# QUALITY ASSURANCE IN PHYSICIAN OFFICE LABS


**OFFICE OF INSPECTOR GENERAL**

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# EXECUTIVE SUMMARY

## PURPOSE

This inspection examines the characteristics of physician office laboratories (POLs), discusses concerns regarding the quality of testing in POLs, and evaluates State and Federal efforts to regulate them.

## BACKGROUND

Physicians operating office laboratories conduct approximately 25 percent of all laboratory testing in the country. Sixteen States have laws pertaining to them. About $20 billion is spent nationally on laboratory services annually, of which POLs receive $5 billion. Each year Medicare pays POLs over $400 million. Prior to 1987, neither the Clinical Laboratories Improvement Act of 1967, which covers interstate laboratory activities, nor the Medicare program, which certifies laboratories for payment, regulated the vast majority of POLs.

The quality of testing in unregulated POLs concerned Congress and others involved with the laboratory community. Consequently, Congress mandated in the Omnibus Budget Reconciliation Act (OBRA) of 1987 that, effective January 1, 1990, POLs performing over 5,000 tests a year meet Medicare quality standards as established by the Secretary.

In October 1988, following a series of congressional hearings regarding laboratory issues and release of our draft report, the Clinical Laboratory Improvement Amendments (CLIA) of 1988 were enacted. While OBRA of 1987 mandates regulation of only high volume POLs billing Medicare, the CLIA of 1988 requires all laboratories, including POLs, to be regulated based on complexity of testing rather than size or volume.

## METHODOLOGY

Information was gathered through interviews with State and Federal officials, national associations representing the medical and laboratory communities, and manufacturers of laboratory equipment. Previous studies, Federal reports and journal articles were reviewed. In addition, a national survey of 200 randomly selected physicians' offices was conducted to estimate how many POLs are operating in the country.

This report reflects data collection and analysis performed prior to the passage of CLIA of 1988.

## FINDINGS

*Estimates of the number of POLS and the type of testing performed in them varies widely.*

- Based on our national survey, we estimate there are approximately 98,400 POL sites in the country. Previous estimates vary from 20,000 to 200,000 due to: (1) lack of a uniform State and Federal POL definition, and (2) dependence on physician self-reporting.

- The complexity of testing performed in POLs varies widely, as does the type of equipment being used. This is largely because there are no restrictions on the type of testing POLs can perform.

***Quality of POL testing concerns respondents; many believe the greatest risk comes from lack of training and attention to quality control.***

- Quality of testing in POLs concerns all but a few of the 79 respondents. Staff qualifications, training and the lack of proficiency testing are their primary concerns. There is no consensus regarding whether POLs should be held to the same Medicare standards as Independent Labs (ILs).

- Respondents believe the greatest risk of test error comes from the operator's lack of training and attention to quality control, rather than from the equipment itself.

- Efforts by the private sector to address the quality of testing in POLs have not been particularly effective because participation is voluntary.

***Few states regulate POLS; OBRA of 1987 is viewed as well-meaning but impractical.***

- Thirty-four States do not regulate POLs. They cite lack of legislative support or funding as the most common reason for lack of regulation.

- Sixteen States have legislation pertaining to POLs, although five have not fully implemented their laws. These State programs are not uniform and most exempt large numbers of POLs from regulation. Identification of POLs is the most often cited problem.

- Many respondents believe that OBRA of 1987 is a well-meaning attempt to regulate POLs. However, they are concerned about the practicality of implementing the statute. If POLs performing over 5,000 tests are held to the same Medicare standards as ILs, we estimate the annual cost of implementing the OBRA of 1987 provision to be approximately $63 million. Estimates will vary, depending on how "POL" and "test" are defined.

- Many respondents believe quality standards, based on complexity of testing, should apply uniformly to all laboratories.

## RECOMMENDATIONS

Following the Inspector General's congressional testimony regarding POLs and the release of our draft report in June 1988, Congress passed and the President signed into law CLIA of 1988 (P.L. 100-578). These amendments incorporate our draft recommendations by mandating:

1) that all laboratories be regulated based on complexity of testing;

2) that all POLs register and meet certain standards and inspection requirements as appropriate; and

3) that a registration fee be imposed on all laboratories which will provide funding for the laboratory registration and inspection program and will save the Department millions of dollars in operating costs.

Our POL recommendations will be implemented under the Public Health Service Act, rather than under the Medicare statutes which was our original intent. The recommendations, as they appeared in the draft report, are contained on pages 19-23 of the report. Specific discussion regarding how these amendments will effect POLs billing Medicare are also included.

We wish to thank all who commented on our draft report. Many of the suggestions to help clarify and strengthen the text have been included in the final report.

# INTRODUCTION

## PURPOSE

The purpose of this inspection is to: (1) identify physician office laboratory (POL) characteristics, (2) provide an overview of quality assurance in POLs, (3) discuss State experiences in regulating POLs, and (4) identify and evaluate Federal strategies being developed to help ensure accurate laboratory testing in POLs.

## BACKGROUND

This report reflects data collection and analysis performed prior to the passage of the Clinical Laboratory Improvement Amendments (CLIA) of 1988. The draft report was released to the public at the congressional hearing concerning laboratory legislation. For further information regarding CLIA of 1988, refer to the recommendation section of this report.

Industry estimates of POLs operating in the country range from as low as 20,000 to as high as 200,000 with a projected growth rate of 16 percent annually through 1990. The Health Care Financing Administration (HCFA) estimates the number of POLs to be about 100,000. The laboratory industry estimates that testing POLs represents about 25 percent of the laboratory market, resulting in about $5 billion in payment to physicians for these services. Medicare's share represents over $400 million annually.

The following chart provides information regarding Medicare's 1985 outpatient laboratory payments, volume of services, and average payment per service. Hospital inpatient and outpatient laboratory services are excluded from this data.

***MEDICARE PART B 1985 LABORATORY STATISTICS***

| | LABS | | |
|---|---|---|---|
| **TESTING SITE** | **ILs** | **POLs** | **OTHER** |
| Test Volume | 4.7 Million | 58.7 Million | 9.5 Million |
| Total Payment | $510 Million | $425 Million | $201 Million |
| Average Payment | $10.00 | $7.00 | $19.00 |

SOURCE: *Part B Medicare annual data (BMAD) file.*

Currently, 16 States have laws governing POLs; however, 5 of these have not fully implemented their laws. Thirty-four States do not regulate POLs. Sixteen of these 34 non-regulating States regulate laboratory sites that conduct certain types of testing such as premarital syphilis, drugs and AIDS. The extent to which these tests are being done in POLs is not known.

