Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CLIA's IMPACT ON THE AVAILABILITY OF LABORATORY SERVICES

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EXECUTIVE SUMMARY

PURPOSE

To determine whether the Clinical Laboratory Improvement Amendments of 1988 have restricted the availability of laboratory services to Medicare patients.

BACKGROUND

In February 1992, the Health Care Financing Administration (HCFA) issued regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These amendments extended Federal regulation to all sites, including a significant number of physician office laboratories (POLs) and other sites that had previously been exempt from Federal regulation. The passage of CLIA has raised concern that laboratory sites, especially POL sites, might cease operations and thus restrict patient access to certain types of laboratory tests. Concerned about this possibility, HCFA requested that we conduct this study.

FINDINGS

Since passage of CLIA in 1988, the volume, number of tests per patient and expenditures have increased rapidly. Growth seems to have slowed after implementation in 1992, but data is incomplete.

The number of laboratory tests used in patient care has risen consistently since 1983. In 1983, Medicare paid for an estimated 139 million laboratory tests. In 1988, the year in which CLIA was passed, Medicare paid for 232 million laboratory test; today, Medicare pays for more than 403 million tests annually. The number of laboratory tests provided to Medicare Part B enrollees has more than doubled from five tests per enrollee in 1985 to an estimated 12 tests per enrollee in 1993.

The CLIA appears not to have affected physician ability to secure laboratory services for their patients.

None of the 232 physician practices, including the rural practices, contacted during this study indicated that they had any trouble securing laboratory tests for their patients. All had access to a laboratory and nearly all (98%) used more than one laboratory to perform testing. We found that the number of physicians having access to an in-office laboratory has remained unchanged since 1988 even though the actual number of POL sites operated by them has decreased. This is, in part, due to the consolidation of medical practices that has resulted in larger physician groups.

Only 38 counties in the United States have no physician medical practices and no laboratories. While POL sites are not as common, rural counties have 7.4 hospital laboratory sites per 100,000 persons versus 5 such sites per 100,000 population in non-rural counties. Since hospital sites are more likely to perform moderate and high complexity testing, persons living in rural areas appear to have available to them laboratory sites equivalent to their non-rural counterparts.

Physicians who changed their in-office laboratory operations were influenced by factors broader than CLIA; these influences include other government regulations and non-government factors, such as sales, mergers and managed care.

Of the 232 physician practices we contacted in our 2 random samples, 18 had closed a POL site and 8 had opened new sites. Eleven primarily cited governmental regulations as reasons for closure, three cited governmental and non-governmental factors, and four cited primarily non-governmental factors. The governmental factors included the Stark Amendments, Occupational, Safety and Health Administration requirements, CLIA and/or other government initiatives. Physician decisions to close an in-office laboratory were often not attributable to a single cause but to the cumulative effect of multiple factors.

Non-government factors have also caused some laboratory operators, including POLs, to re-evaluate the kinds of testing they offer and the number of sites they operate. Between 1988 and 1994, non-government factors appear to have affected physician in-office laboratories. Of the 232 practices we contacted, 64 volunteered information about the sale, merger, or changes in their practices. Of these, 30 noted non-government factors as the major reason for change in their in-office laboratory operations. These changes were the primary influence in their decision to close their in-office laboratory or to limit the kinds of testing they perform.

The CLIA appears to have affected the type of testing performed in POLs. Growth in the volume of tests billed by POLs appears to have slowed. Shifts from moderate and high complexity test procedures to waived testing procedures are evident in glucose, sedimentation rates and other areas of testing. While volume for some other procedure codes billed by POLs has declined, this decline was also experienced by all laboratories billing these codes; thus, indicating that factors other than CLIA may have influenced volume.

COMMENTS ON THE DRAFT REPORT

We received comments on our draft report from the American Medical Association, American Society of Internal Medicine, American Clinical Laboratory Association and HCFA. Based on comments we received, we have reordered and reworded the report findings. The full text of comments received can be found in Appendix E.

The HCFA and the American Clinical Laboratory Association concurred with our report findings. The American Medical Association and the American Society of Internal Medicine pointed out that our study does not address CLIA's impact on patient convenience or the speed and quality of testing afforded by physician in-office laboratory testing. While important subjects, these issues were beyond the scope of our inquiry which was simply to determine whether CLIA has restricted the availability of laboratory services.

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INTRODUCTION

PURPOSE

To determine whether the Clinical Laboratory Improvement Amendments of 1988 have restricted the availability of laboratory services to Medicare patients.

BACKGROUND

Clinical laboratory regulation

In February 1992, the Health Care Financing Administration (HCFA) issued regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These amendments require HCFA to identify and regulate all sites where analysis of blood, urine, tissue and other specimens derived from the human body takes place. The passage of CLIA marks the first time that Federal regulation of laboratories was extended to all sites, including a significant number of physician office laboratories (POLs) and other testing sites that had previously been exempt from Federal regulation.

Initially, the new amendments divided laboratories into three groups based on the sophistication of the testing they perform.[1] All laboratory tests are classified as either waived, moderate or high complexity. The nine tests in the waived category include those that:

- are approved for home use by the Food and Drug Administration,
- pose no reasonable risk of harm to patients if performed incorrectly, and
- employ simple and accurate test methodologies that reduce the likelihood of erroneous results.

Laboratory sites performing tests in the moderate and high complexity categories must institute quality assurance programs and meet specific personnel standards and quality control requirements. These laboratories are subject to periodic onsite inspections and must successfully engage in an approved proficiency testing program. The test

[1] Physician-performed microscopy (PPM) was later added as a separate sub-category of moderate complexity testing. While physicians performing tests in this sub-category are not subject to routine inspections, they must meet the same standards that apply to moderate complexity testing with the exception of personnel standards. In a final rule published April 24, 1995, HCFA expanded the "physician-performed microscopy" sub-category to include PPM tests performed by certain mid-level practitioners in addition to physicians. The name of the sub-category was changed, accordingly, to "provider-performed microscopy."

methodologies in the moderate and high complexity categories are more complex and can pose great risk of harm to the patient if not performed correctly.

All laboratory sites must pay registration fees and must follow manufacturers' instructions to ensure that equipment functions properly and that test results are reliable. However, laboratory sites performing only waived tests are exempt from CLIA standards including quality assurance requirements.

Registration and inspection fees are based on the level and volume of testing being performed. An inspection fee is charged only if the laboratory undergoes an inspection.

Laboratory specimen collection and analysis

Many physicians collect patient blood, urine, tissue and other specimens for laboratory analysis in their office. When the physician has an office laboratory some or all of the patient's specimens will be analyzed onsite. Tests that the physician office is incapable of performing are usually picked up by courier(s) and transported to independent or hospital-owned reference laboratories capable of performing the desired tests.

When specimens are not collected in the physician's office, patients are sent to an independent or hospital-owned laboratory or collection site. Nothing requires a physician to use the nearest laboratory facility; consequently, the distance a patient must travel to obtain laboratory tests varies considerably. Patient preference, urgency, the nature of the test, insurance requirements, physician contractual obligations and practice affiliations are but a few of the factors that influence how far a patient may have to travel to obtain laboratory services. Consequently, patients living in urban areas where laboratory testing site density is greatest often travel distances comparable to patients living in rural areas to secure laboratory tests.[2]

In most cases, laboratory test results are returned to the ordering physician in 24 hours or less. Turnaround times greater than 24 hours were usually encountered when testing methodologies required longer processing times (i.e., cultures).[3]

Other environmental influences

Regulations implementing the Clinical Laboratory Improvement Amendments were published in February 1992. Between passage of the law in 1988 and its implementation in 1992, numerous other changes were also taking place.

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[2] "CLIA-88: Clinical Laboratory Improvement Amendments of 1988 Impact Study," Levine Associates, Inc., April 1992, Vol 1, Page A-17.

[3] When physicians need a test result immediately (i.e., to confirm a diagnosis for a potentially life threatening situation and to decide whether to admit a patient to the hospital) they will request that a test be done "STAT." Such requests are rare and when STAT testing is required, the closest laboratory capable of doing the testing is usually used. In many cases this is a hospital laboratory.

On the private side, growth of managed care fueled sales, mergers and changes in physician business affiliations. Also influencing physicians, hospitals, clinical laboratories and other health care entities were Occupational, Safety and Health Administration requirements and the "Stark Amendments," which generally prohibit physicians from referring patients to entities in which they have a financial interest.

While POLs are exempt from the Stark Amendments, many joint ventures and other business arrangements between physicians and other laboratory operators are prohibited. Awareness of prohibited business ventures and practices increased during the 5 year period following passage of CLIA. The number of patients enrolled in managed care grew and the number of entities providing managed care services also increased. New Federal and State laws, coupled with policy, billing and payment reforms, the rise in managed care and increased competition for patients, affected nearly everyone involved in providing medical care.

Implementation of CLIA has raised concern that laboratory testing sites, especially POL sites, might cease operations and thus restrict patient access to certain types of laboratory tests. Concerned about this possibility, HCFA requested that we conduct this study.

