
**QUALITY ASSURANCE AND DISCIPLINARY ACTION
FOR INDEPENDENT CLINICAL LABORATORIES**



OFFICE OF INSPECTOR GENERAL
OFFICE OF ANALYSIS AND INSPECTIONS

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OFFICE OF INSPECTOR GENERAL

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This study was conducted to provide the Health Care Financing Administration and other components in HHS with information on the adequacy of Federal and State monitoring of independent clinical laboratories and to determine if timely and appropriate action is taken to correct deficiencies.

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection was to determine (1) whether Federal and State monitoring of Medicare-certified independent laboratories through proficiency testing (PT), personnel standards and on-site inspections adequately identifies marginal or substandard performance and (2) whether appropriate and timely corrective and disciplinary actions are taken to address deficiencies.

BACKGROUND

Recently, Congress and the news media have raised questions about the accuracy of laboratory tests. These concerns have focused on employee drug tests, the Pap smear test for detecting cervical cancer, blood serum tests for cholesterol levels and tests to detect the presence of AIDS antibodies. As a result, Congress held a series of hearings to gather testimony about the quality of laboratory testing and Federal oversight.

In connection with his testimony at these hearings, the Inspector General publicly released the draft of this report. Subsequently, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) of 1988. In accordance with our recommendations, CLIA of 1988 requires that the Health Care Financing Administration (HCFA) (1) issue uniform proficiency testing (PT) standards for all laboratories, (2) work with the Centers for Disease Control to issue standards for Pap testing and (3) issue regulations to implement intermediate sanctions for substandard laboratories.

This report reflects data collection and analysis performed prior to the passage of CLIA of 1988. For further information regarding CLIA of 1988, see the recommendation section of this report.

MAJOR FINDINGS

Few Laboratories Are Terminated

From 1985 through 1987, a total of 78 laboratories were terminated from Medicare participation either fully or for 1 or more specialties. Inadequate quality control and personnel deficiencies accounted for 53 full terminations and 3 specialty terminations. Inadequate proficiency testing performance accounted for 22 specialty terminations.

Budget Restrictions Limit Staff Available to Monitor Laboratories

Because of budget restrictions, HCFA now requires States to perform on-site inspections of only 68 percent of laboratories each year. Many laboratories are visited only once every 2 years. The HCFA does not target laboratories needing additional monitoring for more frequent surveys.

Reporting Delays and Problems with the Survey Process Limit Effective Laboratory Monitoring

States reported that effective oversight of laboratories is impeded by (1) delayed receipt of PT results from testing organizations, (2) use of an outmoded survey form and (3) Federal reluctance to take corrective action.

Lack of Uniform Proficiency Testing Standards Causes Inconsistent Corrective Action

There are currently no national standards for scoring PT results on a State-by-State basis. Consequently, minimum passing requirements vary, and this can lead to inequities.

States Do Not Routinely Document Instances of Inappropriate Handling of Proficiency Testing Specimens

Although almost 90 percent of the State survey staff interviewed believe that laboratories give improper special handling to PT samples, only 27 States, or 53 percent, had evidence of this.

Some Terminated Laboratories Continue to Receive Medicare Payments

Three of 37 laboratories terminated from participation in Medicare in 1987 continued to receive Medicare payments without interruption.

State Surveyors Want Broader Sanction Authority

Almost two-thirds of the State respondents believe that current sanction authority is inadequate for some situations and that fines and civil penalties could provide increased clout and flexibility.

Most States Do Not Have Special Regulations Covering AIDS or Pap Tests

Most States have no special regulation of Pap or AIDS tests. Current Federal standards for monitoring laboratory performance for these test procedures are inadequate.

RECOMMENDATIONS

The Health Care Financing Administration should:

- issue uniform PT standards for all laboratories regulated under Medicare and CLIA. The standards should include (1) national minimum passing scores for each specialty or subspecialty and (2) acceptable time frames for reporting PT results to States, the laboratories and HCFA;
- work with the Centers for Disease Control to develop and implement regulations with appropriate standards for Pap tests for cervical cancer;
- issue regulations implementing the intermediate sanctions mandated in Section 4064 (d) of the Omnibus Budget and Reconciliation Act of 1987;
- issue guidelines to insure that laboratories test PT specimens in a "routine" manner, the same as for any clinical sample;
- improve the laboratory survey process by (1) revising the laboratory survey instrument and interpretive guidelines to reflect state-of-the-art laboratory operations, (2) streamlining the process for corrective action and (3) developing procedures to target laboratories for inspection based on prior performance and
- develop necessary procedures to insure that carriers do not pay laboratories or other providers that have been terminated from Medicare.

As mentioned previously, CLIA of 1988 implemented the first three recommendations. Although the law partially addressed the fourth and fifth recommendations, full implementation is contingent upon further regulatory and procedural changes. The final recommendation was neither included in our draft report nor addressed by the legislation.

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INTRODUCTION

This inspection on quality assurance and disciplinary action for independent clinical laboratories is one of three related laboratory studies which the Office of Inspector General (OIG) is conducting. The other two studies focus on quality assurance in physician office laboratories and Medicare program costs associated with adopting a national fee schedule for the payment of outpatient laboratory services.