Federal regulation of laboratories is governed by title 18 of the Social Security Act and the Clinical Laboratories Improvement Act of 1967. Title 18 requires that hospitals and independent laboratories meet certain conditions of coverage in order to receive reimbursement under Medicare and Medicaid, and CLIA regulates interstate laboratory activities. Both laws exempt the vast majority of POLs from regulation. Medicare regulates POLs that accept more than 99 referrals, in a particular category of laboratory testing during a calendar year. The CLIA precludes regulation of physicians' office laboratories that perform testing for their own patients but not physicians who accept and test specimens on referral.

Although the majority of POLs have never been regulated by the Federal Government, Medicare legislation over the last 5 years has affected them dramatically and encouraged their growth. When the Medicare program began in 1965, physicians were allowed to bill for laboratory services which they performed in their offices and for laboratory services they purchased from independent laboratories (ILs). The ILs typically discounted their charges to physicians. Many physicians "marked up" the charges they incurred from ILs, creating higher costs for consumers--including Medicare--and higher profits for themselves. Physicians justified charging a higher price to their patients and third-party insurers by claiming the markup was an interpretation fee. Physician markups were prevalent despite HCFA and American Medical Association policies that physicians should not profit from work performed by others.

The Omnibus Budget Reconciliation Act (OBRA) of 1980 tried to eliminate markups on purchased laboratory services by requiring physicians to disclose the actual cost of services purchased from ILs. Enforcement of this law was difficult and many physicians continued to purchase laboratory services at discounted prices and bill at marked up prices. Other physicians began operating their own laboratories or offered expanded laboratory services to preserve their profits and avoid violating the law.

In 1983, the Medicare Prospective Payment System was implemented. Laboratory services performed by hospitals on their inpatients were included in the diagnosis related group (DRG) payment. Thus, the more effectively hospitals contained laboratory costs, the more profit they made from the DRG payment.

Hospital laboratories became cost centers instead of revenue centers. This resulted in the following: (1) physicians began performing preadmission and post-hospital laboratory testing procedures that were previously done in hospitals; and (2) hospitals reduced purchases of laboratory equipment which caused manufacturers to focus their equipment sales on the POL and home testing markets.

In 1984, Congress again tried to address the problem of physician laboratory markups. The Omnibus Deficit Reduction Act of 1984 prohibited physicians from billing for laboratory work they did not perform. It also established regional fee schedules (carrier specific) for reimbursement of Medicare laboratory services performed by ILs or hospital laboratories and required them to accept assignment for Medicare services. In other words, hospitals and ILs could not collect more than the amount Medicare recognized as reasonable for a laboratory procedure. Physicians were exempt from the mandatory assignment requirement. Services performed in POLs were paid at 80 percent of the established regional fee schedules, while physicians who submitted assigned claims were paid 100 percent of the schedules.

During part of 1984, reimbursement for physician services was frozen. Laboratory services billed by physicians were not subject to the freeze. Therefore, increasing their laboratory services was one way physicians could recoup lost revenues.

Other factors besides Federal regulation have influenced the growth in POL testing: (1) convenience afforded the physician and patient; (2) quick turnaround time of test results which permits expeditious treatment decisions; (3) development of reasonable priced, "user friendly, automated, desktop analyzers and (4) increased competition among physicians which encouraged them to offer a broader range of patient services.

The regulated laboratory industry and others expressed concern to Congress that these factors and Federal regulations had resulted in a restructuring of the clinical laboratory industry which gave POLs an unfair market advantage. Consequently, millions of laboratory tests, once performed in ILs and hospitals, have shifted to non-regulated settings primarily under the control of physicians. Not only were POLs not subject to the same payment provisions as ILs and hospitals, they were also exempt from Medicare proficiency testing, personnel, health and safety, and record standards.

Congress responded by including in the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 and the Omnibus Budget Reconciliation Act of 1986, provisions which subjected services performed in POLs to the same percentage of regional fee schedules in effect for independent and hospital laboratories. Previously, fees were set at 60 percent of the prevailing charge levels for tests performed by ILs and by physicians in their offices, and at 62 percent of prevailing charge levels for tests performed by a hospital laboratory for outpatients. They also required POLs to accept assignment, and mandated a move to eventually bring all laboratories under a national fee schedule. In addition, COBRA of 1985 also required the Secretary of Health and Human Services to submit to Congress a report on POLs, and to discuss appropriate quality standards that might be imposed on them.

The Omnibus Budget Reconciliation Act of 1987 mandated that the Secretary of Health and Human Services implement Medicare quality standards for POLs performing more than 5,000 tests per year by January 1, 1990. Originally, there was some uncertainty as to whether "high volume" POLs would have to meet the same Medicare standards as ILs or whether the Secretary had some flexibility in establishing POL standards. The HCFA believes the latter to be true.

## SCOPE AND METHODOLOGY

Information and data regarding POLs were obtained by conducting four surveys. The first involved interviews with national associations representing physicians, medical technologists, bioanalysts, chemists, laboratory equipment manufacturers, hospitals and ILs. The second was a survey of all 50 States, and the third involved interviews with 12 manufacturers of laboratory equipment. Appendix A contains a list of those contacted.

A fourth survey of 200 randomly selected physicians was conducted to ascertain the number of POLs in the country. Physicians or their staff were asked if they performed laboratory tests in their offices. Physicians or staff who indicated they did were asked if their testing exceeded 5,000 tests per year. Information regarding sample selection and methodology can be found in appendix B.

A literature search identified POL quality assurance studies. These studies, journal articles, Federal and State reports (in final and draft), position papers and quality assurance guidelines issued by various associations pertaining to different aspects of testing POLs were reviewed. In addition, representatives from HCFA, the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) were also contacted.

Laboratory testing volume and payment information was obtained from journal articles, previous studies, and from HCFA's Part B Medicare annual data (BMAD) file.

For purposes of this study, we define quality assurance as the overall approach to laboratory testing that ensures the accuracy of the test results. Included in quality assurance are internal quality control measures to ensure that appropriate procedures are followed in collecting and preparing specimens, and in operating and maintaining equipment. Quality control measures also include the use of valid reagents, equipment calibration and systematic procedural checks, error detection and correction, and the review and reporting of test results.

Also included in quality assurance is proficiency testing. Proficiency testing is defined as an external form of quality control which involves sending specimens to a laboratory for analysis. The specimens, although labeled as proficiency testing samples, contain constituents in amounts unknown to the laboratory. The laboratory performs testing on the proficiency testing samples and sends the test results to the proficiency testing organization for evaluation. This organization determines whether the results fall within a prescribed range of grading criteria.

# FINDINGS

*Estimates of the number of POLs and the type of testing performed in them vary widely.*

*Finding:*

Based on our national survey of 200 physicians, we estimate the number of POLs to be approximately 98,400. To our knowledge, this survey is the first of its kind to estimate the number of POLs using random sampling techniques.