SCOPE AND METHODOLOGY

The scope of this study was limited to those factors that would enable us to determine whether the Clinical Laboratory Improvement Amendments of 1988 had restricted the availability of laboratory services to Medicare patients. This study does not address CLIA's impact on patient convenience or CLIA's impact on the quality of physician in-office laboratory testing.

We assessed three major questions through our methodology: overall trends in laboratory usage, physician access to laboratory testing, and influences (both governmental and non-governmental) on laboratory testing patterns. To develop information on these questions, we accessed a number of data sources.

Trends in Overall Volume, Type and Frequency of Testing. We analyzed the volume, type and frequency of laboratory tests provided to Medicare patients between 1985 and 1993, including an analysis of where laboratory testing was conducted. We used 1 percent samples of laboratory data obtained from HCFA's Common Working File and its predecessor the Part B Medicare Annual Data file. These 1 percent samples have been extracted annually, since 1985, by the Office of Inspector General from data maintained and collected by HCFA.

Carrier data in HCFA's Common Working File for 1992 and 1993 was consistent with information collected by the Office of Inspector General in earlier years and with other published statistics. However, the Common Working File hospital outpatient laboratory data for 1992 and 1993 appears to be inconsistent with other data collected

during this study. Therefore, we derived our own estimates of hospital outpatient laboratory test volume and expenditures and did not use the 1992 and 1993 Common Working File data.

We assumed the hospital outpatient department share of the laboratory marketplace to be 40 percent for the years 1990 through 1993. This percentage was reported as the 1990 hospital share of the laboratory marketplace by Levine and Associates, Inc. in a study released in 1992. Other industry estimates place the hospital outpatient market share of laboratory services, in 1994, at 50 percent or more. While some evidence exists to support the higher figure for 1994, we used 40 percent for each year beginning with 1990 and ending with 1993. Hospital outpatient data on laboratory services for years prior to 1992 is based on estimates published in other studies.

Physician Access to Laboratory Testing. This indicator involved two parts. First, we assessed trends in the numbers of physician office laboratories. We recontacted the 200 medical practices that participated in a study we conducted in 1988. We knew from our 1988 study which medical practices were operating a POL in 1988. We recontacted them to determine what, if any, impact CLIA had on their laboratory operations. We were able to contact 176 of the 200 medical practices selected for our 1988 study.

Second, we charted the availability of laboratories to physicians. We used HCFA's Online Survey, Certification and Reporting System database to identify Medicare certified laboratories. Our analysis was based on CLIA certificates and not sites. Therefore, hospitals operating multiple laboratory sites under one CLIA certificate were counted as one site. However, if the hospital chose to have a separate certificate for every site they operated, each site was included in our analysis.

Our decision to count as one entity multiple laboratory sites under a single certificate reduces the number of sites used in our analysis from the 151,658 reported by HCFA to 129,634. The net effect of this decision understates the actual number of laboratories available for use by physicians and patients.

We combined HCFA's Online Survey, Certification and Reporting System data with HCFA provider number information and with 1990 census information. This resulting data set enabled us to analyze the number and location of medical practices and laboratory sites available to physicians and patients.

Government and Non-Government Influences on Testing. To understand what factors may have affected laboratory testing (both governmental and non-governmental) we used the responses of the 176 medical practices that participated in our 1988 study. We also used a HCFA file that identified 1,532 medical practices. Each of these medical practices had advised HCFA that they would no longer perform laboratory tests. Using this file, United States Postal Service zip codes and 1990 census information enabled us to identify 658 medical practices that met our definition of rural. We selected 112 of these 658 rural practices using simple random sampling, and

attempted to contact them by telephone to determine the current status of their laboratory operations. We also wanted to know whether they were experiencing any problems in securing laboratory services for their patients.

Of the 112 rural practices selected at random, 56 agreed to participate in this study. The remaining 56 fell into 2 groups. One group consisted of 12 practices that refused to participate in our study and the other consisted of 44 practices that had closed, merged or moved outside the rural county in our sample.

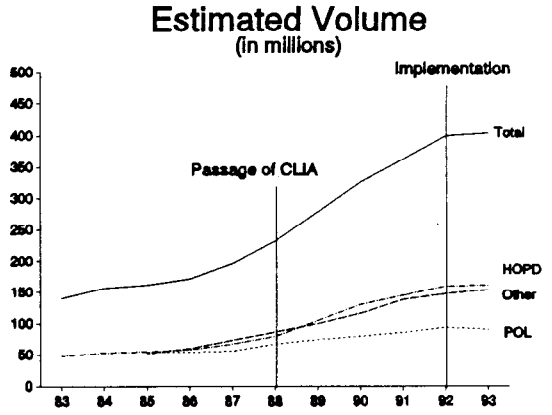
To identify rural counties, we used statistics from the United States Bureau of the Census. If the Bureau of the Census classified more than 50 percent of the residents in a county as rural, we classified that county as a rural county. Medical practices within these counties were considered "rural" for purposes of this study.

Overall, in our two samples, we spoke to 232 physician practices, the American Medical Association, the American Clinical Laboratory Association, the American Society of Internal Medicine and the Health Industry Manufacturers Association for their views on the impact of the 1988 laboratory amendments. We also reviewed a number of other studies and articles about CLIA, physician practice trends and laboratory services.

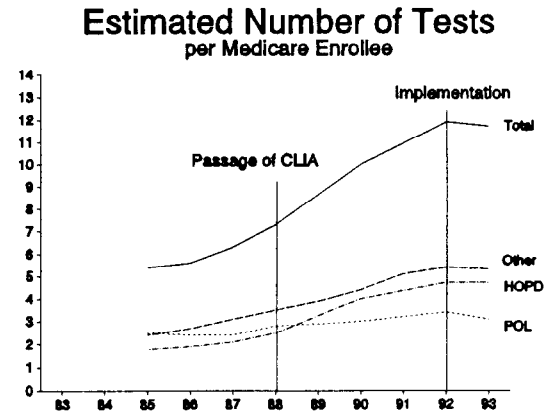
FINDINGS

Finding 1: Since passage of CLIA in 1988, the volume, number of tests per patient and expenditures have increased rapidly. Growth seems to have slowed after implementation in 1992, but data is incomplete.

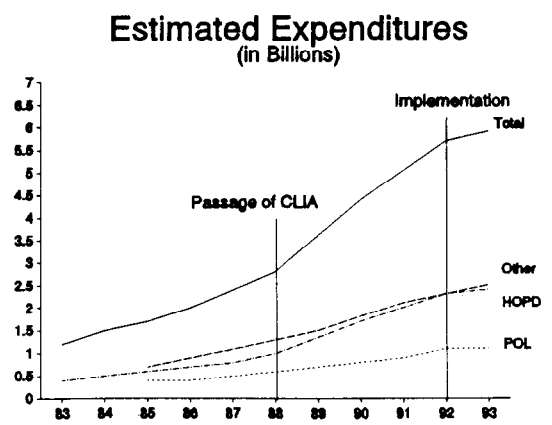
Continued growth in the laboratory marketplace indicates that the 1988 amendments have not impaired the availability of laboratory services. The volume of laboratory services provided to Medicare patients has increased each year since 1983. The top graph to the right shows estimated growth in the volume of laboratory tests experienced by the Medicare program. In 1983, the Medicare program paid for an estimated 139 million laboratory tests. In 1988, the year CLIA was passed, Medicare paid for 232 million tests. By the end of 1993, this number had grown to over 403 million tests annually.



The middle graph shows the estimated average number of laboratory tests provided to Medicare Part B enrollees. This number has more than doubled between 1985 and 1993. In 1985, Medicare paid for five laboratory tests per Medicare Part B enrollee. In 1988, the year CLIA became law, Medicare was paying for approximately seven tests per Part B enrollee. By the end of 1993, Medicare was paying for nearly 12 tests per Part B enrollee.



The bottom graph reflects our estimate of the total dollars paid by the Medicare program for outpatient laboratory services. In 1983, Medicare expenditures for these services were just over $1 billion. In 1988, the year CLIA became law, Medicare was paying $2.8 billion. At the close of 1993 payments had risen to $5.9 billion.



As these graphs show, the number of laboratory tests used in patient care has risen consistently since the passage of CLIA in 1988.[4] Over the last 10 years, the number of Medicare beneficiaries has increased by less than 3 percent a year. Growth in the volume of laboratory services provided to them has averaged 17 percent a year.

The 1993 data appears to show that the rapid growth of Medicare laboratory services has slowed and that POL services declined slightly since implementation of CLIA in 1992. However, our data is incomplete. Only when hospital outpatient data becomes more reliable will we be able to determine whether growth has, in fact, leveled off, declined or continues to increase.

Finding 2: The CLIA appears not to have affected physician ability to secure laboratory services for their patients.

All of the 232 physician practices we contacted in our 2 random samples indicated that they had access to a laboratory and nearly all (226 of the 232 or 98.3%), including those operating POLs, used more than one laboratory to perform some of their testing. Medical practices that collected their own patient specimens had daily courier service(s) that picked up specimens for analysis at other laboratory sites. Physicians who did not collect laboratory specimens in their office sent their patients to nearby collection sites.