The objectives of this inspection were to determine (1) whether Federal and State monitoring of Medicare-certified independent laboratories through proficiency testing (PT), enforcement of personnel standards and on-site inspections adequately identifies marginal or substandard performance and (2) whether appropriate and timely corrective and disciplinary actions are taken to address deficiencies.

BACKGROUND

Clinical laboratories conduct diagnostic tests on blood, fluids and other substances obtained from the human body. An independent laboratory is defined under current regulations as one which is organizationally and financially separate from attending or consulting physicians' offices as well as hospitals. Many independent laboratories are part of national or regional chains. Approximately 4,500 of the 12,000 federally-regulated clinical laboratories are classified as independent.

Extensive Federal regulation of laboratories began in 1966 with the passage of Medicare and Medicaid and in 1967 with the Clinical Laboratories Improvement Act (CLIA). The CLIA provisions cover all laboratories engaged in interstate commerce. Responsibility for regulating laboratories is shared between two agencies within the Department of Health and Human Services (HHS), the Health Care Financing Administration (HCFA) and the Centers for Disease Control (CDC). A memorandum of understanding between the two agencies makes HCFA responsible for developing and enforcing standards, procedures and regulations pertaining to laboratories under either CLIA or Medicare. The CDC is responsible for providing scientific and technical expertise to HCFA in order to carry out these responsibilities.

The College of American Pathology (CAP) operates a laboratory accreditation program with a set of 14 standards and an annual or biennial inspection process. Most CAP-accredited laboratories are in hospitals. Hospital laboratories accredited by CAP are deemed acceptable for accreditation by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).

Concerns About Laboratory Performance

Recently, Congress and the news media have raised questions about the accuracy of laboratory tests. These concerns have focused on employee drug tests, the Pap test for detecting cervical cancer, blood serum tests for cholesterol levels and tests to detect the presence of AIDS antibodies. As a result, Congress held a series of hearings in the spring and summer of 1988 to gather testimony about the quality of laboratory testing and Federal oversight. Media and congressional interest coincide with longstanding efforts within HHS to define the appropriate Federal regulatory role for laboratory proficiency testing, personnel standards and on-site survey and inspection activities.

A 1987 Wall Street Journal article alleged that Pap tests failed to reveal cervical cancer or cell abnormalities 20 to 40 percent of the time, "making the test one of the most inaccurate of all clinical laboratory procedures." A television news documentary shown in the District of Columbia area in December 1987 publicized the life threatening consequences of false negative Pap test readings. This news program asserted that (1) untrained technologists are used in laboratories, (2) patients die because of incorrect test results and (3) cytotechnologists who do the initial screening of Pap tests often must review two to three times the recommended volume of cases per day.

Concern about false positive and false negative test results is also a highly publicized factor in tests for the AIDS antibody. This is so despite the fact that the incidence of false AIDS tests results is quite low, especially in low risk populations. Researchers at CDC estimate that if the 3.8 million people in the United States who marry each year were tested for AIDS, there would be approximately 1,600 positive tests. About 400 of these would be false positives. In addition, about 100 of the 3.8 million tests would be false negatives. Additional evidence from AIDS testing in the military shows that the incidence of false positive test results is extremely small.

Previous Office of Inspector General Study

In 1981, the OIG issued an audit report with a number of findings pertaining to PT and enforcement of independent laboratory standards. The major findings included the following:

- Actions to revoke a laboratory's license or to terminate Medicare participation for a specialty or subspecialty are subject to long delays or to reversals.
- The HHS does not have an effective mechanism to remove substandard laboratories from the Medicare program.
- Regulators lack a single, acceptable set of national standards defining satisfactory PT performance.

Regulation and Oversight

Medicare regulations require clinical laboratories to meet seven conditions of coverage:

1. The laboratory conforms to all applicable State and local laws.
2. The laboratory is under the direction of a qualified director.
3. The laboratory is supervised by qualified personnel.
4. The laboratory performs only tests that it is qualified to perform and participates in a PT program.
5. The laboratory has a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.
6. The laboratory maintains records and facilities which are adequate and appropriate for the services offered.
7. The laboratory has satisfactory quality control procedures and practices.

Additional CLIA regulations, which include a requirement for Federal licensing, apply to laboratories that receive specimens across State lines. The HCFA supplements Medicare and CLIA regulations through interpretive guidelines.

State regulation of laboratories varies considerably. Although approximately half the States have licensing laws, only a few States carry out comprehensive quality assurance programs. In half the States, the only standards are those required by Federal law and regulation. Medicare regulations require laboratories to comply with State laws. If Federal standards are more stringent, laboratories must meet these. A comparison of State regulation of independent laboratories is contained in the appendix.

Proficiency Testing

Medicare conditions of coverage require all independent laboratories to participate successfully in a PT program in all applicable specialties and subspecialties for which an approved PT program is available. Each PT program must be approved by the Secretary of HHS. The HCFA guidelines require State surveyors to determine that (a) the specimens are tested by employees who are regularly assigned to testing in the applicable specialty, (b) the laboratory uses its routine methods and (c) the laboratory actually tests the PT specimens in-house. Laboratories that do not meet these specifications are not in compliance with Medicare's conditions of coverage.

