Service intensive physicians could continue to increase the intensity of services they provide, penalizing physicians whose practice of medicine is more conservative.

The VPS represent an innovative approach to control total costs. The challenge remains to provide incentives for controlling individual use of services. We believe that a strategy exists that will meet this challenge at the level of individual behavior and is compatible with and supportive of VPS.

FINDING 5: Rolling Laboratory Reimbursement Into Office Visit Payments Is A Promising Strategy To Ensure Appropriate Use.

The use of laboratory roll ins (LRIs) appears to be a promising strategy for curbing the use of laboratory services. Under LRIs, reimbursement for individual laboratory tests would no longer be made by the Medicare program. Clinical laboratory reimbursement would be rolled into Medicare's recognized charge for physician office visits and treated as an indistinguishable part of a physician office visit. Medicare would no longer process any claims for diagnostic clinical laboratory services (HCPC procedure codes 80000 through 89999). Reimbursement for laboratory services would be a fixed amount added to the recognized charge for physician outpatient office visits (HCPC procedure codes in the 90000 series excluding inpatient services). The new recognized charge (which includes the LRI) for physician outpatient office visits would continue to be subject to deductible and coinsurance.

To illustrate how a LRI might be calculated, we used the 1988 BMAD file and redistributed the $1.84 billion Medicare allowed for laboratory services across paid physician office visits (90000 series procedure codes). This calculation resulted in a base LRI of $13.50 per office visit ($1.84 billion Medicare allowed/1.37 million office visits).

To determine the potential impact on physician specialties, we compared the $13.50 LRI with each specialty's average reimbursement for laboratory services under the FFS system. Allowed amounts and service volume for clinical laboratory services billed by pathologists, osteopathic (DO) pathologists and nonphysician specialties such as ICLs, were distributed to all physician specialties based on the proportion of services each physician specialty ordered from an outside source. To do this we isolated patients who were seen by a single physician in 1988. This enabled us to obtain a complete picture of all laboratory services a patient received, no matter who billed. From this initial step we were able to calculate the number of POL services provided by each specialty to each patient in the sample. We were also able to calculate the number of services each specialist ordered from an outside source. The same method was used to determine the dollar value of tests.

The financial impact that a $13.50 base LRI would have on physicians is shown in the table on the following page. The last two columns of the table compares the average laboratory payment for each office visit under the FFS system with a base LRI of $13.50. The last column in the table indicates whether the physicians in each specialty are likely to paid more or less than they were under the FFS system.