We found that the number of physicians with access to an in-office laboratory has remained unchanged since 1988. In 1988, we projected that 162,100 physicians had access to an in-office laboratory (operating a POL). Based on our recontacts with these medical offices, we project that 162,300 physicians still had access to an in-office laboratory in 1994. This information (obtained from physicians who were in active practice in 1988 and who were still in active practice in 1994) indicates that CLIA has had little impact on physician access to in-office laboratories. Complete survey information can be found in Appendix A.

Examination of survey results shows that the number of POLs (41,400) operated by physician groups remains unchanged, although the number of physicians in the groups has increased. The number of POLs operated by physicians in solo practice had declined from an estimated 57,000 sites in 1988 to an estimated 44,500 sites in 1994. This decline in the number of POLs operated by physicians in solo practice appears to reflect the ongoing trend away from solo practice and toward larger group practices.[5]

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[4] Data for POLs and "Other" sites (primarily independent clinical laboratories) is actual billing data. The hospital outpatient department (HOPD) data is projected. Totals reflect projected hospital outpatient data and actual Part B data for POLs and Other.

[5] Philip R. Kletke, David W. Emmons and Kurt D. Gillis, "The Changing Proportion of Employee Physicians: Evidence of New Trends." (Chicago: American Medical Association, 1994).

As of January 30, 1995, HCFA had issued CLIA certificates to 151,658 laboratory sites.[6] On average, there are nearly 51 clinical laboratory sites for every 100,000 persons and nearly 1 site for every 4 physicians. All but 66 of the 3,140 counties in the United States have at least 1 medical practice site and at least 1 laboratory site. Of the 66 counties without a single laboratory, 38 have no physician medical practices and no laboratory sites. Additional information about the types and numbers of CLIA certificates and counties without laboratories can be found in Appendices B and C, respectively.

Adjusting for population density, rural counties compare favorably with non-rural counties. While rural counties have fewer POL sites and independent laboratory sites they make up for this shortage with other laboratory sites. For example, rural counties have 7.4 hospital laboratory sites per 100,000 persons versus 5 such sites per 100,000 population in non-rural counties. Since hospital sites are more likely to perform moderate and high complexity testing, persons living in rural areas appear to have available to them laboratory sites equivalent to their non-rural counterparts. However, rural POL sites are not as common as in non-rural areas. Table A provides additional information on how rural counties compare to their non-rural counterparts.

Table A

Average Number of Laboratories by Type for Rural and Non-Rural Counties			Average Number of Laboratories per 100,000 Population by Type for Rural and Non-Rural Counties		
TYPE	RURAL	NON-RURAL	TYPE	RURAL	NON-RURAL
Hospital-owned laboratories	1.1	5.5	Hospital-owned laboratories	7.4	5.0
Independent laboratories	0.2	4.1	Independent laboratories	0.5	1.6
Physician office laboratories	6.0	65.4	Physician office laboratories	24.2	30.7
Other Laboratories	4.4	25.6	Other Laboratories	26.5	19.1

[6] For analysis purposes we eliminated multiple certificates issued to laboratories located at the same site. This reduced the number of laboratory sites used for analysis to 129,634 sites.

Finding 3: Physicians who changed their in-office laboratory operations were influenced by factors broader than CLIA; these influences include other government regulations and non-government factors, such as sales, mergers and managed care.

POL Closures

Of the 232 physician practices we contacted in our 2 random samples, 18 had closed a POL site and 8 had opened new sites. Eleven primarily cited governmental regulations as reasons for closure, three cited governmental and non-governmental factors, and four cited primarily non-governmental factors. The governmental factors included the Stark Amendments, Occupational, Safety and Health Administration requirements, CLIA and/or other government initiatives.[7] Physician decisions to close an in-office laboratory were often not attributable to a single cause but to the cumulative effect of multiple factors. Government related reasons given for closing an in-office laboratory include:

- Management or other arrangements for procuring laboratory services that might violate Federal or State statutes enacted since 1988. (2 of the 1988 sites)

- Increased cost of doing business to comply with personnel, quality control and proficiency testing regulations and/or the cost to comply with CLIA regulatory requirements. (4 of the 1988 sites and 6 rural sites)

- Red tape, hassle and inability to show a profit due to non-specified Federal or State regulations. (2 rural sites)

- Low reimbursement. (4 rural sites)

Information collected during this study indicates that some medical practices may have closed their POL prematurely. More than half of all the practices in this study that reported closing their POL due to CLIA did so during the period between passage of the amendments in 1988 and publication of the final regulations in February 1992. This indicates that their decision to close was not based on the final regulations as published by HCFA.

Between the passage of the Amendments in 1988 and the implementation of the final regulations in 1992, there was much speculation as to what the final regulations would be and what the effect of regulation would be on POLs. The final regulations actually allowed more laboratory tests into the waived category than were originally anticipated. The final regulations governing personnel standards and other controversial aspects of CLIA were also considerably different than first proposed.

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[7] As noted earlier, POLs are exempt from requirements of the Stark Amendments. Despite this, respondents did note this as a factor in their decision to close their POL.

Additional evidence that some POLs may have prematurely closed can be found in the number of POLs that advised HCFA that they were closing operations due to CLIA and subsequently did not do so. In our rural sample, we found 33 of 56 physician practices that had advised HCFA that they would close their POL due to CLIA had reconsidered this decision and were still operating their in-office laboratory.

Non-government influences may have had a greater impact on physician in-office laboratory testing than did government influences. Of the 232 physician practices contacted during this study, 7 of 18 POLs that closed indicated that their decision was influenced in part, or totally, by non-government factors.

Sixty-four told us in unsolicited discussion that the organization of their practice had changed since 1988. About a third of the 64 practices indicated that they had downsized. The rest indicated that their affiliation with other physicians or institutions had resulted in a larger medical practice organization. Many had become employees of a hospital, others had merged with other physician practices and some had become more involved with health maintenance organizations and other managed care entities.

Of the 64 practices that volunteered information about the sale, merger or changes in their practice, nearly half (30 practices) indicated that the change had affected their in-office laboratory testing. Respondents provided anecdotal information about what happened to their in-office laboratories. Several indicated that, after their practice was sold to a hospital, testing at the office was reduced to waived tests or eliminated altogether. Several respondents mentioned that, following the hospital acquisition of their practice, an in-office laboratory was established to perform waived tests. In virtually all cases involving hospital acquisition of a physician practice, the hospital required that tests of moderate and high complexity be sent to the hospital. Other physician respondents indicated that their affiliation with a managed care entity required them to use a specific laboratory and that they subsequently closed their in-office laboratory because the managed care entity would not pay them for in-office laboratory testing.

At this point in time, information about physician business practices and alliances is available. However, without reliable hospital outpatient laboratory data and managed care laboratory data the impact of the changing business environment on POLs is unclear. Information obtained from study respondents suggests that sales, mergers and other changes in physician practice have influenced the number of POL sites in operation and the types of tests performed at those sites.

POL Testing

To assess the extent to which CLIA may have limited the kinds of tests being offered by POLs, we analyzed 60 laboratory procedures billed to Medicare carriers between January 1, 1985 and December 31, 1993. Analysis of billing data for these 60 laboratory tests shows POL volume for chemistry tests has increased each year since

the passage of CLIA.[8] The increase in POL chemistry test volume indicates that POLs continue to provide this testing and the volume continues to increase.

The 1988 amendments dictated that billers differentiate waived testing procedures from moderate and high complexity testing procedures. This differentiation is seen in certain procedure code volume data. The volume of tests billed by POLs for quantitative glucose, a moderate category test under CLIA, have decreased sharply. On the other hand, there has been a corresponding increase in glucose testing by reagent strip (82948), which falls in CLIA's waived test category. Similar shifts in POL volume from moderate to waived testing procedures is evident for sedimentation rate tests and other tests. Tables containing the information used for this analysis can be found in Appendix D.[9]

The CLIA appears to have had some effect on the volume and types of tests being billed by POLs. Shifts from moderate and high complexity test procedures to waived testing procedures are evident in glucose, sedimentation rates and other areas of testing. Volume for some other procedure codes billed by POLs has also declined. However, volume decreases experienced by all types of laboratories for these codes indicate that factors other than CLIA have influenced volume and where laboratory tests are performed.

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[8] Policy, billing and processing changes initiated by HCFA have resulted in a decline in the volume of some chemistry, hematology and other procedures performed by all laboratories. For example, change in policy has resulted in a decline in procedure code 80012, used to describe a 12 chemistry tests, and in declines for other chemistry tests codes (i.e., 84132 potassium, 82465 cholesterol). The change in policy is reflected in increases in procedure codes 80002 through 80019.

[9] Our analysis took into consideration all of the procedure codes used that might be used by laboratories having a certificate of waiver. Some codes with no volume or extremely low volumes were not used in our analysis, since including them would have had no impact on the analysis or conclusions drawn from the data.