Most independent laboratories participate in PT programs offered by their State licensing and certification agency, CAP or the American Association of Bioanalysts. Only a few States offer extensive PT through their State laboratories. Almost all States provide syphilis serology testing.

Specimens are mailed by the PT organization to each laboratory on a periodic basis, usually quarterly. The laboratory tests each specimen and returns the analysis for grading. Laboratories must maintain records showing the action taken for each shipment of PT specimens. The PT organization scores the laboratory PT analysis and sends the results to the laboratory and State agency. The State licensing and certification agency determines if the results are satisfactory, marginal or unsatisfactory.

Unsuccessful PT scores in three consecutive quarters or three out of four quarters should result in a specialty or subspecialty decertification recommendation from the State to HCFA. Before taking action to terminate, however, HCFA staff must document whether there are mitigating factors. A decertified laboratory may be reinstated only after achieving satisfactory PT performance for two consecutive quarters or being judged satisfactory in testing specimens onsite during two separate visits by State surveyors.

In December 1987, CDC issued a proposal for departmental consideration to establish a uniform PT program for laboratories regulated under Medicare and CLIA. The purpose of the proposed PT standards is "to identify laboratories whose level of performance constitutes a threat to public health and not to provide educational benefits or to establish an optimum in laboratory performance." Private sector PT organizations would continue to conduct the tests for laboratories in accordance with the new CDC standards and test grading criteria. Laboratories would need to maintain an 80 percent score in the specialty or subspecialty in order to pass.

Enactment of the Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578)

The Inspector General publicly released the draft of this report when he testified before Congress on pending legislation regarding laboratory regulation. Subsequently, Congress passed and the President signed Public Law 100-578, the "Clinical Laboratory Improvement Amendments of 1988." This law requires, among other provisions, that the Secretary of HHS:

- establish uniform criteria for acceptable performance under a PT program;
- include in the standards a system for grading PT performance to determine whether a laboratory has performed acceptably for a particular quarter;
- require laboratories to agree to treat PT samples in the same manner as they treat laboratory examinations or other procedures in the ordinary course of business;

- perform a program of on-site proficiency testing to insure that laboratories continue to meet their certificate requirements;
- establish national standards for quality assurance in cytology services that include eight specific criteria pertaining to the conduct of the tests, the proficiency of laboratory staff and the quality of test specimen preparation and
- impose intermediate sanctions, such as civil money penalties or directed plans of correction, in lieu of suspension, revocation and limitation actions when deemed appropriate.

These six provisions are responsive to most of the findings and recommendations contained in the draft version of this report.

Current Issues Regarding Laboratory Regulations

Between the time the Inspector General released the draft of this report and Congress passed CLIA of 1988, HHS issued revisions to the clinical laboratory regulations as a Notice of Proposed Rulemaking in the Federal Register. These proposed regulations cover many of the issues most central to this study and to CLIA of 1988 insofar as they:

- place more emphasis on proficiency testing and other outcome measures of performance;
- emphasize responsibilities and duties of personnel rather than formal credentialing requirements;
- call for incorporating national PT standards (including the CDC standards and test grading criteria) and
- establish comprehensive guidelines for Pap smear testing.

Since the proposed regulations are based on earlier law, they require revision before they can be implemented under CLIA of 1988. The findings of this report reflect research performed prior to issuance of the Notice of Proposed Rule Making and passage of CLIA of 1988.

Comments on Draft Report

We requested professional organizations representing the laboratory industry and other experts on laboratory performance to review the draft of this report. These reviewers generally supported the recommendations. They also made several suggestions for steps HHS could take to improve proficiency testing. The main

suggestions were that (1) HCFA establish requirements for laboratories to return PT results to PT organizations within specified timeframes, (2) any timeframes for getting results from PT organizations take into account the type of analysis required and not necessarily be uniform across all disciplines, (3) HCFA institute a small random sample of unannounced surveys in addition to focused surveys based on performance screens or complaints and (4) HCFA require PT programs to use combinations of specimen identification codes so that laboratory personnel could not be sure if they have received the same specimens as other laboratories. Laboratories would then be unable to compare their test results.

The CAP took exception to the proposal that HCFA prepare specific guidelines for State agencies to insure that laboratories follow the standards for conducting proficiency testing in a routine manner. The CAP agrees that laboratories handle PT specimens differently than other test samples but alleges that "experience shows that special manipulations of PT samples does not move laboratories from 'unacceptable to acceptable' for regulatory purposes. We would advise caution in developing specific standards for this area of proficiency testing." The JCAHO also does not believe that promulgation of standards will necessarily insure that laboratories handle PT tests in a "routine" manner but suggests that selective on-site observations of the processing of the PT samples could overcome laboratory efforts to "beat the system."

METHODOLOGY

The OIG staff surveyed all 50 State certification agencies to determine (1) the extent of any problem with laboratory certification and proficiency testing and (2) whether adequate follow-up activity is being carried out. We conducted interviews with approximately 50 experts to obtain their views on the relative effectiveness of quality assurance programs. We obtained data from HCFA showing the number and types of Federally-regulated laboratories, deficiencies cited and termination actions taken in 1985, 1986 and 1987. We compared the HCFA data with carrier records to see if the carriers had discontinued Medicare payments to terminated laboratories.