Shortcomings in data maintained by HCFA and the States, coupled with the diversity in estimates as to the number of POLs, were instrumental in our decision to sample physicians to arrive at our own estimate as to the number of POLs. We asked 200 randomly selected physicians or their staff if they conducted laboratory tests in their office and if they estimated they performed over 5,000 tests a year. (It should be noted, that for survey purposes, the definition of "test" was determined by the respondent.) Based on our national survey, we estimate there are 98,400 POLs and approximately 34,000 of them perform 5,000 or more tests annually. Appendix B provides more detail on our sample methodology.

The BMAD file can be used to identify physicians billing for laboratory services and to derive volume and payment data. This file cannot identify the number of POLs because physicians are allowed to hold multiple provider numbers, and because the billing codes showing where services were performed are often inaccurate.

The 16 States that govern POLs admit they too cannot identify the total number of POLs operating within their States because: (1) all but 2 exempt some POLs from regulation; and (2) most depend on the physician to voluntarily identify the laboratory site. Those States that require POLs to be licensed, as a condition for Medicaid payment, may have greater success in identifying POLs. The 34 States that do not regulate POLs also admit they cannot provide an accurate estimate of POLs operating in their States.

Other estimates as to the number of POLs vary from 20,000 to 200,000. This variance is due to: (1) lack of uniform POL definition; (2) absence of uniform State regulations; (3) dependence on self-reporting by physicians who operate laboratories; and (4) absence of Federal definitions and regulations.

Medicare and most States do not specifically define a POL. Most States that regulate POLs define a POL as one where physicians use a laboratory to perform tests for their own patients; as one operated by several physicians for the benefit of their own patients; or as one that does not accept more than 99 specimens per category per year from another source. Medicare exempts from regulation any laboratory maintained by a physician for his patients, provided the laboratory does not accept over 99 specimens from physicians outside the practice during a calendar year.

*Finding:*

The complexity of testing in POLs varies widely, as does the type of equipment being used. This is largely because there are no restrictions on the type of testing that POLs can perform.

Data indicate that POLs are usually operated by primary care physicians; e.g., family practitioners, pediatricians and internists. They are likely to perform one or more of the following: analysis of urine, blood sugars, presence of blood in stools and white blood counts. These tests are common because they are easy to perform, provide rapid results, and do not incur large overhead costs.

Advances in medical technology have allowed physicians to expand the scope and complexity of their testing. Some POLs have evolved to such an extent that it is impossible to distinguish the nature of their testing from that conducted in Medicare certified independent and hospital laboratories. Test menus offered by some POLs are more extensive than those offered by some regulated laboratories. This is supported by Medicare payment data for 1986; which indicate that complicated, quantitative procedures, such as radioactive immunological assays, aerobic bacterial cultures, and Pap smears, are performed in POLs. Appendix C lists the procedures most often billed as being performed in POLs during 1985 and 1986. Topping these lists is urinalysis. In both 1985 and 1986, more than 45 percent of all Pap smears billed to Medicare were claimed to have been performed in POLs.

This range in POL testing is due to the advancement in laboratory technology. Laboratory equipment is marketed to POLs based on desktop utility and its purported "error-free" operation. It is priced to accommodate any physician's practice and budget. The range of technology and price goes from simple dipstick reagent strips for urinalysis, which can be purchased for $5 - $10 from the local drug store, to sophisticated analyzers incorporating microprocessor technology available for $3,000 - $50,000 from manufacturers or their distributors. A physician is limited only by whether the size of the practice (current or projected) can support the initial investment and the fixed costs of operating and maintaining the equipment.

***Quality of POL testing concerns respondents; many believe the greatest risk comes from the lack of training and attention to quality control.***

*Finding:*

Quality of testing in POLs concerns almost all of the 79 respondents contacted in the association, State, and manufacturer surveys. Staff qualifications and training, and the lack of proficiency testing are their primary concerns.

Testimony regarding inaccurate laboratory test results was heard at a number of recent congressional hearings. Many of our respondents related anecdotal stories similar to those heard by Congress. One respondent, representing a laboratory equipment manufacturer, reported receiving a call from a POL employee who wanted to know "where do you get the serum?" The "serum" was the patient blood sample needed to run the test. Most of our respondents,

knowledgeable and expert in this area, believe a national problem exists and that there should be Federal intervention in this area.

State concerns focused on the lack of quality control procedures and untrained staff. All professional associations representing laboratorians had grave concerns regarding the quality of testing in POLs. The lack of mandatory quality assurance programs, proficiency testing, and untrained or unqualified staff were problems most often mentioned by these respondents.

All of the laboratory equipment manufacturers agree there are difficulties in maintaining quality control in POLs. Many felt that physicians were reluctant to commit the necessary staff time and resources needed to maintain adequate quality control. They believe, as do others, that POLs lack an understanding as to the purpose of quality control in the laboratory. One respondent summed up the problem by stating that POL personnel (physicians, physician assistants, nurses, receptionists) are "people oriented, not technically oriented."

Most of the laboratory experts we spoke to, and the studies we read, acknowledge the ability of today's modern analyzers to produce accurate test results rapidly. However, these same sources also point out that equipment and reagents are not totally error-free. If equipment is properly maintained and calibrated, and if valid controls of known composition are run in conjunction with samples of unknown composition, the results produced are highly reliable. To achieve valid test results, specimens need to be properly obtained and prepared for analysis. Equipment must be properly calibrated, and controls run. More important, the operator must rigidly adhere to the manufacturer's recommended procedures. Many believe that the greatest risk of error comes from the operator's lack of training and attention to quality control, rather that the equipment itself.

Laboratory equipment must be approved by the FDA before it can be marketed. The FDA process assures that analyzers are capable of consistently producing accurate results. The FDA does not address the risk of error or the likelihood of inaccurate results from improper operation or complexity of equipment.

While there are few independent sources to confirm equipment manufacturers' claims, one consumer group called the Emergency Care Research Institute has begun (but not yet published) independent evaluations of medical devices, including those targeted to POLs. The American Association for Clinical Chemistry is also considering evaluating laboratory equipment used in POLs.

One study indicates that approximately two-thirds of those conducting testing (including physicians) have little or no formal laboratory training. Another study indicates 44 percent have little or no formal training. Our respondents felt that POL employees have inadequate training, and as a result often do not recognize that something has occurred with the sample, the equipment, or the reagent that may have compromised the accuracy of laboratory test results. Other studies indicate that larger group practices, doing high-volume and more complex testing, often employ qualified laboratory technicians, thus greatly reducing this risk.