Table 1

Effect of $13.50 base LRI on Physician Specialties

Specialties	Total Office Visits	Avg. OV Per Bene	Total[1] Lab Services	Average[1] Lab Svcs. Per Visit	Total[1] Paid For Lab	Average Lab Paid/OV Under FFS	+/- [2]
	FFS Data						
01 General Practice	164397	4.04	171047	1.04	$1,994,179	$12.13	+
02 General Surgery	59213	2.25	44058	0.74	$ 688,192	$11.62	+
03 Allergy	4873	3.86	1993	0.41	$ 27,603	$ 5.66	+
04 ENT	30316	1.75	9109	0.30	$ 156,879	$ 5.17	+
05 Anesthesiology	1720	2.04	1488	0.86	$ 17,574	$10.22	+
06 Cardiovascular Disease	68718	2.82	61454	0.89	$ 770,907	$11.22	+
07 Dermatology	31090	2.05	19163	0.62	$ 476,851	$15.34	-
08 Family Practice	2033692	3.86	248498	1.22	$2,969,973	$14.58	-
09 Gynecology (DO Only)	158	1.93	121	0.76	$ 1,604	$10.15	+
10 Gastroenterology	19166	2.04	20824	1.09	$ 279,981	$14.61	-
11 Internal Medicine	414798	4.07	581949	1.40	$6,927,411	$16.70	-
12 Manipulative Therapy (DO)	2719	4.07	2775	1.02	$ 32,614	$11.99	+
13 Neurology	20595	1.85	10206	0.50	$ 143,340	$ 6.97	+
14 Neurological Surgery	4734	1.61	1628	0.34	$ 20,450	$ 4.32	+
15 Obstetrics	62	3.88	6	0.10	$ 89	$ 1.44	+
16 OB-Gynecology	15791	1.59	14780	0.94	$ 162,037	$10.26	+
17 EENT (DO only)	776	1.69	829	1.07	$ 10,011	$12.90	+
18 Ophthalmology	51108	1.87	19544	0.38	$ 259,173	$ 5.07	+
19 Oral Surgery	490	1.49	467	0.95	$ 8,965	$18.30	-
20 Orthopedic Surgery	44331	2.10	13663	0.31	$ 198,422	$ 4.48	+
23 Peripheral Vascular (DO)	364	2.55	145	0.40	$ 3,162	$ 8.69	+
24 Plastic Surgery	3185	1.64	2035	0.64	$ 55,851	$17.54	-
25 Physical Medicine	4545	2.11	1212	0.27	$ 19,235	$ 4.23	+
26 Psychiatry	5171	2.24	5731	1.11	$ 79,640	$15.40	-
28 Proctology	1195	1.56	696	0.58	$ 8,621	$ 7.21	+
29 Pulmonary Disease	18896	2.79	14146	0.75	$ 194,073	$10.27	+
30 Radiology	5403	1.71	2810	0.52	$ 39,368	$ 7.29	+
31 Radiology (DO)	394	4.86	1234	3.13	$ 12,169	$30.89	-
32 Radiation Therapy	221	1.44	158	0.71	$ 1,907	$ 8.63	+
33 Thoracic Surgery	6529	1.64	2805	0.43	$ 39,938	$ 6.12	+
34 Urology	42338	2.13	63880	1.51	$ 618,795	$14.62	-
36 Nuclear Medicine	157	1.91	147	0.94	$ 4,422	$28.17	-
37 Pediatrics	2820	3.21	2926	1.04	$ 34,838	$12.35	+
38 Geriatrics	429	3.06	488	1.14	$ 5,832	$13.60	-
39 Nephrology	8042	3.03	10162	1.26	$ 126,568	$15.74	-
40 Hand Surgery	240	1.95	82	0.34	$ 1,240	$ 5.17	+
41 Optometry	4085	1.40	2242	0.55	$ 28,757	$ 7.04	+
48 Podiatry	28746	2.14	13134	0.46	$ 173,675	$ 6.04	+
49 Misc. Physician	1779	2.96	4568	2.57	$ 81,513	$45.82	-
70 Clinic or Group Practice	91362	3.62	123852	1.36	$1,706,841	$18.68	-
88 Unknown	40	2.22	55	1.38	$ 266	$ 6.65	+
99 Unknown Physician	259	2.35	1122	4.33	$ 15,597	$60.22	-

Source: One percent sample of the 1988 BMAD files

[1] *Includes laboratory services billed by non-physician specialties such as independent clinical laboratories which were distributed among the physician specialties. This was done because only physicians are reimbursed using LRI.*

[2] *This column represents whether a physician specialty, on average, would be paid more or less under LRI than under the fee-fo service system.*

Strengths of this approach.

There appears to be little disagreement among researchers and experts in health economics that "Effective cost control can be achieved only by controlling prices and the number of services simultaneously...."[52] Studies have explored the possibility of Medicare controlling the cost of some services "...by redefining the payment unit from a narrow procedure to a more comprehensive bundle of services."[53]

Rolling laboratory reimbursement into Medicare's recognized charge for an office visit would redefine the office visit payment unit from a narrow procedure to a more comprehensive package of services. The resulting increase in office visit charges will increase patient cost sharing through the effect of deductibles and coinsurance, and may affect their decision to seek health care.[54,55] Furthermore, carriers have told us that it is easier to evaluate the medical necessity of office visits compared to the time and effort needed to make such decision on individual laboratory tests.