COMMENTS ON THE DRAFT REPORT

We would like to thank the American Medical Association (AMA), American Society of Internal Medicine (ASIM), American Clinical Laboratory Association and HCFA for responding to our request for comments on the draft of this report. Based on comments we received, we have reordered and reworded three of the report findings. The full text of comments received can be found in Appendix E.

The HCFA and the American Clinical Laboratory Association concurred with our report findings. The AMA and ASIM expressed concern that our study does not address CLIA's impact on patient convenience or the speed and quality of testing afforded by physician in-office laboratories. While important subjects, these issues were beyond the scope of our inquiry which was simply to determine whether CLIA has restricted the availability of laboratory services.

The AMA suggests that we have not estimated correctly the number of physicians in active practice in 1988, and hence questions the accuracy of other estimates in the report. We believe the difference in OIG and AMA estimates of physicians in active practice is largely due to differences in definition and does not affect the accuracy of other estimates in this report.

Our estimate of the number of physicians in active practice in 1988 reflects physicians who made themselves available to the general public. We realize that our definition is a more restrictive one than the common definition used by the AMA. We considered a physician to be available to the general public if they were listed in the yellow pages or listed with telephone directory assistance. The AMA definition of active practice includes physicians who do not make themselves available to the general public. These physicians are employed by health maintenance organizations, hospitals, government, community clinics or other entities. While the organizations for whom they work may advertise for patients, the individual physicians employed by them do not solicit patients by advertising in the yellow pages or other means. Given this difference in definition, and other factors, the magnitude of discrepancy between the AMA's data and our data should not affect our projections, since the excluded physicians generally do not operate in-office laboratories.

APPENDIX A

1988 POL Survey Methodology and results of 1994 recontacts with physicians who participated in that survey

Note: The information presented on the following pages was used to determine what, if any, impact CLIA had on physicians in active practice in 1988 who were still in active practice in 1994. The data provided does not reflect the number of POLs in operation today. It does not take into consideration physicians entering into medical practice since 1988 and their access to POLs.

Projections are based on information obtained from States in 1988. Today, more accurate information as to the number of physicians in active practice is available. Using this information and the experience gained during our 1988 and 1994 surveys suggests that the current universe of laboratory sites that could be considered POLs ranges somewhere between 97,000 and 114,000 sites.

POL SURVEY METHODOLOGY

The 1988 and 1994 physician surveys both used a two-stage cluster sample to estimate the number of physician office laboratories (POLs) nationwide. In 1988, the States were selected at the first stage with probability proportional to size, where the size of the State was determined by the total number of laboratory procedures billed under Medicare Part B during 1985. This data does not include hospital outpatient data.

The information on the total number of laboratory services was obtained from the Health Care Financing Administration's 1985 Part B Medicare data file. Ten States were selected for inclusion in the survey. Table 1 gives the States selected, the corresponding estimated total number of laboratory services and the proportion that total is of all laboratory services for 1985. This proportion represents the probability of selection associated with each State.

CARRIER	NUMBER OF LABORATORY SERVICES*	PERCENT OF TOTAL
Aetna Oregon	12,651	1.09
Florida BS	99,694	8.59
Aetna Oklahoma	12,516	1.08
Pennsylvania BS	53,678	4.63
Prudential NC	33,908	2.92
Illinois BS	42,234	3.64
BS of Greater NY	60,610	5.22
Kansas BS	10,193	0.88
Gen'l Am Life (Missouri)	14,587	1.26
Prudential GA	25,842	2.23
Sample Total	365,913	31.53
TOTAL OF ALL STATES	1,160,530	100.00

* Numbers presented are from a 1% random sample of all laboratory services in calendar year 1985.

Table 1

At the second stage of sampling, each selected State was contacted and requested to provide a listing of all physicians licensed in that State. Three of the selected States were unable to provide this listing. Each of these 3 States were, instead, asked to provide a listing of the name and address for approximately 45 physicians selected at random. This approach was considered acceptable due to the independent nature of the sampling within each State. From the listings for the seven remaining States, physicians were selected within each State using simple random sampling. The only criteria for selection of a physician was that the physician's mailing address be within

the selected State and that the physician be licensed as a medical doctor (MD). All other physician groups, such as doctors of osteopathy, podiatrists, and chiropractors, were excluded from this survey.

Each State in the sample was also asked to provide a count as to the number of licensed physicians with addresses in the State. This enabled us to identify the universe of physicians within each State and to exclude out-of-State licenses from the State universe. All of the selected States were asked to provide this count as of the date of our inquiry.

It was felt that sampling 20 physicians in active practice, per State, was sufficient for purposes of this study. We attempted to secure a telephone number from directory assistance for each physician selected for study contact.

CARRIER	NUMBER OF LICENSED PHYSICIANS	NUMBER OF CONTACTS	ADJUSTED UNIVERSE**
Aetna Oregon	5,824	37	3,148
Florida BS	23,000*	47	9,787
Aetna Oklahoma	4,794	32	2,996
Pennsylvania BS	27,092	31	17,479
Prudential NC	11,500*	53	4,340
Illinois BS	24,316	36	13,509
BS Greater NY	53,745	45	23,887
Kansas BS	3,648	38	1,920
GAL (Missouri)	12,745	36	7,081
Prudential GA	7,224	36	4,013

* Estimates supplied by the State.
** Adjustment is based on 20 physicians per State in the final sample.

Table 2

Telephone calls were made to all physicians with listed telephone numbers until we reached 20 physicians in active practice. Physicians with unlisted telephone numbers and those with listed telephone numbers who could not be reached, or whose answering service could not be reached after three attempts, were assumed not to be in active practice or not holding themselves out to the general public. We realize that our definition is more restrictive than the common definition used by the American Medical Association.

Each of the physicians (or office staff) contacted were asked to confirm whether or not the physician was in active practice. The universe for each State was adjusted to eliminate those physicians not considered to be in active practice.

When we had located 20 active practices, they were asked to participate in our study. Approximately 10 percent refused. Those that agreed to participate were asked if

they performed laboratory tests in their office. If they responded yes, they were asked if laboratory testing exceeded 5,000 tests a year. Our wording of these questions was consistent with the language of the Omnibus Budget Reconciliation Act of 1987 provision.

The results of the 1988 sampling process and the final adjusted estimates of the number of active physicians in each State are displayed in Table 2 on the previous page.

This methodology allowed us to estimate the number of physicians who use a POL. In order to estimate the number of POLs, we also asked each interviewed physician if any other physicians used this same laboratory, and if so, how many. From this information we were able to estimate the number of POLs used by a single physician and, using the mode of the distribution from the responses indicating more than one physician used a given POL, we estimated the number of POLs used by more than one physician. Using the proper weight, based upon the sampling design, we were able to produce the national estimates given in Table 3. Included in this table are the lower and upper bounds for the 90 percent confidence interval. All values in this table are rounded to the hundreds position.

CATEGORY	ESTIMATED NUMBER	90% CONFIDENCE INTERVAL	
		Lower	Upper
# of Licensed Physicians	567,200	428,500	705,400
# in Active Practice*	299,500	225,200	373,900
# Using POLs	162,100	118,200	206,100
Total # of POLs	98,400	71,100	125,700
# with Single Physician	57,000	35,800	78,100
# with Multiple Physicians	41,400	28,100	54,700
# POLs > 5,000 Laboratories/Year	34,000	26,800	41,400
# with Single Physician	10,000	5,300	14,800
# with Multiple Physicians	24,000	16,900	31,200
* According to the criteria explained in this report.			

Table 3

Results of 1994 Physician Office Laboratory Survey

The 1994 survey was designed to determine what happened to the 299,500 medical practices that were active in 1988. Using data derived from recontacting the 200 physicians who participated in 1988, we were able to make the following projections about the 299,500 physicians in active practice in 1988.

1) Projected number of medical practices that have closed POL operations since our 1988 survey. Includes practices that have ceased testing altogether and those that have consolidated sites:*

Estimated # of POL Closures	90% Confidence Interval
17,170	12,470 - 21,870

2) Projected number of new POL sites:*

Estimated # of POL Openings	90% Confidence Interval
14,900	6,500 - 23,300

3) Projected number of physicians operating POLs based on the 1994 survey:*

Estimate	90% Confidence Interval
162,300	114,600 - 210,000

4a) Projected number of physicians in solo practice and group practice in 1994:*

Physicians per Practice Type in 1994	Estimate	90% Confidence Interval
# of physicians in solo practice	81,000	59,200 - 102,800
# of physicians in group practice	195,000	148,600 - 241,400

* Based on physicians in active practice in 1988 who were still in active practice in 1994.