Physician association representatives recognize that POLs have problems replicating test results and realize that regulation is inevitable. A paper entitled "Regulation of Office Laboratory Testing in the Physician Office," presented by Loschen and Steindel at the 1986 College of American Pathologists (CAP) conference, reflects the position of the physician representatives interviewed. The paper states:

> *Most primary care physicians who operate POLs recognize that there are some legitimate concerns about the quality and accuracy of the results generated by some POLs. Although it would be misleading to say that POLs welcome Federal regulation, most physicians are reasonable enough to recognize the value of uniform regulatory standards by which their laboratories' performances could be assessed against their peers' performances. Most physicians also recognize that in the future, reimbursement by Medicare might be tied to successful participation in laboratory improvement, proficiency testing, and accreditation programs. Physicians would generally welcome the educational components of such a program.*
>
> *It is hoped that such regulation will be reasonable in their expectations, as voluntary as possible, and administered by the private sector, with deemed status being granted by the governmental regulatory agencies. Such regulations should make use of local pathologists and their technical staffs in the assessment and improvement of the POL.*

***Finding:***

Efforts by the private sector to address the quality of testing in POLs have not been effective because participation is voluntary.

In 1985, representatives from the American Academy of Family Practitioners, the American Society of Internal Medicine (ASIM) and the College of American Pathologists (CAP) formed the Commission on Laboratory Office Assessment (COLA). The purpose of this commission is "to establish a voluntary educational and assessment program to insure the quality of data produced in POLs, and to provide a mechanism for accreditation/certification."

While still in the planning stages, COLA plans to become an independent corporation and offer a voluntary program of office laboratory assessment. The COLA's program will include: (1) an internal quality control system, (2) proficiency testing, (3) a self-assessment checklist, and (4) consultative and educational materials. Two other associations, the National Council on Clinical Laboratory Standards (NCCLS) and ASIM have issued or are developing quality assurance guidelines for POLs.

Physician response to voluntary quality assurance programs is reported to be low. While the International Society for Clinical Laboratory Technology offers an accreditation program for POL staff, overall there are few training or accredited programs specifically designed for physician office staff. This is primarily because there has been little demand for such programs. However, a number of respondents stated they would be prepared to offer training given sufficient demand.

The CDC have offered training courses for laboratory personnel for a number of years at their Headquarters in Atlanta. In an effort to reach a larger audience, CDC, laboratory and professional societies are joining together to form regional consortia, offering training to laboratory personnel. These training centers may consider offering programs directly targeted to POL staff if the need for such training becomes apparent.

Like educational programs, all sponsors of proficiency testing programs admit to low POL participation. Proficiency testing has been available to POLs for many years. The CAP offers the External Comparative Evaluation for Laboratories program, and provides data processing and technical support to ASIM which offers the Medical Laboratory Evaluation program. Both programs are targeted for POL use. The American Association of Bioanalysts, manufacturers and several States, including three States that regulate POLs, also offer proficiency testing modules for use in POLs. Approximately 3,000 POLs participate in the proficiency testing programs offered by CAP and ASIM. The exact number of POLs participating in State and equipment manufacturers' proficiency testing programs is unknown. All of these sources for proficiency testing indicate POL participation is very low. One State told us it offered proficiency testing to POLs for $65 a year. At this low price, this State could not generate enough POL participation to warrant continuation of the program. Respondents generally felt that POLs which voluntarily engage in proficiency testing, represent the "cream of the crop.

***Finding:***

Association and State respondents overwhelmingly agree that proficiency testing, continuing education or training, and record keeping should be included in a quality assurance plan for POLs. Personnel standards were the most controversial.

Of the 79 State, association and manufacturer respondents, 25 felt that the same quality standards should apply to all laboratories. Forty-seven respondents believe different standards should apply based on a number of factors such as complexity of testing, type of personnel needed to operate the equipment, volume of testing, and size of group practice. Seven respondents had no opinion or did not respond to the question.

In our survey of associations and State officials, we included a list of possible quality standards and asked respondents to indicate which of these should apply to POLs. There was overwhelming consensus on four quality measures: (1) a written quality assurance plan, (2) continuing education or training, (3) proficiency testing and (4) record keeping.

A written document, detailing quality assurance measures, and continuing education are two elements considered essential to a good quality assurance program. Our respondents strongly support continuing education and training with emphasis on laboratory procedures. Many feel that for training to be effective, it should be adapted to the POL environment. One State reports greater success with "on-site" training at POLs.

The third quality assurance element on which everyone agrees was proficiency testing. All believe proficiency testing should be flexible enough to accommodate the type and sophistication of testing POLs.

The fourth element considered essential was record keeping. Requirements respondents support most strongly are:

- documentation that control samples were run and with what frequency (80 percent);
- a written procedural manual for the techniques used for each test performed (92 percent);
- a quality control log showing daily quality control measurements, problems encountered, investigative and corrective actions taken (92 percent); and
- written procedures for routine maintenance and calibration of equipment, and a repair log (92 percent).

Respondents feel that record format mattered less than the ability to reconstruct what has actually been done in the POL. Others expressed concern that patient confidentiality be protected and that record retention requirements be specified.

While these four elements are endorsed by virtually everyone as essential to a good quality assurance program, there was less consensus in the area of personnel qualifications. Seventy-five percent of the respondents thought there should be restrictions on who can conduct testing, but there was no agreement as to who should be prohibited from testing. Many believe it depends on the complexity of the testing.

***Few states regulate POLS; OBRA of 1987 is viewed as well-meaning but impractical.***

***Finding:***

The 34 States that do not regulate POLs cite lack of legislative support or funding as the most common reason for nonregulation.

Thirty-four of the 50 States contacted do not regulate POLs, although 4 of these have some form of legislation pending. Eighteen of these 34 States have no laboratory regulations at all. Sixteen of these 34 States have regulations pertaining to certain kinds of tests that could affect POLs. For example, if a POL did premarital or prenatal syphilis testing, it theoretically should be regulated in these 16 States.

These 34 States were asked why they did not regulate POLs. Most cited lack of general or legislative support, including statements to the effect that there was "no interest" or "no need." Some indicated a lack of funding to support a regulatory effort. Several others mentioned active physician opposition. Appendix D lists States that do not regulate POLs.

*Finding:*

Sixteen States have legislation pertaining to POLs. Identification of POLs is the most difficult problem they encounter in regulating them.

Sixteen States have laws regulating POLs, including two States that have laws but do not enforce them, and three States that have passed laws but are still developing implementing regulations. According to the respondents' estimates, approximately 9,000 POLs fall under some form of State regulation.