FINDINGS

Few Laboratories Are Terminated

From 1985 through 1987, a total of 78 laboratories were terminated from Medicare participation either fully or for 1 or more specialties. Of these, 53 were full terminations based on recommendations from State licensing and certification agencies. The primary reasons for full termination were inadequate quality control, lack of trained staff and violations of State licensure laws which were identified during on-site surveys. In addition, 22 laboratories were terminated in one or more specialties because of unsatisfactory proficiency testing performance, and 3 were terminated in a single specialty for inadequate quality control or personnel deficiencies.

LABORATORIES TERMINATED 1985 THROUGH 1987	
	NUMBER TERMINATED
Laboratories fully terminated for licensing, quality control and personnel deficiencies	53
Laboratories terminated in a specialty for unsatisfactory PT tests	22
Laboratories terminated in a specialty for quality control or personnel deficiencies	3

SOURCE: HCFA Office of Survey and Certification

The major reason for the low number of Medicare terminations is that HCFA and many State agencies view termination as the last resort, to be used only when efforts to bring a laboratory into compliance have failed. Very often, States are able to achieve compliance without recommending decertification. Either the laboratory will come into compliance on its own, or it will voluntarily drop a test or specialty area where unsatisfactory performance has been noted. In one region, where there have been no decertifications for several years, the HCFA laboratory specialist explained, "Laboratories will do anything to avoid decertification. They will voluntarily stop performing a particular test or will contract with another laboratory for it. Because of this voluntary action by the laboratories, there is seldom a need for formal Federal compliance measures." In another region, the HCFA laboratory specialist explained, "The value of monitoring is to establish an ongoing dialogue between the State and the laboratory rather than the action taken against a laboratory if the laboratory fails."

At least 16 States indicated that they try to work with a deficient laboratory to improve performance prior to initiating adverse action. For failed proficiency testing, many States will contact a laboratory directly to discuss solutions and warn of the consequences for continued failure. The number of warning letters that States send laboratories is many times higher than the number of termination referrals to HCFA. For example, Illinois has sent out 30 to 40 warning letters during the past 3 years, but has not recommended any terminations to HCFA. If a laboratory is unable to improve, many States seek voluntary withdrawal.

About half the States (24) have licensing laws and can take action independent of the Medicare conditions of coverage. These States indicated that they prefer taking action under their own authority using the threat of losing State licensure as an incentive for compliance. Many respondents noted that such State action is faster and more effective because HCFA must exercise due process constraints beyond that of many States. Others commented that HCFA sometimes will piggyback on State licensure actions.

Budget Restrictions Limit Staff Available to Monitor Laboratories

In recent years, budgetary constraints have limited the number of State surveyors available to monitor laboratories. Because of the reduced number of surveyors, HCFA modified its requirements so that States could intensify their inspections of other providers such as nursing homes, which are considered to pose greater safety risks to patients. The HCFA now requires States to perform on-site inspections of only 68 percent of laboratories each year. Nevertheless, about 10 States continue to conduct on-site inspections of all laboratories at least once a year.

Data were obtained from the States showing the number of Medicare-certified independent laboratories in each State and the number of State staff available to perform Medicare-required survey and certification activities. The data show a wide range in the number of laboratories that an individual State surveyor monitors. For example, Idaho has 1 surveyor for every 6 Medicare-certified laboratories while 7 States have 1 surveyor for 60 or more laboratories. These figures are approximate, because some States assign health professionals other than the Medicare contract staff to survey laboratories. In several States, staff survey physician office laboratories in addition to hospital and independent laboratories.

Because of limited staff resources, surveyors in six States suggested targeted inspections based on prior survey results. Laboratories performing in a satisfactory manner would not be visited as often as laboratories with multiple deficiencies. Current survey scheduling does not formally distinguish between laboratories that perform in a satisfactory manner and those that do not. "What is needed," said one surveyor, "is a system in-between visiting a laboratory about one day a year or every other year and having a resident inspector at the laboratory."

Lack of Uniform Proficiency Testing Standards Causes Inconsistent Corrective Action

There are no national standards for scoring PT results by specialty or subspecialty. A PT organization will judge performance relative to the true value for a PT specimen or the best available estimate of the true value. In many cases, because the PT specimen is a biological sample and biological samples can vary, there is not a single value for that sample that can be called the "true" value. Determining true values is also difficult because of wide variations in methodology, instrumentation and standardization among clinical laboratories. In these cases, performance is judged relative to the largest appropriate group of laboratories using comparable methods.

Efforts are underway to introduce criteria for accuracy which are considered clinically or medically relevant. The PT organization sets an acceptable range for test results which differs for each specimen. There is currently no national standard for what that range should be. Consequently, ranges vary from one testing organization to another.

Each State establishes its own protocol for evaluating PT performance. Scoring varies considerably from State to State. For example, some States consider 70 percent to be passing while other States require a passing score of 80 percent for the same specialty or subspecialty. This could result in the termination of a laboratory in one State, while a laboratory with the same level of performance in another State would remain certified.