4b) Projected number of POLs being operated in 1994 by physicians who were in active practice in 1988 and who are still in active practice in 1994. This number has been broken down to show the number of POLs being operated by physicians in solo practice and to show the number of POLs being operated by physicians in group practice:

Estimated # of POLs in 1994	86,000

# of POLs by Practice Type in 1994	Estimate	90% Confidence Interval
POLs operated by solo practices	44,600	29,800 - 59,400
POLs operated by group practices	41,400	27,300 - 55,500

5a) Percent of practices using national reference laboratories, local independent laboratories, hospital-owned laboratories or no reference laboratories (N=176):*

Laboratory Type	Estimated percent	90% Confidence Interval
National reference laboratory	42.1%	34.8% - 49.4%
Local independent laboratory	23.7%	16.7% - 30.7%
Hospital-owned laboratory	32.0%	20.4% - 43.6%
None	2.2%	0.4% - 4.0%

* Based on physicians in active practice in 1988 who were still in active practice in 1994.

5b) Percent of practices using national reference laboratories, local independent laboratories, hospital-owned laboratories or no reference laboratories by Practices With or Without POLs in 1994:*

TYPES OF REFERENCE LABORATORIES USED		
National Reference Laboratory	Estimated Percent	90% Confidence Interval
POL	79.0%	69.3% - 88.7%
No POL	21.0%	11.3% - 30.7%
Local Independent Laboratory	Estimate	90% Confidence Interval
POL	64.3%	53.2% - 75.4%
No POL	36.7%	25.6% - 47.8%
Hospital-Owned Laboratory	Estimate	90% Confidence Interval
POL	30.2%	9.8% - 50.6%
No POL	69.8%	49.4% - 90.2%
No Reference Laboratory Used	Estimate	90% Confidence Interval
POL	*	*
No POL	*	*
* Numbers too small to report.		

* Based on physicians in active practice in 1988 who were still in active practice in 1994.

APPENDIX B

CLIA Laboratories by Type

CLIA LABORATORIES BY TYPE AS OF 01/30/95		
Type of Laboratory	Frequency	% CLIA Applications
Ambulatory Surgical Center	1,001	0.7%
Community Clinic	4,585	3.0%
Comprehensive Outpatient Rehabilitation Facility	53	0.0%
Ancillary Testing Site in a Health Care Facility	2,100	1.4%
End Stage Renal Disease Dialysis Facility	1,747	1.2%
Health Fair	212	0.1%
Health Maintenance Organization	952	0.6%
Home Health Agency	6,907	4.6%
Hospice	423	0.3%
Hospital	8,789	5.8%
Independent Clinical Laboratory	5,778	3.8%
Industrial	1,265	0.8%
Insurance	39	0.0%
Intensive Care/Mental Rehabilitation Facility	545	0.4%
Mobile Unit	609	0.4%
Pharmacy	243	0.2%
School/Student Health Service	1,061	0.7%
Skilled Nursing/Nursing Facility	13,157	8.7%
Physician Office	89,195	58.8%
Other Practitioner	2,194	1.4%
Tissue Bank/Repositories	32	0.0%
Blood Banks	316	0.2%
Other	10,421	6.9%
Unknown*	34	0.0%
TOTAL	151,658	100.0%

* Not validated by HCFA. Based on how laboratories classified themselves on HCFA's CLIA application.

APPENDIX C

Tables of U.S. Counties Without Laboratories

The information presented on the following pages was derived using information from the United States Bureau of the Census, HCFA's Online Survey, Certification and Reporting System and from HCFA's Unique Physician Identification Number (UPIN) file. We used 1990 census information. The HCFA data reflects information in file at the end of February 1995.

Table 1

COUNTIES WITHOUT LABORATORIES AND PHYSICIANS			
County, State	Population	County, State	Population
Aleutians West, AK	9,478	Storey, NV	2,526
Wade Hampton, AK	5,791	Billings, ND	1,108
Echols, GA	2,334	Sheridan, ND	2,148
Kalawao, HI	130	Slope, ND	907
Camas, ID	727	Hanson, SD	2,994
Clark, ID	762	Ziebach, SD	2,220
Issaquena, MS	1,909	Borden, TX	799
Golden Valley, MT	912	Briscoe, TX	1,971
Petroleum, MT	519	Glasscock, TX	1,447
Yellowstone National Park, MT	52	Hartley, TX	3,634
Arthur, NE	462	Irion, TX	1,629
Banner, NE	852	Kenedy, TX	460
Hayes, NE	1,222	King, TX	354
Keya Paha, NE	1,029	Loving, TX	107
Loup, NE	683	McMullen, TX	817
McPherson, NE	546	Oldham, TX	2,278
Thomas, NE	851	Roberts, TX	1,025
Wheeler, NE	948	Daggett, UT	690
Esmeralda, NV	1,344	Greensville, VA	8,853

Table 2

COUNTIES WITHOUT LABORATORIES WITH 1 TO 10 PHYSICIANS		
County, State	Population	# of Physicians
Cleburne, AL	12,730	10
Perry, AR	7,969	3
Ouray, CO	2,295	2
Glades, FL	7,591	5
Chattahoochee, GA	16,934	1
Long, GA	6,202	1
Montgomery, GA	7,163	4
Quitman, GA	2,209	1
Schley, GA	3,588	3
Keweenaw, MI	1,701	4
Treasure, MT	874	1
Blaine, NE	675	1
Logan, NE	878	1
Sioux, NE	1,549	1
Harding, NM	987	1
Stanley, SD	2,453	1
Sully, SD	1,589	2
Carson, TX	6,576	2
Hudspeth, TX	2,915	1
Jack, TX	6,981	5
Throckmorton, TX	1,880	3
Titus, TX	24,009	1
Rich, UT	1,725	2
Falls Church, VA	9,578	4
James City, VA	34,859	1
King and Queen, VA	6,289	1

Table 3

COUNTIES WITHOUT LABORATORIES WITH MORE THAN 10 PHYSICIANS		
County, State	Population	# of Physicians
Stephens, TX	9,010	13
Fredericksburg City, VA	19,027	19

APPENDIX D

Laboratory Procedure Codes
by Place of Service
1985 - 1993

The following tables were used to determine if changes in where testing takes place have occurred since the passage of CLIA. The tables span the period beginning January 1, 1985 through December 31, 1994.

The data used from this analysis was first collected by the Office of Inspector General in 1985 and has been collected each year since that time. The data represents a 1 percent sample. The samples were drawn annually from HCFA's Common Working File and its predecessor the Part B Medicare Annual Data (BMAD) file.

The procedure codes represented on the following pages were initially identified for use in our report entitled *Quality Assurance in Physician Office Labs*. At the time these procedure codes were selected they represent procedure codes most often billed as being performed in POLs.

We compared the volume data for 1987 with the volume data for 1993 to determine if the billing for a particular procedure code had risen or fallen since the passage of CLIA in 1988. The volume for some procedure codes has vacillated from year to year. For purposes of this analysis, reasons for such vacillation was not taken into consideration. A change was considered to have occurred if the volume for a procedure code in 1993 was lower than the volume in 1987.

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
80002	OTH	4406	3835	5089	6477	6842	7285	8456	9831	14015
	POL	4682	5609	5879	7018	7381	8171	8799	9992	10858
	ALL	9088	9444	10968	13495	14223	15456	17255	19823	24873
80003	PLACE									
	OTH	2523	3017	3753	3849	4180	4361	5055	5079	5314
	POL	3268	3748	4058	4717	4226	4650	5201	5427	5612
	ALL	5791	6765	7811	8566	8406	9011	10256	10506	10926
80004	PLACE									
	OTH	6502	6606	6938	7717	7618	8249	8575	8311	7997
	POL	2776	2672	2425	2653	2740	2749	3100	3377	3531
	ALL	9278	9278	9363	10370	10358	10998	11675	11688	11528
80006	PLACE									
	OTH	3601	4266	4708	5251	5235	5827	7320	7618	8115
	POL	1549	1437	1466	1527	1541	1765	2267	3055	3583
	ALL	5150	5703	6174	6778	6776	7592	9587	10673	11698
80012	PLACE									
	OTH	3104	3333	3461	3259	3236	2975	2776	2525	2628
	POL	3547	3258	3188	3703	4022	4311	3902	3129	2608
	ALL	6651	6591	6649	6962	7258	7286	6678	5654	5236
80016	PLACE									
	OTH	6170	4761	4897	4928	5043	5180	5494	5310	6535
	POL	4152	4720	6198	7535	8933	9646	11705	13659	15585
	ALL	10322	9481	11095	12463	13976	14826	17199	18969	22120
80018	PLACE									
	OTH	4385	5085	5593	6943	6772	7067	7804	8053	8805
	POL	2655	3178	3525	4055	4291	4592	5841	6799	7905
	ALL	7040	8263	9118	10998	11063	11659	13645	14852	16710
80019	PLACE									
	OTH	46638	59498	70183	84082	98165	106989	121398	120324	126095
	POL	7454	6111	6713	8363	9209	10566	13516	24727	25320
	ALL	54092	65609	76896	92445	107374	117555	134914	145051	151415