States use a variety of criteria for determining which POLs come under regulation. The most common criteria are: (1) size of group practice, (2) type or complexity of tests performed and (3) prerequisite for Medicaid reimbursement. Four States have a "tiered" system, where the degree of regulation depends on the "tier" in which the POL is categorized. Placement in a tier is usually determined by either the type or the complexity of testing. By the same token, most States exempt some POLs from regulation based on the above criteria. All regulating States require certain POLs to proficiency test and some have mandated personnel requirements. The chart on the following page demonstrates the difference in the regulating programs we reviewed.

Identification of POLs is the "loophole" or shortcoming mentioned most often by officials in States that regulate. Some States depend entirely on physicians voluntarily coming forward and identifying themselves. Other States sent out mass mailings to all licensed physicians requesting they come forward and identify their POLs. Still others require all POLs to register and disclose whether they meet the criteria for regulation or exemption.

The States that require POLs to be licensed or registered as a condition for Medicaid payment, or the two that use reimbursement data to target "potentials," have a better chance of identifying POLs. However, most States do not have the personnel, time, or financial resources to find POLs who have not identified themselves, or to validate the information provided by POLs.

Other regulatory shortcomings mentioned were the inadequacy of group practice size as an indicator of testing volume or complexity, the inability of State regulations to keep up with technological changes, and the "voluntary" aspects of some State regulations on proficiency testing. Another shortcoming appears to be the lack of a viable mechanism to identify POLs in violation of State laws.

On-site inspection of POLs varies tremendously from State to State, depending on the total number of regulated POLs in relation to the State's staff and funding. We did not specifically ask the States about the frequency and content of their inspections. However, staff from one State said they "had the authority but have not done many" because of a shortage of manpower. Another, with 200 "regulated" POLs, has been able to inspect only 50 so far. Two States with regulations pending anticipate doing on-site visits only when proficiency testing performance shows a problem, or in response to a complaint.

# STATE REGULATION OF PHYSICIANS' OFFICE LABORATORIES

| State | Regulation Criteria: No. in Group | Test Complexity | Medicaid Reimbursement | All State Labs Must Register (R) or do Proficiency Testing (PT) | Requirements of POLs Subject to Regulation: Proficiency Testing | On-site Inspections | Quality Control | Personnel Standard |
|---|---|---|---|---|---|---|---|---|
| California | | | | | | | | |
| Licensed | --- | --- | X | PT | X | X | X | X |
| in PT pgrm | --- | --- | --- | PT | X | --- | --- | --- |
| Florida | 5 | --- | --- | --- | X | X | X | X |
| Idaho | --- | --- | --- | R | X | X | X | --- |
| Maryland | | | | | | | | |
| Permits | 3 | --- | --- | PT | X | X | X | X |
| in PT pgrm | --- | X | --- | PT | X | --- | --- | --- |
| Massachusetts | | | | | | | | |
| Full Lic. | 2 | X | --- | --- | X | X | X | X |
| Ltd Lic. | 2 | X | --- | --- | X | X | X | Director |
| Michigan | 5 | --- | --- | --- | X | X | X | X |
| Nevada | --- | --- | X | R | X | X | X | Director |
| Oregon | 4 | --- | --- | --- | X | X | X | Director |
| Pennsylvania | | | | | | | | |
| Level 1 | --- | X | X | R | --- | --- | X | --- |
| Level 2 | --- | X | X | R | X | --- | X | --- |
| Level 3 | --- | X | X | R | X | X | X | X |
| W. Virginia | --- | --- | X | --- | X | X | X | X |
| Wisconsin | 2 | --- | X | --- | X | X | X | Director |

HW - current State law has authority to require proficiency testing in POLs, but has never exercised this authority

IL - recently passed law regarding POLs, but is still developing implementing regulations

ME - recently passed law regarding POLs, but is still developing implementing regulations

NJ - current State definition of "clinical laboratory" includes physician group practices of 4 or more; revisions of implementing regulations, including provisions specific to POLs, mandated before the end of 1988

NY - has 3-tier system based on types of tests performed. Due to limited resources, little more than "educational" surveys of POLs has been done.

Source: "State Regulation of Physician Office Laboratories," Gorove, C., et.al., Laboratory Medicine, Vol. 17, No, 1, January 1986. Supplemented by OAI discussions with State regulatory agencies, 1988.

***Finding:***

While many respondents believe that OBRA of 1987 is a well-meaning attempt to regulate POLs, they are concerned about the practicality of implementing the statute.

Most respondents feel that implementation of OBRA of 1987 would be extremely difficult. "Test," as used in the statute, would need to be more clearly defined. Furthermore, identifying POLs performing over 5,000 tests annually without access to nongovernment data would be problematic, in that HCFA would most likely have to rely on the physicians to identify themselves, their laboratory sites, and the volume of testing they perform. Physician self-identification was a major problem mentioned by both regulating and non-regulating States. Some respondents feel that the statute will never be implemented because the cost of implementation will be prohibitive or because of intensive political pressure from physician groups.

***Finding:***

Applying current Medicare IL standards to POLs may be costly, and could increase the current HCFA workload by a factor of seven.

The OBRA of 1987, under one departmental option, would allow HCFA to apply Medicare IL requirements to "high-volume" POLs. The Medicare IL requirements include: (1) compliance with applicable State and local laws, (2) personnel qualifications, (3) proficiency testing, (4) environmental safety compliance, (5) maintenance of adequate records, (6) adherence to stipulated quality control procedures, and (7) on-site review.

Our survey estimates that there are 98,400 POLs in the country and approximately 34,000 performing over 5,000 tests annually. It should be noted that we did not define "test" in our POL survey because OBRA of 1987 does not define this term. Therefore interpretation was left to the individual respondent. The HCFA estimates 100,000 POLs in operation and believes that the majority of them perform over 5,000 tests per year. These estimates vary not only because there is no uniform definition of a POL, but also because there is no uniform definition of "test." Multiple tests (called "profiles") are sometimes counted as one test and sometimes as more than one test. Should a "test" be defined as an individual component of a profile or panel, then it is possible that most POLs would exceed the 5,000 test threshold and the cost of regulation would be higher than estimated below.

The HCFA regulates approximately 4,500 ILs. Should provisions of OBRA of 1987 be implemented by imposing Medicare IL standards on POLs, we doubt that the IL certification process, as it currently stands, could remain effective with such an increase in workload. The HCFA indicates that precise projections for the anticipated costs of regulating POLs will vary depending on the scope of the regulatory model selected and the size of the regulated population. Applying current Medicare IL standards to POLs would have to include at a minimum the following:

A. costs to hire additional HCFA and State staff to process paperwork and to track proficiency testing;

B. costs to hire and train State surveyors to perform required on-site reviews;

C. costs of surveying the 34,000 POLs performing over 5,000 Medicare and non-Medicare tests per year (an estimated $61 million annually at $1,800 per visit);

D. carrier costs to reprogram computer systems to monitor POLs and ensure that payment is made only for those tests where proficiency testing scores are acceptable (estimated at $1 million); and

E. hearings and appeals costs resulting from adverse actions taken against POLs (estimated at $1 million).

This partial listing of potential costs totals at least $63 million if Medicare IL standards are imposed on "high volume" POLs. The HCFA anticipates additional unidentified costs that cannot be estimated and foresees problems that would have to be resolved; e.g., use of multiple provider numbers, limitations of current billing codes, and proficiency testing categories.