Nearly 65 percent of State respondents indicated that the lack of national standards for PT grading is a problem. Nearly all laboratory and national association staff also mentioned this issue as a problem. Several States also indicated that the actual grading was made more difficult. As one State surveyor noted, "Grading is a big problem. We don't have enough time to properly score and analyze PT tests. Our standards should be higher than they are. At least national standards would help raise State levels if they are too low." In Regions VII and X, the States and the HCFA regional staff negotiated common standards for PT scoring. In contrast, five State respondents opposed national scoring standards, suggesting that States should have flexibility in grading and that national standards would not necessarily lead to greater testing accuracy.

About 10 percent of the State respondents mentioned problems in comparing laboratories that use different PT organizations which have different degrees of complexity for the same tests. Non-State respondents, however, did not indicate this was a problem.

States Do Not Routinely Document Inappropriate Handling of Proficiency Testing Specimens

About 90 percent of the State survey staff and other respondents believe that laboratories process PT samples differently than samples sent routinely from physician offices. Despite this widespread belief, only 27 States have collected evidence. State survey staff indicated that laboratories have strong incentives to make PT results as accurate as possible. As one State surveyor explained, "As long as PT is used as a regulatory system, laboratories will have to handle PT samples differently. Common sense tells us that a laboratory will put its best foot forward."

Inappropriate handling of PT samples includes any handling which the laboratory would not routinely carry out with that sample. Nonroutine handling could include (1) having the laboratory's best analyst handle the specimen, (2) spending more time and effort analyzing the sample, (3) reviewing the same sample two or more times, (4) discussing sample test results with workers in other laboratories or (5) sending the sample to an outside laboratory for an independent reading.

A review of laboratories decertified over the past 3 years shows that no laboratories were decertified because of handling a PT sample in a manner inconsistent with the standards or the interpretive guidelines. One State surveyor explained, "I know it happens, but I don't have evidence. I would fine the laboratories if I did have the evidence."

States indicate that it is frequently difficult to identify special PT handling. Nonroutine practices such as informal consultation about a PT sample or having the "best" analyst run it are difficult to document. Sometimes documentation of special handling is uncovered almost by accident. Several States reported that laboratories occasionally will return the PT specimen analysis to the PT organization with records showing that an outside reference laboratory actually performed the testing. One reference laboratory said that a request from a laboratory to test an obvious PT sample would be refused. Another State reported that laboratories sometimes submit results of PT tests requiring equipment which the laboratory does not have--clear evidence that an outside laboratory did the test for them. Test scores for PT samples which do not evidence normal statistical variation offer further evidence that a laboratory has given special attention to the sample.

Some laboratories destroy required records showing when a PT specimen is run, who ran it and how often it was run. One HCFA regional laboratory specialist reported that billing records uncovered during a routine inspection showed that the laboratory had sent a PT sample to an outside laboratory for testing. When a follow-up visit was made to verify this, however, the records were missing. According to the HCFA specialist, the laboratory "got the word to correct its records to hide evidence of second opinions from surveyors."

Reporting Delays and Problems with the Survey Process Limit Effective Laboratory Monitoring

Although 80 percent of State respondents believe that the current survey and certification process identifies problem laboratories, some problems were identified that limit its effectiveness. Surveyors complained about (1) delays in receiving PT results from the PT organizations, (2) delays in getting final action from HCFA on deficiencies found in the survey process and (3) an outmoded laboratory survey form.

About 27 percent of States reported problems in timely submission of PT test results from PT organizations. This limited State and laboratory ability to take corrective action. The CAP was identified most often as causing delays. Most States felt a 30- to 60-day turnaround time was reasonable. Sometimes test results did not arrive until the next quarter, when the laboratory could be taking a new PT series. From the laboratory's point of view, results that are 2 or 3 months old are of less value for internal corrective action. According to some State and HCFA regional office staff, CAP has improved recently in transmitting timely test results to States.

When a State finds a deficiency as a result of an inspection, the laboratory is supposed to be notified within 10 days. The laboratory then has 19 days either to rebut the deficiency notice or to submit a corrective action plan. Upon receipt of an acceptable corrective action plan, the State submits the deficiency notice and the plan to HCFA. The laboratory usually has 45 days under the plan to correct the deficiency.

Sometimes the State will make a follow-up visit to the laboratory to verify compliance. Because of limited resources, the State may not follow-up until the next scheduled inspection, which could be 1 to 2 years later. Submission of an acceptable plan effectively removes the finding of a deficiency at least until the next on-site inspection. As one State certification director noted, "In order to decertify a laboratory, we have to move cautiously and carefully. After we cite a deficiency, the back and forth can go on for years."

About one-quarter of the State respondents believe that final action by HCFA is subject to excessive delays. They believe that HCFA is overly cautious in decertifying a laboratory. One State surveyor commented, "HCFA usually sits on cases we have referred to them or they tell us to go back and resurvey the laboratory. Many of our cases just die on the vine." Another State surveyor said, "HCFA gives labs a lot more opportunities than we would. Their attitude seems to be to let the labs get back into compliance rather than to decertify them."

About 50 percent of the respondents said the survey process should be revised. They indicated that the survey instrument does not reflect advances in technology, particularly concerning the need to monitor automated equipment. The survey instrument was developed when most procedures were still performed manually. The form contains many obsolete items and excludes many items that should be

inspected. For example, the form requires the laboratory to perform "linearity checks" to determine an analyzer's range of accuracy. Several brands of analyzers which are now on the market, however, do not require such checks. Any revision in the survey process needs to be flexible enough to take into account rapidly evolving laboratory technology.