This approach to paying for clinical laboratory services is not without precedent. HMOs and the Diagnostic Related Groups to reimburse hospitals for inpatient care are the most visible examples. Other less visible packages include global surgical fees and demonstration projects involving high volume procedures such as cataract and coronary artery bypass surgeries.[56]

LRIs would provide physicians with appropriate incentives to control use

When the laboratory and medical professional associations were asked why laboratory use has increased they mentioned the need to reduce uncertainty, searching for asymptomatic disease, need to be complete and many of the other factors documented by researchers. Everyone mentioned the rise in malpractice litigation as a primary cause of increased clinical laboratory use.

Everyone we spoke to agrees that the use of laboratory procedures is likely to decline if Medicare's reimbursement for them is combined into a more comprehensive physician office visit package. Many people expressed concern that physicians would severely curtail their use of clinical laboratory services resulting is poor quality of patient care. While we agree that laboratory use will decline, we find the argument that the decline would jeopardize the quality of patient care to be unlikely. The adoption of LRIs will not change all the forces that have caused the increased use of laboratory services. In fact some, like the threat of malpractice, will work in conjunction with LRIs to prevent the possibility of under-treatment. It appears unlikely that most physicians would risk malpractice litigation for the small sums of money needed to secure laboratory work.

The possibility that test use would decline to such low levels as to impair the quality of patient care is further mitigated by the development of practice guidelines or protocols. These guidelines would set minimum requirements for tests needed to determine a given diagnosis, thus providing definitions and boundaries for evaluating possible under-treatment. Even

without national uniform guidelines, Professional Review Organizations (PROs) could use local standards of practice to initiate action to sanction physicians who provide inadequate care to patients.

LRIs will lower administrative costs

Bundling all laboratory reimbursement into the recognized charge for physician office visits would eliminate over 25 percent of the line items currently processed by Medicare carriers. The elimination of laboratory bills would save the Medicare program at least $100 million in administrative costs annually. Existing billing codes, systems and payment procedures need not be revised. Only Medicare's recognized charge for an office visit changes under LRIs.

Medicare could concentrate its efforts to enforce laws and regulations designed to ensure quality testing, rather than police the legality of physician/laboratory joint ventures and other financial arrangements. Carrier time would be freed to pursue activities which result in program savings. Medical necessity reviews would focus on the need for office visits and target physicians who increase their office visits, rather than individual laboratory tests or procedures.

Issues for Further Exploration

During the course of this study several issues were raised concerning the impact of LRIs. Many of the issues raised were beyond the scope of this study but need to be considered before implementation of a LRI.

The following areas need to be explored:

- How could hospital outpatient services be included in calculating the base LRI? Exclusion of hospital outpatient laboratories from a LRI would in all likelihood shift services to hospital laboratories and undermine program savings.

- Should the base LRI be adjusted to account for geographic variations (e.g. rural vs. urban)?

- Should the base LRI be adjusted for certain physician specialties, or should certain specialists be excluded from a LRI payment method?

- Should certain tests be excluded from a LRI payment method?

- Would the quality of patient care suffer if physicians curtail testing?

- Will quality of testing suffer as physicians become more cost conscious?

- Will the forces (malpractice, need to reduce uncertainty, etc.) that have influenced physician ordering decisions in the past be adequate to prevent under use of laboratory services in a LRI system?

- Can practice guidelines be used to prevent under use?

- Will patient access to care be impaired?

Some of these issues will be examined in greater detail in an additional OIG report, to be released shortly.

CONCLUSION

The LRI has the potential to alter the forces inherent in the current FFS system which encourage and reward excessive use of laboratory services. At the same time, it recognizes the physician's authority in determining which tests are medically necessary, does not unjustly penalize patients for decisions out of their control and leaves the marketplace and its dynamics unrestrained.

The major features of this mechanism would:

- be relatively easy to implement;

- provide appropriate incentives which allow for predictable, controlled growth of Medicare laboratory expenditures;

- reduce the number of claims line items processed by carriers by 25 percent;

- reduce the paperwork burden for billers and carriers;

- use deductibles and coinsurance where they can be most effective in affecting overall utilization of health care.