***Finding:***

The majority of respondents feel that all laboratories should be subject to some form of Federal regulation regardless of site or volume of testing. Many believe quality standards should be based on the type and the complexity of testing being performed.

The majority of respondents welcome some form of Federal POL regulation; however, there was no agreement regarding whether IL standards should apply to POLs. Respondents felt patients should be assured of the accuracy of their laboratory tests regardless of where they are performed.

As previously mentioned, respondents were concerned that staff conducting laboratory testing be adequately trained. These same respondents also stated that many people working laboratories, doing the same procedures daily, can produce highly accurate test results. Many respondents believe the ability to consistently produce accurate test results depends on proper initial training, periodic review of test technique and participation in ongoing refresher courses. Discussions regarding who should perform the tests and what training and experience were necessary, often focused on the complexity of the equipment and the degree of human interaction required to perform a test.

A wide range of laboratory services are conducted in POLs. Some of these tests should only be performed by an experienced, qualified medical technologist, because the risk of error associated with these procedures is extremely high. Our respondents felt that the type of equipment and the complexity of reagent preparation and technique, coupled with the degree of subjectivity in interpretation of tests, should be factors taken into consideration when making decisions as to whom should perform laboratory tests.

The ability of a laboratory to consistently produce highly reliable results is the ultimate goal of regulation. All laboratories should be held to uniform standards which facilitate accurate test-

ing. Based on our study, we conclude that in order to develop uniform quality standards, additional study is needed to: (1) determine the degree of risk associated with equipment in use; (2) assess the potential for error due to complexity of equipment, test procedure and other factors; and (3) determine the degree of training required to minimize errors.

# RECOMMENDATIONS

## RECENT EVENTS

Following the Inspector General's congressional testimony regarding POLs and the release of our draft report in June 1988, Congress passed and the President signed into law, CLIA of 1988 (P.L. 100-578). Specifically, this legislation mandates laboratories, including POLs billing Medicare, to be certified under the Public Health Service Act and meet specified standards ad inspection requirements. Laboratories that perform only drug testing and that are certified for testing Federal employees are exempt. However, if the Secretary finds that certain criteria are met, laboratories may receive a certificate of waive from these requirements.

## DRAFT RECOMMENDATIONS - POLS

Following are the recommendations as they appeared in the draft report, and a description of the impact CLIA of 1988 will have on all POLs billing Medicare. In effect, CLIA of 1988 require implementation of our draft recommendations 1, 4, 5, and 7. The amendments also incorporate recommendation 3 and include parts of recommendations 2 and 6.

### I. LONG-RANGE QUALITY ASSURANCE PLANNING

The ultimate goal of regulation is to assure that laboratories consistently produce highly reliable results. All laboratories, regardless of volume of testing or location site, should be held to standards that facilitate accurate testing.

> Recommendation 1: *We recommend that HCFA develop a laboratory regulatory strategy, based on complexity of testing instead of volume or setting.*

*Congressional Action*

As previously mentioned, the amendments mandate quality standards for laboratories, including POLs, based on the complexity of testing in the laboratory, rather than on size or volume of testing.

### II. INITIAL POL REGULATION

As a first step toward a long-range quality assurance program, we recommend that HCFA concurrently move to: develop regulatory standards as set forth in recommendation 2, and seek legislative authority to regulate all POLs, per recommendation 3. This would enable HCFA to begin to collect the information necessary to develop quality assurance standards, based on complexity of testing, while meeting the need for initial action to regulate POLs.

## A. Quality Standards

Recommendation 2: *We recommend that HCFA implement, through regulations pursuant to OBRA 1987, quality standards for POLs that, at a minimum, require POL directors to:*

operate an internal evaluation of laboratory staff that ensures their proficiency in conducting tests and operating equipment in accordance with appropriate quality control mechanisms, including those stipulated by the manufacturer of the equipment;

- participate in laboratory training programs and provide continuing laboratory education for staff;

- maintain a laboratory record keeping system which records all testing and equipment maintenance activities; and

- participate in HCFA-approved proficiency testing program.

***Congressional Action***

In general, CLIA of 1988 require laboratories to operate a quality assurance program that ensures reliability and accuracy of the test; that meets requirements regarding collection, transportation and storage of specimens, and that provides for properly maintained records, equipment and facilities necessary for proper operation of the laboratory. In addition, the Secretary may establish personnel qualification for direction, supervision, and performance of testing in the laboratory. These standards shall take into consideration competency, training, experience, job performance, and education. The standards may very depending on the type of testing being performed and the risks and consequences that erroneous results would cause patients. Also, laboratories must participate in approved proficiency testing programs.

## B. Legislative Authority

To achieve an effective regulatory strategy, all POLs must be subject to regulation.

Recommendation 3: *We recommend that HCFA, at the same time it develops the regulations discussed above, seek a technical amendment to OBRA 1987 that would remove the 5,000 test volume requirement, thus giving HCFA the necessary legislative authority to regulate all POLs.*

If a technical amendment to OBRA 1987 is not forthcoming by January 1990, HCFA should impose the quality standards, discussed above, on POLs performing over 5,000 laboratory tests per year. We recognize that implementation of an unamended OBRA 1987 will require HCFA to define a laboratory test and seek ways to identify "high volume" POLs. Even if it be-

comes necessary to begin regulation with just those POLs performing more than 5,000 tests. HCFA should continue to seek a technical amendment which would enable them to regulate all POLs.

*Congressional Action*

The CLIA of 1988 require all laboratories to submit an application and identify the type and volume of testing being performed to the appropriate authorities. If certain criteria are met, they may then receive a certificate of waiver which excludes them from certain standards and inspection requirements. However, those receiving waivers must report any changes in the scope of testing within specified time frames. Thus, the intent of recommendation 3 has been accomplished. The scope of testing in all POLs will be known and regulated to the appropriate extent.