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
81000	OTH	23128	25379	28961	31455	33259	36867	41632	41565	43007
	POL	109664	116330	106154	124286	129331	134665	142747	138712	132458
	ALL	132792	141709	135115	155741	162590	171532	184379	180277	175465
81002	PLACE									
	OTH	888	1719	1927	2377	4122	5007	4924	5476	4603
	POL	7740	9570	9704	12307	13333	14706	14364	15577	20163
	ALL	8628	11289	11631	14684	17455	19713	19288	21053	24766
81005	PLACE									
	OTH	809	1943	2997	3479	3228	3872	2462	2016	1438
	POL	3885	3856	3921	4278	4529	4882	5183	4682	4040
	ALL	4694	5799	6918	7757	7757	8754	7645	6698	5478
81015	PLACE									
	OTH	1095	1502	1630	1842	944	869	887	897	1084
	POL	2999	2807	2703	3116	3152	2727	2771	2712	3009
	ALL	4094	4309	4333	4958	4096	3596	3658	3609	4093
82270	PLACE									
	OTH	1756	2000	2619	3173	3597	4191	4557	4461	4792
	POL	24260	25688	26405	34270	38383	42090	45274	41310	41985
	ALL	26016	27688	29024	37443	41980	46281	49831	45771	46777
82465	PLACE									
	OTH	1593	2457	4391	7422	8376	7196	6867	6381	4960
	POL	3339	4335	6690	12598	15064	13268	12645	10505	7466
	ALL	4932	6792	11081	20020	23440	20464	19512	16886	12426
82565	PLACE									
	OTH	2145	2901	3114	3022	3093	3248	3293	3191	2681
	POL	2231	2421	3029	3359	3476	3540	4013	4109	3593
	ALL	4376	5322	6143	6381	6569	6788	7306	7300	6274

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
82643	OTH	9260	11911	13635	15222	16931	18986	21885	21843	11558
	POL	2147	1656	2045	2453	2705	3130	3720	4904	2202
	ALL	11407	13567	15680	17675	19636	22116	25605	26747	13760
82756	PLACE									
	OTH	3557	5283	7183	8196	9469	10995	11793	13646	8877
	POL	1163	969	1335	1446	1562	1641	1951	3404	1478
	ALL	4720	6252	8518	9642	11031	12636	13744	17050	10355
82947	PLACE									
	OTH	22165	24460	24661	24135	23688	24261	26151	25629	24889
	POL	50356	52987	50885	56139	57296	56960	55046	50467	43919
	ALL	72521	77447	75546	80274	80984	81221	81197	76096	68808
82948	PLACE									
	OTH	1078	132	271	345	408	909	1755	1874	1377
	POL	8009	8684	9132	11384	11999	13436	14609	14873	15348
	ALL	9087	8816	9403	11729	12407	14345	16364	16747	16725
83036	PLACE									
	OTH	2257	3256	4426	5748	7631	9758	12148	12796	14372
	POL	1144	1388	1817	2369	2907	3437	4706	8503	9963
	ALL	3401	4644	6243	8117	10538	13195	16854	21299	24335
83718	PLACE									
	OTH	4490	8271	19786	27174	34238	45888	48724	50464	60396
	POL	1566	1895	3319	6257	8671	9713	12940	18493	16815
	ALL	6056	10166	23105	33431	42909	55601	61664	68957	77211
84132	PLACE									
	OTH	10007	9668	8973	8240	8423	8052	8441	8104	7250
	POL	14783	15683	16879	18927	18670	17331	16747	13999	11134
	ALL	24790	25351	25852	27167	27093	25383	25188	22103	18384
84295	PLACE									
	OTH	1967	1944	1574	1637	1788	1480	1252	1238	823
	POL	2924	2818	3225	4024	4122	3932	3468	2709	1896
	ALL	4891	4762	4799	5661	5910	5412	4720	3947	2719

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
84420	OTH	1843	2674	2888	3528	4005	4557	5007	4220	2198
	POL	1147	1549	2197	2618	2739	3028	2981	3068	1204
	ALL	2990	4223	5085	6146	6744	7585	7988	7288	3402
84435	PLACE									
	OTH	4241	3716	3540	2736	2787	2905	3350	3132	1518
	POL	1740	1826	2033	2205	2849	3617	4666	5421	2419
	ALL	5981	5542	5573	4941	5636	6522	8016	8553	3937
84436	PLACE									
	OTH	12991	20432	24704	30188	32890	35555	40635	40749	38428
	POL	2520	2270	2935	3431	3848	4083	4817	7786	8442
	ALL	15511	22702	27639	33619	36738	39638	45452	48535	46870
84443	PLACE									
	OTH	4216	6354	8859	13008	17148	22917	32139	37664	38066
	POL	1763	1854	2755	3712	4826	6252	8932	14606	14816
	ALL	5979	8208	11614	16720	21974	29169	41071	52270	52882
84478	PLACE									
	OTH	3598	3480	4702	6554	7686	7872	8517	9079	7432
	POL	2620	2776	3632	5072	5799	5731	6182	6043	4799
	ALL	6218	6256	8334	11626	13485	13603	14699	15122	12231
84479	PLACE									
	OTH	5764	8930	11305	12573	13815	16900	20682	22504	19719
	POL	1336	1366	1647	1992	1874	1960	2525	4130	3656
	ALL	7100	10296	12952	14565	15689	18860	23207	26634	23375
84520	PLACE									
	OTH	2566	2912	2860	2785	3177	4013	5821	5245	4026
	POL	3906	4249	4686	4801	4643	4239	4095	3703	3100
	ALL	6472	7161	7546	7586	7820	8252	9916	8948	7126
84550	PLACE									
	OTH	1060	1264	1259	1121	1263	1176	1170	925	780
	POL	2190	2173	2100	2316	2214	1849	1838	1527	1215
	ALL	3250	3437	3359	3437	3477	3025	3008	2452	1995

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
85007	OTH	6676	5533	5130	5302	5096	4404	5031	5337	5032
	POL	4100	3905	4605	5403	5432	5318	5353	5417	4656
	ALL	10776	9438	9735	10705	10528	9722	10384	10754	9688
85014	PLACE									
	OTH	1337	1521	1760	1896	2364	2706	3413	4382	3620
	POL	10689	10513	9347	9820	9380	8908	8085	6855	5104
	ALL	12026	12034	11107	11716	11744	11614	11498	11237	8724
85018	PLACE									
	OTH	1298	1441	1645	1837	2326	2542	3105	3872	3509
	POL	13323	13115	11382	13020	12766	12477	11857	9588	7705
	ALL	14621	14556	13027	14857	15092	15019	14962	13460	11214
85021	PLACE									
	OTH	10295	10983	10260	11162	7740	11415	6725	5786	6076
	POL	10128	10759	13024	14268	13447	13494	12293	10558	7931
	ALL	20423	21742	23284	25430	21187	24909	19018	16344	14007
85022	PLACE									
	OTH	24930	36008	32831	21973	15366	10741	9026	5582	3707
	POL	20235	22885	23212	24085	21734	18301	15486	12101	8611
	ALL	45165	58893	56043	46058	37100	29042	24512	17683	12318
85027	PLACE									
	OTH	1717	2907	4389	5294	5627	6078	6480	6933	7312
	POL	1929	2921	4802	7115	8203	8806	9754	9762	9172
	ALL	3646	5828	9191	12409	13830	14884	16234	16695	16484
85028	PLACE									
	OTH	11048	9937	656	11	0	0	0	0	0
	POL	3934	2322	404	11	1	0	0	0	0
	ALL	14982	12259	1060	22	1	0	0	0	0
85031	PLACE									
	OTH	11851	6921	6593	5650	4730	2834	1932	1699	1196
	POL	24489	24057	21098	20358	17601	14456	12276	9038	6152
	ALL	36340	30978	27691	26008	22331	17290	14208	10737	7348

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
85044	OTH	1175	1473	1840	2163	2731	4149	5185	5766	4869
	POL	1417	1280	1350	1484	1478	1469	1556	1533	1301
	ALL	2592	2753	3190	3647	4209	5618	6741	7299	6170
85048	PLACE									
	OTH	371	511	342	371	319	414	544	787	987
	POL	6338	6133	5411	5879	5267	5280	3944	3063	2366
	ALL	6709	6644	5753	6250	5586	5694	4488	3850	3353
85580	PLACE									
	OTH	5380	6082	8013	7670	3325	2960	2817	2506	1458
	POL	8816	9244	9607	9474	8844	7614	6470	5666	1658
	ALL	14196	15326	17620	17144	12169	10574	9287	8172	3116
85595	PLACE									
	OTH	3433	3983	3203	3363	2954	3004	2918	2525	2832
	POL	4249	4925	5459	6161	5960	5603	4857	3997	3595
	ALL	7682	8908	8662	9524	8914	8607	7775	6522	6427
85610	PLACE									
	OTH	15725	19711	22691	23844	27052	33036	42137	47669	58800
	POL	13153	13178	13883	16099	18487	19926	23862	28827	31441
	ALL	28878	32889	36574	39943	45539	52962	65999	76496	90241
85650	PLACE									
	OTH	5418	5557	5937	6096	6331	6550	6500	5850	2615
	POL	11096	11491	10486	10960	10974	10630	10418	9997	4220
	ALL	16514	17048	16423	17056	17305	17180	16918	15847	6835
85651	PLACE									
	OTH	3769	5526	6693	8369	9530	11152	13216	13720	17077
	POL	6252	7174	8556	10456	11289	12333	13986	15999	20630
	ALL	10021	12700	15249	18825	20819	23485	27202	29719	37707
87060	PLACE									
	OTH	651	521	614	745	693	811	992	947	1041
	POL	1311	1507	1375	1520	1493	1531	1491	1430	1157
	ALL	1962	2028	1989	2265	2186	2342	2483	2377	2198