Implementation of the LRI would result in significant savings from increased coinsurance and lower administrative costs. We will shortly issue a report which further explores the financial cost implications of these features of the LRI reimbursement mechanism.

ENDNOTES

1. *Social Security Bulletin. Annual Statistical Supplement*, 1988, p. 282.

2. William L. Roper, M.D., "Perspectives on Physician-Payment Reform," *New England Journal of Medicine*, September 29, 1988, P. 866.

3. Roper, p. 866.

4. Roper, p. 866.

5. U.S. Dept. of Health and Human Services, Health Care Financing Administration, *Economic Factors in the Use of Laboratory Tests by Office-Based Physicians*, by Patricia Munch Danzon, R-2525-1-HCFA, (Santa Monica, CA: Rand, August 1982), p. 60.

6. Patricia Munch Danzon, Willard G. Manning, and M.S. Marquis, "Factors Affecting Laboratory Test Use and Prices," *Health Care Financing Review*, Summer 1984, p. 23.

7. Spencer Vibbert, "Is Utilization Review Paying Off?" *Business & Health*, February 1989, p. 24.

8. Danzon, *Economic Factors in the Use of Laboratory Tests by Office-Based Physicians*, p. 61.

9. Office of Technology Assessment, *Payment for Physician Services: Strategies for Medicare*, (1986), pp. 48-49, 56.

10. Thomas Rice, "Physician-induced Demand for Medical Care: New Evidence from the Medicare Program," *Advances in Health Economics and Health Services Research*, 1984, pp. 129-160.

11. Stan N. Finkelstein, M.D., "Technological Change and Clinical Laboratory Utilization," *Medical Care*, October 1980, p. 1055.

12. E.L. Overholt, "The Use of the Laboratory: Dollars and Sense," *Wisconsin Medical Journal*, 1989, pp. 38-41.

13. Judith Thompson Barr, "Design and Analysis of Interventions to Modify Utilization of Therapeutic Drug Monitoring," Diss. Harvard 1987, pp. 31-39.

14. Finkelstein, pp. 1055-1056.

15. Lawrence S. Linn et al., "Differences in the Numbers and Costs of Tests Ordered by Internists, Family Physicians, and Psychiatrists," *Inquiry,* Fall 1984, p. 266.

16. Linn et al., p. 266.

17. U.S. Dept. of Health and Human Services, Office of Inspector General, Office of Analysis and Inspections, *Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress,* OAI-12-88-01410, (Washington, D.C.: May 1989), p. 18.

18. J.M. Eisenberg et al., "Computer-Based Audit to Detect and Correct Overutilization of Laboratory Tests," *Medical Care,* 1977; 15:915-921; summarized in Judtih T. Barr, "Improved Laboratory Utilization and Information Production: The Administrator's New Role," *Journal of Medical Technology,* October 1986, p. 512.

19. S.A. Schroeder et al., "The Failure of Physician Education as a Cost Containment Strategy," *Journal of the American Medical Association,* 1984;252: 225-230; summarized in Barr, "Improved Laboratory Utilization and Information Production," p. 512.

20. P. Griner and B. Liptzin, "Use of the Laboratory in a Teaching Hospital," *Annals of Internal Medicine,* 1971; 75:157-163, summarized in Barr, "Improved Laboratory Utilization and Information Production," p. 513.

21. S.P. Martin et al., "Inputs into Coronary Care During 30 Years," *Annals of Internal Medicine,* 1974; 81:289-293, summarized in Barr, "Improved Laboratory Utilization and Information Production," p. 513.

22. Margaret DiNatale and Judith Barr, "Variations in Clinical Laboratory Utilization: Lessons for Relative Rank Feedback Strategies," unpublished draft, August 27, 1989.

23. Judith Barr, "Clinical Laboratory Utilization: The Role of the Clinical Laboratory Scientist," in *Clinical Laboratory Practice,* ed. Brenta G. Davis, Michael L. Bishop, and Diana Mass, pp. xxxi-xlv.

24. *Laboratory Payment Issues,* Testimony of the American Clinical Laboratory Association Before the Subcommittee on Health and the Environment. June 8, 1989, p. 35.