## C. Implementation and Enforcement

Recommendation 4: *We recommend that HCFA encourage POLs to rely on private sector, Federal, State and manufacturer programs like those offered by COLA, NCCLS and CDC regional consortia, to provide them with quality assurance guidelines and expertise in implementing the quality standards indicated above.*

*Congressional Action*

The CLIA of 1988 state that a laboratory (including POLs) may be accredited, for purposes of obtaining a certificate, if the laboratory meets the standards of an approved accreditation body and authorizes the accreditation body to release records and other information regarding the laboratory to the appropriate authorities. In effect, quality assurance programs offered by private sector, State, and other not-for-profit organizations can be used by POLs to meet the certification requirements, if these accreditation conditions are met.

Recommendation 5: *To implement the above quality standards and monitor POL compliance, we recommend that HCFA:*

- require registration of all POLs billing Medicare; and
- perform unannounced, random on-site inspections of POLs and inspection of POLs which fail to pass proficiency testing.

*Congressional Action*

As mentioned earlier, under CLIA of 1988, all POLs must apply for a certificate or a waiver. In addition, the amendments provide for announced or unannounced inspections of laboratories by appropriate authorities. These will be performed either on a biennial basis or more frequently, if necessary, in order to determine compliance with certification requirements

and standards. The amendments also provide for on-site proficiency testing to assure compliance.

Recommendation 6: *We further recommend that this POL regulation program include one or more of the following enforcement mechanisms:*

- that noncompliance with POL standards be grounds for removing the POL from participation in the Medicare Program;

- that failure to pass certain proficiency testing modules be grounds for suspension of Medicare payment until the POL deficiency is corrected;

- that failure to meet POL standards be grounds for medical licensure sanctions or revocation;

- that failure to register a POL, failure to provide accurate information concerning a POL or noncompliance with POL standards, waive the physician's right to a defense on counts of negligence in malpractice cases involving laboratory testing; and

- that physicians operation POLs be required to attest to compliance with POL standards; in cases of misrepresentation, civil monetary penalties and other sanctions could be invoked.

***Congressional Action***

Besides providing for suspension, revocation or limitation of laboratory's certificate, the amendments also provide for intermediate sanctions if the laboratory is found to no longer substantially meet the requirements for certification. Intermediate sanctions may include directed plans for correction, civil monetary penalties, payment of costs for on-site monitoring or any combination of the above.

## D. Cost Management

On-site inspection of laboratories is essential to information gathering, educational endeavors and enforcement. It is, however, costly. The HCFA estimates the cost of surveying ILs to be $8.1 million annually. The cost of random and targeted visits to POLs could increase these costs by a factor of five.

Recommendation 7: *We recommend that HCFA offset these costs by imposing a registration fee on all Medicare certified laboratories. The total fees should not exceed departmental costs for performing on-site inspections. Imposition of a registration fee*

*could save the program an estimated $43.5 million annually. Further details are provided on pages 24-25.*

*Congressional Action*

The CLIA of 1988 allow the Secretary to collect a fee from each laboratory applying for a certificate. A nominal fee is required for the issuance and renewal of a certificate of a waiver. The amendments state that the fees shall cover the general costs of administering the certification program, including the evaluation and monitoring of approved accrediting bodies. Additional fees will be charged for the inspection for laboratories not accredited by an approved body, and for performing proficiency listing on laboratories which do not participate in approved proficiency testing programs. These fees must be sufficient enough to cover the entire cost of the above activity.

The amendments stipulate that the fees should vary by group or classification of laboratories. The secretary has discretion in determining the amount of fees, however, it may vary based on the dollar volume and scope of testing being performed. Imposition of a registration fee should save the Department millions of dollars that would have otherwise been spent on the registration and inspection of laboratories. Program savings resulting from the fees can be calculated as soon as the fee schedule has been set.

## RATIONALE FOR DRAFT RECOMMENDATIONS

With emphasis on POL ability to produce consistent acceptable outcomes, we believe initial quality standards for POLs need not be identical to current Medicare IL standards. At a minimum, physicians or laboratory directors should ensure that staff involved in testing have completed approved training program(s) designed to sensitize them to the problems that could occur in laboratory testing, and that they are following recommended quality controls. The POL records should provide an audit trail sufficient to assist surveyors in determining the cause of proficiency test failures, and to evaluate the accuracy of tests performed. These audit trail should enable surveyors to assess POL adherence to manufacturers' recommendations for equipment calibration and standardization. Specimen collection and test methodology records should also show what tests were performed in the POL, that controls were run, and at what frequency.

States that regulate POLs indicate that identification of physicians operating laboratories is the biggest problem they face. Requiring physicians to register each POL site they operate, as a condition for receiving Medicare payment, will provide a needed incentive for physician cooperation. This registration requirement should identify most POLs operating in the country, including those operated by physicians who do not bill Government programs. Services not payable under the Medicare program are not payable by Medicaid and often are not payable by other third parties. We believe this will provide additional incentive for registration of POL sites.

Identification of all sites where blood, urine, tissue and other specimens derived from the human body are analyzed is prudent and necessary in ensuring the health and safety of the nation and the quality of laboratory results. Implementation of registration as a condition of payment would be relatively simple. Anyone billing for laboratory services, would need to identify the registered site on their claim. Since fields for this already exist on Medicare paper claims and on electronic media claims, implementation could occur quickly and without extensive change to current systems are now required to recognize certified IL sites and the specialties they perform.

Our purpose in proposing mandatory proficiency testing is to enable independent measurement of the quality of POL testing. Despite some problems with proficiency testing by unscrupulous providers, we feel it is still the best measure of the quality of a laboratory's testing. Failure to arrive at an acceptable result for a proficiency challenge would result in an on-site visit, the purpose of which would be to determine the cause of the failure and to correct the situation. On-site visits to other laboratories would be conducted at random and in proportion to funds available from registration fees.

A laboratory registration fee would be paid to register each laboratory site. These fees would be used to offset the expenses of on-site visits. The HCFA currently surveys approximately 4,500 ILs, at an estimated cost of $8.1 million annually (4,500 x $1,800). Assuming 10 percent of all POLs are randomly surveyed each year, surveying costs for POLs could amount to $35.4 million annually (19,680 x $1,800), for total annual surveying cost of $43.5 million (4,500 + 19,680 x $1,800).

We believe on-site inspection of POLs is essential to information gathering as well as to enforcement of POL regulations. However, the cost of such a program will be expensive. In addition, many State respondents indicated that the current IL surveying program is understaffed and underfunded. To rectify this situation, we recommend a registration fee be imposed on all ILs and POLs billing Medicare. Assuming that 4,500 ILs and 19,680 POLs are surveyed each year at $1,800 per site visit, charging ILs and POLs a registration fee of $425 per year would make the laboratory survey program budget neutral and save the program approximately $43.5 million dollars. Additional savings, which cannot be estimated, would be realized by improvements in the quality of POL testing.