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
87070	OTH	3094	4601	5147	5915	7002	7915	8851	9191	8689
	POL	1603	1636	1690	1758	1618	1662	1603	1719	1530
	ALL	4697	6237	6837	7673	8620	9577	10454	10910	10219
87081	PLACE									
	OTH	391	488	514	343	572	479	555	554	598
	POL	1113	1024	863	957	995	940	1021	888	798
	ALL	1504	1512	1377	1300	1567	1419	1576	1442	1396
87086	PLACE									
	OTH	6260	8444	10481	11917	12856	15627	18943	20149	23856
	POL	6133	6698	7985	8825	9304	9845	10720	11506	10571
	ALL	12393	15142	18466	20742	22160	25472	29663	31655	34427
87088	PLACE									
	OTH	2265	3608	4797	5964	6479	7383	8771	9713	8442
	POL	1510	2063	2502	2991	3411	4152	4500	4961	4601
	ALL	3775	5671	7299	8955	9890	11535	13271	14674	13043
87101	PLACE									
	OTH	121	133	154	197	205	204	249	238	161
	POL	1663	1897	2030	2481	2805	3217	3009	2512	1553
	ALL	1784	2030	2184	2678	3010	3421	3258	2750	1714
87184	PLACE									
	OTH	4335	5583	6237	6470	6263	6481	7139	6160	5344
	POL	3517	4164	5141	5765	6004	6397	6828	6439	5745
	ALL	7852	9747	11378	12235	12267	12878	13967	12599	11089
87205	PLACE									
	OTH	1022	1179	1324	1549	1854	2316	2723	2911	3298
	POL	1514	1521	1438	1664	1763	1885	1969	1962	1951
	ALL	2536	2700	2762	3213	3617	4201	4692	4873	5249
87210	PLACE									
	OTH	127	157	146	209	226	243	231	197	245
	POL	1590	1750	1715	2111	2298	2394	2657	2384	2247
	ALL	1717	1907	1861	2320	2524	2637	2888	2581	2492

		YEAR								
		1985	1986	1987	1988	1989	1990	1991	1992	1993
		SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES	SERVICES
		SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM	SUM
HCPCS	PLACE									
88150	OTH	3390	3583	4248	4456	4907	5847	5613	5132	4452
	POL	3095	2956	2068	2561	2774	3017	2519	2277	1754
	ALL	6485	6539	6316	7017	7681	8864	8132	7409	6206
88302	PLACE									
	OTH	5540	4961	4834	4790	4435	4391	4281	3224	2886
	POL	1078	781	732	697	810	719	656	384	293
	ALL	6618	5742	5566	5487	5245	5110	4937	3608	3179
88304	PLACE									
	OTH	15706	17383	19843	21072	22864	24869	27474	15492	13809
	POL	5918	6572	7595	8013	9278	10333	11502	4255	2555
	ALL	21624	23955	27438	29085	32142	35202	38976	19747	16364
89205	PLACE									
	OTH	190	226	322	213	244	282	260	152	117
	POL	2975	3118	2089	2196	2055	1760	1620	1152	852
	ALL	3165	3344	2411	2409	2299	2042	1880	1304	969

APPENDIX E

Copies of Comments Received on the Draft of this Report

American
Clinical Laboratory
Association

May 15, 1995

BY FACSIMILE

June Gibbs Brown
Inspector General
5250 Wilbur J. Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Inspector General Brown:

As President of the American Clinical Laboratory Association ("ACLA"), I am writing to thank you for the opportunity to comment on the Office of Inspector General's recent draft report, "CLIA's Impact on the Availability of Laboratory Services." As you know, ACLA is an association representing independent clinical laboratories located throughout the United States. All ACLA members were directly affected by the passage of CLIA'88 and the subsequent regulations implementing that law.

ACLA has always believed that all patients should be assured that their clinical laboratory testing was being performed in a facility that met certain basic quality and personnel requirements, regardless of whether that testing was being performed in an independent clinical laboratory, a hospital laboratory, or a physician's office laboratory. For that reason, ACLA members strongly supported the enactment of CLIA '88, and have continued to support the enforcement of its provisions.

As a result of our concern about these issues, we read with great interest the OIG's recent report. We believe its basic--and most important--conclusion is stated at the bottom of page 7 of the report. The report notes:

> Despite changes in POL [Physician Office Laboratory] testing capabilities, none of the practices that participated in our study indicated that they have any trouble in securing laboratory services for their patients. The availability of POLs, independent clinical laboratories and hospital laboratories appears to be adequate to meet the needs of physicians and patients.

[redacted]

In short, the report concludes that CLIA's imposition of basic quality and personnel standards has not limited patients' access to laboratory services. We believe this conclusion is an important one to bear in mind as consideration is given to proposals to modify the law.

Thank you for the opportunity to comment on this report. If we can be of any further assistance, please do not hesitate to contact me.

Sincerely yours,

David N. Sundwall

David N. Sundwall, M.D.
President

American Medical Association
Physicians dedicated to the health of America

James S. Todd, MD
Executive Vice President

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

May 15, 1995

June Gibbs Brown
Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, DC 20201

Dear Ms. Brown:

The American Medical Association (AMA) appreciates the opportunity to comment on the Office of Inspector General's draft report entitled "CLIA's Impact on the Availability of Laboratory Services." Clearly, no other regulation has caused more concern, anxiety, and unrest in the physician community than has CLIA. We are, therefore, pleased that the Administration has made the request that your office study CLIA and its effects on the medical profession -- especially on those physicians who have opted to perform laboratory testing in their office.

In requesting the study, HCFA had raised concerns that testing sites, especially physician office laboratory (POL) sites, might cease operations and thus restrict patient access to certain types of laboratory tests. The study concludes that CLIA has had little or no impact on the availability of laboratory services. What the study fails to address is the effect CLIA may have had on the availability of <u>In-office</u> testing, regardless of whether outside laboratory services were available, and what such a decrease in the availability of In-office testing may mean to patient convenience and quality of care.

Certainly, lab closure was one possibility that POLs had to consider when faced with volumes of regulatory requirements. Other possibilities include the higher costs associated with the provision of laboratory services brought about by compliance with CLIA, costs associated with inspections of private physician office practices, and excessive administrative requirements. As the study indicates a number of physicians did opt to close their laboratories. However, we would challenge a number of the study's other conclusions.

For example, we maintain that it is questionable, as the draft study suggests, that the reduction in the number of POLs from 57,000 in 1988 to 44,500 in 1994 can be attributed primarily to physicians moving from solo practices to group practices. While group practices are growing in number, many physicians may have closed their labs due to multiple factors such as the cost of complying with CLIA requirements, lower reimbursements for lab services, OSHA requirements, and managed care requirements.

In addition, we believe that the report does not provide enough evidence to support its conclusions concerning the underlying reasons for the apparent shift on the part of physicians from solo practitioners to group practices. Specifically, the report does not provide enough evidence of this shift as it only accounts for 1994. According to AMA's Socioeconomic Monitoring Survey, it is a fact that the percentage of physicians in solo practice has fallen (from 35% in 1990 to 29%) in 1994. What is less certain, however, is that the reduction in POLs operated by solo physicians can be necessarily associated with the decrease in their numbers without evidence that would specifically link POL closures to the trend of physicians merging practices. Thus, it would be more accurate to conclude that some, but not all, of the lab closures are the result of physicians joining groups.

We also find it troubling that the study does not differentiate between employee and self-employed physicians. Surely, self-employed physicians are more likely to respond to CLIA's cost implications because they bear the financial risks directly. The study ignores the fact that although physicians are able to maintain necessary laboratory services, they may also incur additional costs.

In addition, it should be noted that some of the numerical projections in the study utilize magnitudes that may be questionable. For example, the study shows an estimated 299,500 of 567,200 licensed physicians in active practice in 1988. Our records indicate, however, that in 1988 there were approximately 567,587 licensed physicians, of which 521,328 were in active practice (According to the AMA's Physician Characteristics and Distribution in the U.S.). These estimates, which are in our view inaccurate, make the other projections used in the study suspect.