25. U.S. Dept. of Health and Human Services, Office of Inspector General, Office of Audit, *Changes are Needed in the Way Medicare Pays for Clinical Laboratory Tests,* CIN:A-09-89-00031 (Revised) (Washington, D.C.) pp. 5-6.

26. *Laboratory Payment Issues*, p. 41.

27. *Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress*, pp. 11, 17.

28. James R. Wood, "Cooperative Partnership," *American Clinical Products Review*, April 1988, p. 22.

29. David Hemenway, "Physicians Responses to Financial Incentives," *New England Journal of Medicine*, Vol. 322:15, April 12, 1990, pp. 1059-1063.

30. J. Stephen Kroger, M.D., "Legislation, Regulations Provide Opportunities, Pitfalls," *The Internist*, September 1985, p. 17.

31. *Financial Arrangements Between Physicians and Health Care Businesses*, p. 18.

32. Vibbert, p. 24.

33. Finkelstein, p. 1055-1056.

34. Vibbert, p. 24.

35. Danzon, *Economic Factors in the Use of Laboratory Tests by Office-Based Physicians*, p. 60.

36. Danzon, Manning, Marquis, "Factors Affecting Laboratory Test Use and Prices," p. 23.

37. *Payment for Physician Services: Strategies for Medicare*, pp. 48-49, 56.

38. Kroger, p. 17.

39. R.A. Hughes et al. "The Ancillary Services Review Program in Massachusetts," *Journal of the American Medical Association*, 1984;252: 1727-1732, summarized in Barr, "Improved Laboratory Utilization and Information Production," p. 512.

40. Finkelstein, p. 1055-1056.

41. Danzon, Manning, Marquis, "Factors Affecting Test Use and Prices," p. 23.

42. 42 CFR 421, Subpart C.

43. *Laboratory Payment Issues*, p. 35.

44. *Changes are Needed in the Way Medicare Pays for Clinical Laboratory Tests*, p. 7.

45. Janet B. Mitchell et al., "Packaging Physician Services: Alternative Approaches to Medicare Part B Reimbursement," *Inquiry*, Winter 1987, pp. 324-325.

46. Rhonda L. Rundle, "How Doctors Boost Bills by Misrepresenting the Work They Do," *Wall Street Journal*, December 6, 1989, p. 1.

47. 42 CFR 421.200 (a)(2).

48. Linn et al., p. 266.

49. *Medicare Contractors*, Testimony of Richard P. Kusserow, Inspector General, Dept. of Health and Human Services Before the Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, and Education, February 28, 1989, p. 8.

50. "About Lab-net, Inc." *Physicians' Laboratory Newsletter*, 4, No. 4 (Spring 1987), pp. 2-3.

51. *Financial Arrangements Between Physicians and Health Care Businesses*, p. 18.

52. Mitchell et al., p. 325.

53. Dept. of Health and Human Services, Health Care Financing Administration. *Growth in the Volume and Intensity of Physician Services: Issues and Options*, (1989), p. ES-8.

54. *Payment for Physician Services*, pp. 48-49, 56.

55. Danzon, Manning, Marquis, "Factors Affecting Test Use and Prices," pp. 25-27.

56. *Growth in the Volume and Intensity of Physician Services: Issues and Options*, pp. 4-4 to 4-6.