# APPENDIX A

## INSPECTION CONTACTS

### *ASSOCIATIONS*

1. American Academy of Family Physicians
2. American Association for Clinical Chemistry
3. American Association of Bioanalysts
4. American Clinical Laboratory Association
5. American Hospital Association
6. American Medical Association
7. American Society for Medical Technology
8. American Society of Clinical Pathologists
9. American Society of Internal Medicine
10. Clinical Laboratory Management Association
11. College of American Pathologists
12. Committee on Office Laboratory Assessment
13. Health Industry Manufacturers Association
14. International Society of Clinical Laboratory Technology
15. Joint Commission on Accreditation of Healthcare Organizations
16. National Accrediting Agency for Clinical Laboratory Science
17. National Council for Clinical Laboratory Standards

### *MANUFACTURERS*

1. Abbott Laboratories
2. Becton Dickenson Primary Care Diagnostics
3. Coulter Diagnostics
4. Diagnostic Division of Miles Inc.
5. Eastman Kodak
6. E.L. DuPont de Nemours & Company
7. Electro-Nucleonics
8. E-M Diagnostic Systems
9. Labsystems
10. Orion Biomedical
11. Sequoia-Turner Corporation
12. Technicon Instruments

# APPENDIX B

APPENDIX B

POL SURVEY METHODOLOGY

This study used a two-stage cluster sample to estimate the number of physician office laboratories (POLs) nationwide. 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. 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. The following table 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 Lab Services[1] | 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 |

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 three States were, instead, asked to provide a listing of the name and address for

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

| HCPCS | NAME | Place of Service (BMAD 85) | | | | | Place of Service (BMAD 86) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Physicians Office | | | Total | | Physicians Office | | | Total | |
| | | # | Allw | % of Tot | # | Allw | # | Allw | % of Tot | # | Allw |
| 87210 | Smear, Primary, w/ interpret. (wet mount) | 1,590 | $10,182 | 92.6% | 1,717 | $11,113 | 1,750 | $10,822 | 91.8% | 1,907 | $11,912 |
| 83718 | HDL Chol. : Precip. Method | 1,566 | $17,137 | 25.9% | 6,056 | $66,343 | 1,895 | $22,521 | 18.6% | 10,166 | $117,423 |
| 80006 | Auto tests: 6 chemistries | 1,549 | $17,910 | 30.1% | 5,150 | $58,181 | 1,437 | $16,900 | 25.2% | 5,703 | $62,976 |
| 87205 | Routine Smear, Primary, w/ interpret. | 1,514 | $9,137 | 59.7% | 2,536 | $15,674 | 1,521 | $9,198 | 56.3% | 2,700 | $16,512 |
| 87088 | Bacteria Culture, Urine, identification | 1,510 | $16,661 | 40.0% | 3,775 | $40,604 | 2,063 | $23,099 | 36.4% | 5,671 | $63,352 |
| 85044 | Blood Count: Reticulocyte Count | 1,417 | $8,745 | 54.7% | 2,592 | $16,103 | 1,280 | $7,997 | 46.5% | 2,753 | $17,346 |
| 84479 | Triiodothyronine (T-3), Resin Uptake | 1,336 | $13,251 | 18.8% | 7,100 | $62,522 | 1,366 | $14,063 | 13.3% | 10,296 | $92,810 |
| 87060 | Bacteria Culture, aerobic, throat or nose | 1,311 | $12,895 | 66.8% | 1,962 | $20,850 | 1,507 | $15,396 | 74.3% | 2,028 | $21,386 |
| 82756 | Free Thyroxine Index (T-7) | 1,163 | $17,868 | 24.6% | 4,720 | $71,271 | 969 | $15,281 | 15.5% | 6,252 | $95,674 |
| 84420 | Theophylline, Blood or Saliva | 1,147 | $23,042 | 38.4% | 2,990 | $60,488 | 1,549 | $31,257 | 36.7% | 4,223 | $86,286 |
| 83036 | Hemoglobin: Glycosylated (A1C) | 1,144 | $15,958 | 33.6% | 3,401 | $48,356 | 1,388 | $19,209 | 29.9% | 4,644 | $66,125 |
| 87081 | Bacteria Culture, screening, single organis | 1,113 | $9,608 | 74.0% | 1,504 | $13,850 | 1,024 | $8,685 | 67.7% | 1,512 | $14,005 |
| 88302 | Surgical Path: presum. normal | 1,078 | $28,615 | 16.3% | 6,618 | $169,974 | 781 | $20,972 | 13.6% | 5,742 | $149,114 |
| | | 493,175 | $3,500,834 | 57.1% | 864,409 | $7,515,233 | 479,472 | $3,538,514 | | 891,422 | $8,298,415 |
| | Total Labs | 544,250 | $4,251,427 | 51.0% | 1,066,860 | $11,367,923 | 535,404 | $4,363,452 | | 1,133,011 | $12,972,132 |

# APPENDIX D

APPENDIX D

STATES REGULATING LABORATORIES

| STATE | IL | POL |
|---|---|---|
| ALABAMA | X | |
| ALASKA | X | |
| ARIZONA | X | |
| ARKANSAS | | |
| CALIFORNIA | X | X |
| COLORADO | X | |
| CONNECTICUT | X | |
| DELAWARE | X | |
| DISTRICT OF COLUMBIA | | |
| FLORIDA | X | X |
| GEORGIA | X | |
| HAWAII | X | X |
| IDAHO | | X |
| ILLINOIS | X | X |
| INDIANA | X | |
| IOWA | | |
| KANSAS | | |
| KENTUCKY | X | |
| LOUISIANA | | |
| MAINE | X | X |
| MARYLAND | X | X |
| MASSACHUSETTS | X | X |
| MICHIGAN | X | X |
| MINNESOTA | | |
| MISSISSIPPI | X | |
| MISSOURI | | |
| MONTANA | | |
| NEBRASKA | | |
| NEVADA | X | X |
| NEW HAMPSHIRE | X | |
| NEW JERSEY | X | X |
| NEW MEXICO | | |
| NEW YORK | X | |
| NORTH CAROLINA | | |
| NORTH DAKOTA | | |
| OHIO | | |
| OKLAHOMA | | |
| OREGON | X | X |
| PENNSYLVANIA | | X |
| RHODE ISLAND | X | |
| SOUTH CAROLINA | X | |
| SOUTH DAKOTA | | |

| STATE | IL | POL |
|---|---|---|
| TENNESSEE | X | |
| TEXAS | | |
| UTAH | | |
| VERMONT | | |
| VIRGINIA | | |
| WASHINGTON | | |
| WEST VIRGINIA | X | X |
| WISCONSIN | X | X |
| WYOMING | X | X |
| PUERTO RICO | | X |

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