About 10 percent of respondents mentioned that the survey process was overly concerned with paperwork rather than with substantive review. "Paperwork reviews can't tell you everything, and day-to-day practices can't be reviewed on an annual basis," said one State laboratory surveyor. These surveyors feel that many of the deficiencies cited during on-site inspections are minor problems or "paper compliance issues." These include such issues as lighting or certain fire and safety codes. At least one regional quality control officer for a laboratory chain said, however, that the State Medicare surveyors were more flexible in interpreting survey requirements than some professional certification organization representatives.

State Surveyors Want To Keep Personnel Standards

Personnel standards are one of the most controversial areas in Federal regulation of laboratories. Current regulations mandate credentials for every category of laboratory personnel from director to technician. The debate centers upon whether these Federal standards should be relaxed in favor of reliance on outcome measurement. Almost 75 percent of the State agency respondents believe that the Medicare conditions of coverage, which have detailed personnel standards, are appropriate for independent laboratories. Almost 50 percent of the respondents singled out the importance of maintaining the current personnel standards. Only six State respondents suggested that personnel standards are unrealistic or overly rigid and should be removed. Most of the laboratory professional associations want to maintain personnel standards which mandate credentialing for their specialty.

Some Terminated Laboratories Continue to Receive Medicare Payments

During 1987, HCFA terminated 21 independent laboratories from Medicare participation for deficiencies in quality control or personnel standards. An additional 15 laboratories were terminated in a specialty because they failed proficiency testing. One laboratory was terminated in a specialty due to quality control problems.

To determine whether the terminations were carried out, OIG staff obtained laboratory enrollment information from Medicare carriers servicing each of the 37 laboratories. The carrier data indicated that no termination action had been taken on three (8 percent) of the laboratories. There is no indication whether HCFA sent the carriers termination instructions in each instance. Ordinarily, HCFA sends the carriers a copy of the termination letter sent to the laboratory. The

carriers must decide from the letter what action to take, whether to stop payment for all laboratory Medicare services or for one or more specialties. Regional HCFA staff stated that the letter can be confusing to carrier staff and should be replaced by a simple form. They also stated that they usually do not follow up with carriers when laboratory termination notices are issued and normally do not review carrier action on termination notices when they evaluate carrier performance.

State Surveyors Want Broader Sanction Authority

Under current regulations, the major sanction authority for Medicare laboratories is decertification leading to termination from participation. Fines, civil money penalties or other intermediate sanctions have not been used as remedies for laboratory deficiencies.

Nearly two-thirds of the State respondents believe that current sanction authority is inadequate. Although fines were mentioned most often, there was no consensus of what should be included in an intermediate sanction program. Most felt that intermediate sanctions would be effective only if they could be imposed without the delays inherent in decertifying a laboratory.

States that license laboratories can revoke licenses for cause. Five states have the authority to impose fines. Surveyors from at least a third of the States suggested that a program of fines would provide increased flexibility to impose sanctions for offenses which do not warrant termination of a specialty or outright closure of a facility. For example, Florida has authority to impose fines up to a maximum of \$500 per day for violations of licensing laws. First offense fines are typically \$250 per day and second offenses \$350. A New Jersey surveyor argued that fines are appropriate and effective, "We can impose fines up to \$250 per day. I'd like to see a faster appeals process, but so far we have gotten a lot of cooperation and have won all our cases."

The Omnibus Budget Reconciliation Act of 1987 (OBRA) mandated HCFA to develop regulations for intermediate sanctions that could be used with laboratories and other categories of providers "in lieu of termination." Regulations to implement these provisions are still under development. The CLIA 1988 also contains a provision regarding intermediate sanctions, as indicated on page 5.

Most States Do Not Have Special Regulations Covering AIDS or Pap Smear Tests

Because of concerns raised about the accuracy of tests for the AIDS antibody or for Pap smear tests for cervical cancer, we asked whether any special regulations or oversight were given to these two tests. Only 20 percent of the States indicated any special oversight for AIDS tests and only 10 percent for Pap smears.

AIDS Testing

Both Medicare and CLIA require that a laboratory enroll in proficiency testing when an approved program is available. Laboratories not subject to Medicare or CLIA regulations or to special State requirements receive no oversight. The CDC testing program is a research activity called the Model Performance Evaluation Program. It is designed to provide answers to questions about the effect of factors such as personnel, methodology and quality assurance on test results. It is not designed to evaluate individual laboratory performance. Both CDC and CAP offer proficiency testing for the AIDS antibody test.

Twenty-four States have no regulations covering AIDS antibody testing, although legislation is pending in several. Much of that legislation deals with confidentiality of test results rather than with testing per se. Three States require that their public health laboratory or the testing laboratory perform a confirmatory test on all positives before reporting them. Three States monitor AIDS testing and send advisories to laboratories. Two States require special licensure. New Jersey, for example, requires special licensure as a precondition for AIDS testing. As part of the application for licensure, the laboratory must submit a testing protocol for State approval. The State agency conducts on-site proficiency testing before the license can be granted. The laboratory also must adhere to strict rules of confidentiality. New York conducts all AIDS antibody testing in its own laboratories, which must have a PT score of 100 percent. By comparison, Oregon, which also requires labs to enroll in either CDC or CAP proficiency testing, accepts a 75 percent passing score.