We agree with the study's fourth finding where it states, "The CLIA appears to have had an impact on the kinds of testing performed by physician office laboratories." Clearly, most physicians have chosen to restrict the variety of laboratory testing they perform for their patients. Tests that had been routinely and safely performed for their patients benefit pre-CLIA were subsequently considered highly complex or moderately complex and became subject to stringent and costly requirements that made it no longer economically practical or feasible to continue to perform those same tests in the POL setting. POLs that did restrict their "menu" of tests were ultimately compelled to use either hospital or independent labs to provide the complimentary additional needed diagnostic data necessary to compile the treatment regiment for their patients. Reducing the menu of tests routinely performed in a POL has resulted in disruptions in both patient and physician access to immediate essential services. The draft study results do not address this problem in particular.

The AMA maintains that the study would be enhanced if it could assess the hardship on patients in having lab testing performed elsewhere other than in a POL. The convenience to the patient and/or physician in having the full regiment of diagnostic services readily available is an important issue. If the costs associated with performing

critical and fundamentally essential testing are so high that physicians must curtail their menu of laboratory testing, then the patient, the physician and the Medicare program loses. The patient is forced to delay the initiation of a drug program or other medical services until lab results are returned from an outside lab. Subsequent patient visits may be necessary to convey the results and establish an appropriate treatment regime. The patient and physician must adjust busy schedules to accommodate the additional visits.

For the physician the convenience of being able to perform essential lab tests that complement his or her practice can mean that a more conservative course of treatment can begin as quickly as possible. Waiting even twenty-four hours for lab results can mean the difference between conservative treatment or surgery, patient anxiety or patient satisfaction, professional autonomy or unnecessary government oversight.

The study should also recognize that the increase in the utilization of lab services per patient and in expenditures has occurred, in part, due to the availability of sophisticated automated lab equipment. That equipment is now being used safely and effectively by hospitals, independent labs and physician office labs.

It is ironic that the regulation being examined by this study was enacted into law to improve the quality of patient care by assuring the accuracy of laboratory testing, and yet, the study draws no conclusions about the impact of the law on quality. If lab work is delayed, quality is not improved. If a physician is unnecessarily restricted from being able to practice medicine due to excessive costs and regulations, quality is not improved. The study should attempt to correlate the benefits (improvements in the quality of medical care) that accrue to physician office practices that are able to provide a full array of necessary, in office lab testing to their patients, where access is not a problem.

The AMA appreciates the opportunity to comment on the draft report. Should you have questions about these comments please contact Jack Emery in our Washington Office at (202) 789-7414.

Sincerely,

James D. Todd MD

James S. Todd, MD

asim
american society of internal medicine

May 15, 1995

The Honorable June Gibbs Brown
Inspector General
Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Brown:

Thank you for giving the American Society of Internal Medicine (ASIM) the opportunity to provide comments on the Office of Inspector General's draft report entitled "CLIA's Impact on the Availability of Laboratory Services." In general, we find that this study does not address the true impact of the CLIA law on physician office laboratories.

The study concludes that CLIA has had little or no impact on the availability of laboratory services. This conclusion is based on the findings that there has not been a significant decrease in the number of physicians operating in-office laboratories since CLIA was enacted in 1988 and that none of the physicians contacted during the study indicated that they had trouble securing laboratory tests for their patients from outside sources. *The study fails to address whether CLIA has restricted the availability of in-office laboratory services to Medicare patients and how such a change, if any, may have impacted patient convenience and quality of care.*

The study finds that CLIA has had an effect on the kinds of testing performed by physician office laboratories. Specifically, the study concluded that CLIA contributed to a sharp decline in the volume of 12 tests out of a sample of 60 procedures performed by physician office laboratories between 1987 and 1993. For example, the volume of quantitative glucose and sedimentation rate tests--both moderate complexity tests--performed by physician office laboratories has dropped sharply. There has been a corresponding increase in the volume of the waived versions of these tests. ASIM believes that a large number of physicians have discontinued all but waived testing in order to avoid the costs associated with complying with the CLIA regulations for moderate- or high-complexity laboratories. This would explain both the sharp decrease in office laboratory test volume for some procedures seen in this study, and the fact that over 50 percent of physician office laboratories now fall into the waived or physician-performed microscopy categories. It also would explain why this study did not find a significant decrease in the total number of physicians operating office laboratories.

We believe that this study may actually underestimate the impact CLIA has had on patient access to moderate- and high-complexity testing in the office laboratory setting. The study compares pre-CLIA data from 1987 with 1993 data. We believe the most significant changes in testing volume did not occur until the period from 1991 to 1993. Feedback from our members indicates that the majority of them waited until after regulations were published before changing their test menus. Many waited

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even longer until the regulations were implemented in September of 1992 before discontinuing tests for which no alternative waived method existed.

The study concludes that the apparent change in office laboratory testing capability is not important, suggesting that the physicians contacted during the study had no problems securing laboratory work for their patients from outside sources. We believe this conclusion is misleading and ignores the special benefits of having laboratory services performed where care is being provided. Office laboratories allow physicians to obtain test results while patients are still in the office so that they can begin immediate treatment of their medical problems. Although moderate- and high complexity tests can usually be obtained from outside sources, there often is a substantial delay in receiving the results of those tests. At best, outside laboratories can get results back in a few hours. In some cases, it may take days to obtain test results from commercial laboratories. This means unnecessary delays in test results that may require revisits to the physician's office or changes in treatment. At the least, this greatly inconveniences the patient. At worst, such delays in diagnosis may have serious consequences for the patient, e.g., unnecessary hospitalizations.

Another consequence of the apparent change in the kinds of tests performed by office laboratories is that patients may be sent to outside laboratories for routine tests that were performed for them at their physician's office pre-CLIA. This may pose a hardship for elderly, sick and disabled patients who have difficulties in arranging transportation to other sites. As a result, some patients may forgo obtaining necessary tests altogether. For working patients, this may mean that they must take more time off from work to get test work, resulting in lost wages for the employee and decreased productivity for the employer.

ASIM is also concerned about the possible impact CLIA has had on quality of testing. The study fails to address the possible quality implications if CLIA has indeed caused a large number of physicians to switch to less reliable, but lower category tests rather than use more reliable, but more regulated methods. As noted above, the study also fails to address whether CLIA has caused delays in diagnosis and if patient care has been adversely impacted as a result.

Finally, the study data show that 12,500 office laboratories operated by solo practitioners have closed since CLIA was enacted. We question the assumption made by the study that all these closures can be explained by the move away from solo practice toward larger group practices.

In conclusion, ASIM rejects the overall conclusion of the study that CLIA has had no impact on the availability of tests. Immediate availability of many routine tests in a manner that is convenient to patients and facilitates prompt diagnosis and treatment decisions has been adversely affected by CLIA. Patients no longer have the same access to moderate and high complexity in-office laboratory services as they had pre-CLIA. The study does not adequately address this concern.

Thank you for the opportunity to review and comment on the OIG's report on the impact of CLIA on the availability of laboratory testing. ASIM looks forward to working with you and your staff on this issue in the future.

Sincerely,

Alan R Nelson MD

Alan R. Nelson, MD
Executive Vice President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE MAY 22 1995

TO June Gibbs Brown
Inspector General

FROM Bruce C. Vladeck
Administrator

SUBJECT Office of Inspector General Draft Report: "CLIA's Impact on the Availability of Laboratory Services," (OEI-05-94-00130)

We reviewed the subject draft report which examined whether the Clinical Laboratory Improvement Amendments of 1988 have restricted the availability of laboratory services to Medicare patients. Our comments are attached for your consideration.

Thank you for the opportunity to review and comment on this report. Please advise us if you would like to discuss our comments.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on Office of Inspector General Draft Report:
"Clinical Laboratory Improvement Amendments of 1988
(CLIA) Impact on the Availability of Laboratory Services"
(OEI-05-94-00130)

HCFA Comments on the Report Findings

Page i - We recommend rewording the first finding as follows: "CLIA appears not to have affected physician ability to secure laboratory services for their patients." The statement as it is currently written implies that physicians refer all laboratory services which is not the case. This statement is also on page 5 of the report.

Page ii - We recommend replacing the wording of the last finding with the language contained in the original draft document we reviewed, "Changes in the marketplace have affected where some laboratory tests are performed." The discussion concerning the change in billing codes does not take into account that, until CLIA, waived tests did not have unique codes but were billed under existing billing codes that were not as specific. Stating that coding changes show a shift in physician testing may not be a reliable factor as these unique codes did not exist prior to CLIA. The present wording of the last finding also fails to consider the other factors that are elaborated on in the discussion on page 9. It might be helpful to expand the discussion on page ii to include these other factors. (This finding statement is also on page 9.)

Another factor that should be mentioned in addition to the "Stark Amendment" should be Occupational, Safety, and Health Administration requirements. These came into place around the same time and there is concern in the medical community about these requirements as well. This is also mentioned on page 9.

Page 3 - The discussion in the second paragraph concerning multiple sites is incorrect. Since multiple sites are permitted under one certificate, the total number of laboratory sites should be larger than 151,658, not smaller (129,634). This should also be corrected on page 6.

Appendix C - It would be helpful to know the timeframe from which this information is taken (currently, based on 1990 census . . . .). As it is presented we are unsure of the time period involved. If this is current information is there similar information available so that pre- and post-CLIA comparison could be made?