APPENDIX A

Legislative History and its Effects on Laboratories

Legislation/Regulation	Provisions of Legislation/Regulation	Effects of Legislation/Regulation
OBRA - 1980	Required physicians to disclose the actual cost of the lab services they purchased form ICLs.	The legislation attempted to eliminate reimbursement for mark-ups on lab services. Some physicaians responded by opening their own laboratories or expanding their current physician office lab services.
PPS - 1983	Bundled inpatient lab services into the DRG payments.	Inpatient lab services became unprofitable. Hospitals had incentive to eliminate or contain costs of lab services performed on an inpatient basis. Pre-admission and post-hospital lab testing were encouraged to move from the hospital setting to POLs. Hospitals cut back on the amount of lab equipment they purchased. Manufacturers began to market their lab equipment to POLs and home markets. Physicians were further encouraged to open POLs.
DEFRA - 1984	Established area/regional fee schedules for ICLs and hospital labs. Mandated that ICLs and hospitals accept assignment for laboratory claims. Eliminated beneficiary deductibles and copayments. Required establishment of national fee schedule for lab services. Limited reimbursement for drawing and handling fees. Discontinued reimbursement for interpretation fees. Instituted direct billing provision. Placed a freeze on the customary and prevailing fees for all physicain services	The number of POLs and volume of testing in POLS increased dramatically.

Legislation/Regulation	Provisions of Legislation/Regulation	Effects of Legislation/Regulation
COBRA - 1985 **COBRA - 1986** **OBRA - 1986**	Brought POLs under the regional fee schedule. Required POLs to accept assignment. Placed a ceiling on regional fee schedule. Delayed implementation of the national fee schedule. Lifted MD fee freeze.	Brought POLs under the same regulations as hospitals and ICLs.
OBRA - 1987	Placed a freeze on area rates. Stipulated that a national fee schedule be used beginning 1-1-90. (not implemented) Reduced the national limitations amount. Reduced area ratedson the most common tests. Eliminated CPI increases.	Laboratory use increases 25 percent. Studies suggest that physicians made up for revenues lost during MD fee freeze by increasing use of ancillary services, particularly laboratory services.
CLIA - 1988	License required for all sites where laboratory work is performed. Degree of regulation tied to complexity of testing.	Too early to determine.
OBRA -1989	Bans physicians from referring patients to most labs that they own or in which they have financial interest as of 1-1-92. Physician services to be paid using a resource-based relative value scale. Volume Performance Standards established. HHS to fund outcomes research on quality and appropriateness of medical care. Balance billing limits would apply beginning in 1991. Cap on clinical laboratory fees set at 93 percent of the national median fee.	Too early to determine.

Gloria Randle Scott

Gloria Randle Scott, was the first black woman National President of the Girl Scouts (1975-1978), and is the eleventh president (second female) of Bennett College in Greensboro, North Carolina (1987 to present).

Dr. Scott has been a leader in higher education and an advocate of women's issues for a long time. Her career began in early 1960 as a research associate in genetics and embryology at Indiana University Institute for Psychiatric Research. In 1961, she became the first black biology teacher at a predominantly white college in Indianapolis. It was during her tenure there that she made a decision to work at black colleges. She felt that she and her husband could offer their knowledge and experience to black children by team-teaching. Having been a poor girl herself, she felt there were many other poor children who needed help in making it through. Dr. Scott has been providing support and direction for years, holding faculty and administrative positions at black colleges, including Clark College in Atlanta, Grambling State University, North Carolina State A&T University, and others.

Gloria Scott was born on April 14, 1938, in Houston, Texas. She knows what hard times and segregation are all about. When she was in the second or third grade, she had a paper route. As a little girl, she was not allowed to go to the public libraries in Houston because they were not opened to blacks. Public libraries there did not become desegregated until she was a senior in high school. Nevertheless, it was the money from a trust established, by a rich white man without a family, for black high school students that afforded her the opportunity to go to college. The money that this rich man had was the result of hard labor by black people who worked for him. It was the persuasion of his black bookkeeper that he established the scholarship fund.

Dr. Scott received the Bachelor of Arts and Master of Arts degrees in Zoology in 1959 and 1960, respectively, and the Ph.D. degree in higher education in 1965 from Indiana University. Her honorary degrees include: Doctor of Law from Indiana University in 1977; Doctor of Humane Letters from Fairleigh Dickinson University in 1978; and Doctor of Humane Letters from Westfield State College in 1989. She has extensive leadership experience and has served on numerous boards of directors, including the Greensboro Chamber of Commerce, and Delta Sigma Theta Sorority, Inc.

Gloria Scott believes that one must have a base from which to start and those who have made it must provide the base, direction and support for those who follow.