Almost all professional group respondents and other experts felt that no special emphasis need be given to standards for AIDS testing beyond current PT requirements. According to CAP, "testing for antibody to HIV is among the most accurate tests available today."

Pap Tests

The Pap test is the microscopic evaluation of cells obtained from the uterine cervix stained according to the method originally devised by Dr. George Papanicolaou. Cytopathologist and cytotechnologist respondents identified several factors that lead to Pap test errors. The most important of these are:

- inadequate collection of the Pap smear sample by the physician and failure of the laboratory to reject these samples and request new ones;
- excessive cytotechnologist workloads involving as many as 200 to 300 slides per day rather than the 80 per day as recommended by all national organizations of cytopathologists and cytotechnologists. This problem is exacerbated by cytotechnologist salaries which frequently are based on a per case rate. This causes some cytotechnologists to work a second shift

in a different laboratory and thus to exceed the recommended limit on slides reviewed;

- errors in the initial microscopic reading and laboratory failure to impose an adequate rescreening program;
- cytotechnologists who review the Pap smears at home, away from supervision of the laboratory;
- lack of adequate internal quality assurance and external proficiency testing programs for cytotechnologists and cytopathologists;
- physician failure to provide the laboratory with adequate diagnostic and clinical information about the patient, which can lead to an inaccurate test result and
- failure on the part of the physician to communicate test results to the patient.

New York has the most extensive regulations for Pap tests. These include provision for on-site proficiency testing. Laboratories are rated on 10 smears, some positive and some negative. State officials hand carry the slides to the laboratory and test each cytotechnologist individually. Laboratories are given four chances to pass. From 1978 to 1984, only 10 laboratories out of approximately 1,000 failed 3 tests, and only 1 of those 10 failed a fourth time.

The CDC is assisting HCFA in developing standards and maintaining quality assurance of Pap smear test performance.

RECOMMENDATIONS

RECOMMENDATIONS IMPLEMENTED THROUGH CLIA OF 1988

The following three recommendations were implemented by CLIA of 1988. To fully accomplish these recommendations, HCFA need only implement the regulatory and procedural changes mandated by the law.

RECOMMENDATION #1--UNIFORM PROFICIENCY TESTING STANDARDS

FINDING: Lack of national criteria for scoring PT results can lead to inequitable interpretations of laboratory performance and significant delays in corrective action.

RECOMMENDATION: Uniform PT standards developed by CDC for all laboratories regulated under Medicare and CLIA should be approved and implemented. The standards should include (1) national minimum passing scores for each specialty or subspecialty, (2) timeframes for reporting test results from PT organizations to States and laboratories, (3) consistency among PT organizations and (4) timeframes for States to take necessary corrective action such as warnings or decertification recommendations to HCFA.

IMPACT: Uniform national standards for proficiency testing would lead to more equitable and timely corrective action for all laboratory deficiencies.

CONGRESSIONAL ACTION: The CLIA of 1988 mandates that HHS establish uniform criteria for acceptable performance under a proficiency testing program.

RECOMMENDATION #2--MONITORING PAP SMEARS AND AIDS TESTING

FINDING: Most States have no special regulation of Pap or AIDS tests. Current Federal standards for monitoring laboratory performance for these two test procedures are inadequate.

RECOMMENDATION: The CDC and HCFA should issue guidelines for cytology and Pap tests covering (a) appropriate workload guidelines, (b) standards for the acceptability of specimens submitted to laboratories, (c) standards for patient information required to be submitted with specimens and (d) mandatory proficiency testing.

IMPACT: Issuance of standards to insure the greatest feasible accuracy of AIDS and Pap smear testing would alleviate much of the current concern about the performance of laboratories.

CONGRESSIONAL ACTION: The CLIA of 1988 establishes national standards for quality assurance in cytology services that must include eight specific criteria in areas such as the conduct of the tests, the number of tests to be reviewed by any individual in a 24-hour period, when rescreening of specimens is necessary, the proficiency of laboratory staff and the quality of test specimen preparation.

RECOMMENDATION #3--INTERMEDIATE SANCTIONS

FINDING: Almost two-thirds of State surveyors believed that an increased range of sanction authority, which could be imposed without undue delays, would provide increased clout and flexibility.

RECOMMENDATION: The HCFA should complete and issue regulations implementing the intermediate sanctions provided for in Section 4064 (d) of OBRA 1987 which amends Section 1846 (a) and (b) of the Social Security Act.

IMPACT: Implementation of this authority would give States a range of sanctions to use in lieu of recommending termination.

CONGRESSIONAL ACTION: The CLIA of 1988 imposes a new set of intermediate sanctions, such as civil money penalties or directed plans of correction, in lieu of suspension, revocation and limitation actions when deemed appropriate.

RECOMMENDATIONS ADDRESSED BY CLIA OF 1988 THAT STILL REQUIRE FURTHER ACTION

The following two recommendations were addressed, in part, by CLIA of 1988. To fully accomplish these recommendations, however, HCFA will need to implement regulatory and procedural changes beyond those required by CLIA of 1988.

RECOMMENDATION #4--STANDARDS OF CONDUCT FOR PROFICIENCY TESTING

FINDING: Although most State surveyors believe that many laboratories do not perform proficiency tests in a routine manner, there is little documentation to support this belief.

RECOMMENDATION: The HCFA should approve and implement explicit standards of conduct for laboratories participating in PT. In addition, HCFA should (1) prepare specific guidelines for State agencies to insure that laboratories follow the standards for conducting proficiency tests in a "routine" manner the same as for any clinical sample, (2) instruct States to document instances where prohibited processing of PT samples takes place and (3) instruct States to conduct on-site observation of laboratories processing PT samples on a selective basis.

IMPACT: Close monitoring of laboratory participation in PT, with appropriate corrective action, would reduce instances of inappropriate handling of PT specimens.

CONGRESSIONAL ACTION: The CLIA of 1988 requires that (1) a laboratory agree to treat PT samples "in the same manner as it treats material derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of its business" and (2) the Secretary "perform a program of on-site proficiency testing to insure that laboratories continue to meet their certificate requirements."

HCFA RESPONSE: The HCFA states that the proposed regulations contain explicit standards for conducting PT. Additionally, HCFA is considering a demonstration project to evaluate the feasibility of on-site PT.

RECOMMENDATION #5--LABORATORY SURVEY PROCESS

FINDING: Lack of targeting, coupled with limited staff, results in insufficient attention to laboratories with deficiencies. Portions of the current survey instrument are obsolete because they do not reflect advances in technology.

RECOMMENDATION: The HCFA should (a) revise the laboratory survey instrument and the interpretive guidelines to reflect state-of-the-art laboratory practices, (b) streamline the process for insuring corrective action following a finding of deficiency and (c) develop procedures to target laboratories for inspection based on prior performance so that all laboratories with deficiencies or unusual problems could be inspected more frequently and laboratories without problems less frequently.

IMPACT: A survey process which allows for targeting and adequate timeframes for corrective action will insure adequate monitoring even with increased workloads and resource limitations.

CONGRESSIONAL ACTION: The CLIA of 1988 states that the Secretary may, on an announced or unannounced basis, enter and inspect laboratories which have been issued a required certificate and have access to all facilities, equipment, materials, records and information determined to have a bearing on whether the laboratory is being operated in accordance with national quality standards.

HCFA RESPONSE: The HCFA concurs with this recommendation.

NEW RECOMMENDATION

The following recommendation was not included in the draft report. Because the finding is not addressed by CLIA of 1988, we have decided to include this recommendation in the final report.

RECOMMENDATION #6--REIMBURSEMENT TO TERMINATED LABORATORIES

FINDING: Carriers continue to reimburse some laboratories terminated from participation in Medicare. The HCFA performed no follow-up or verification with the carriers to determine if payment had been stopped.

RECOMMENDATION: The HCFA should develop procedures to verify carrier action on laboratories terminated from Medicare. Additionally, HCFA should modify the way it notifies carriers of terminations. A specialty deletion check-off sheet to the carrier would be appropriate.

IMPACT: Clear instructions and follow-up with carriers by HCFA would eliminate or greatly reduce overpayments to terminated laboratories.

STATE REGULATION OF LABORATORIES

The following matrix identifies States that (a) license independent laboratories (IL), (b) regulate quality control (QC) and laboratory personnel (PERS) and (c) require inspections (INSP).

	IL	QC	PERS	INSP
ALABAMA	X	X	X	X
ALASKA				
ARIZONA	X	X	X	X
ARKANSAS				
CALIFORNIA	X	X	X	X
COLORADO				
CONNECTICUT	X	X	X	X
DELAWARE	X	X	X	X
FLORIDA	X	X	X	X
GEORGIA	X	X	X	X
HAWAII	X	X	X	X
IDAHO		X	X	X
ILLINOIS	X	X	X	X
INDIANA			X	
IOWA				
KANSAS				
KENTUCKY	X	X	X	X
LOUISIANA				
MAINE	X	X	X	X
MARYLAND	X	X	X	X
MASSACHUSETTS	X	X	X	X
MICHIGAN	X	X	X	X
MINNESOTA				
MISSISSIPPI				
MISSOURI			X	X
MONTANA				X
NEBRASKA				
NEVADA	X	X	X	X
NEW HAMPSHIRE	X	X	X	X
NEW JERSEY	X	X	X	X
NEW MEXICO		X	X	X
NEW YORK	X	X	X	X
NORTH CAROLINA			X	
NORTH DAKOTA		X	X	
OHIO			X	
OKLAHOMA		X	X	
OREGON	X	X	X	X
PENNSYLVANIA	X	X	X	X
RHODE ISLAND	X	X	X	X
SOUTH CAROLINA				
SOUTH DAKOTA				
TENNESSEE	X	X	X	X
TEXAS				
UTAH				
VERMONT		X	X	
VIRGINIA				
WASHINGTON				X
WEST VIRGINIA				
WISCONSIN	X	X	X	X
WYOMING	X	X	X	X