

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**Enrollment and Certification Processes in the  
Clinical Laboratory Improvement  
Amendments Program**



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# EXECUTIVE SUMMARY

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## PURPOSE

To identify vulnerabilities in the Clinical Laboratory Improvement Amendments program enrollment and certification processes.

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## BACKGROUND

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establish “quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.” The Centers for Medicare and Medicaid Services (CMS) oversee the CLIA program.

Laboratories that conduct moderate or high complexity testing are surveyed every 2 years by State agencies and private sector accreditation agencies to ensure compliance. Laboratories conducting provider-performed microscopy procedures and/or waived tests are not routinely surveyed. Waived and provider-performed microscopy facilities constitute 75 percent of laboratories certified under CLIA.

Waived tests are determined by the FDA to have “an insignificant risk of erroneous result,” including simple and accurate tests or “those which pose no reasonable risk of harm to the patient if performed incorrectly.” Tests sold over the counter for home use are included in the waived category.

The information presented in this report was collected during the inspection titled: *CLIA Regulation of Unestablished Laboratory Tests*, (OEI-05-00-00250). To produce this report, we conducted additional analyses of the data gathered.

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## FINDINGS

### **Significant Vulnerabilities Exist in CLIA’s Oversight of Waived and Provider-Performed Microscopy Laboratories**

State surveyors and CMS studies indicate that there may be widespread problems at waived and provider-performed microscopy laboratories. Colorado and Ohio surveyors found that about half of waived and provider-performed microscopy laboratories were not following manufacturers’ instructions, did not have manufacturers’ instructions onsite, or were conducting tests they were not authorized to perform. Colorado State

surveyors found 90 percent of provider-performed microscopy laboratories lacked written procedures or could not demonstrate the accuracy of the test method or the competency of testing personnel. These findings have led CMS to initiate a pilot project in eight other States to survey a sample of waived and provider-performed microscopy laboratories.

Because waived and provider-performed microscopy laboratories are not routinely surveyed, surveyors do not have the opportunity to educate staff, or identify and correct problems. Nearly all of our State agency respondents believe that the lack of onsite visits of waived and provider-performed microscopy laboratories is a vulnerability. A majority of State respondents report that they have found these laboratories performing moderate or high complexity tests. We found that 13 percent of waived laboratories and 11 percent of provider-performed microscopy laboratories in our sample were denied Medicare payment for tests they were not authorized to perform.

### **Despite Safeguards, Some Vulnerabilities Also Exist for Moderate and High Complexity Laboratories**

Waived and provider-performed microscopy tests are not evaluated during routine surveys of moderate and high complexity laboratories. Colorado surveyors found significant problems with waived tests conducted at 40 percent of moderate and high complexity laboratories.

The CMS's regulations permit new laboratories to operate for up to 24 months before they are visited to ensure compliance with CLIA requirements. Some States have expressed concern that laboratories may be performing poorly during this period. Although the CLIA regulations allow for 2 years before the initial onsite visit, some States report inspecting most laboratories in under a year, and CMS has encouraged States to inspect new laboratories three months after the initial application is complete.

### **CMS's Reliance on Laboratories to Self-Identify for Enrollment Appears to be a Weakness**

We identified 160 laboratories that had offered laboratory tests and yet were not certified by CLIA to do so. Despite widespread belief that most laboratories voluntarily enroll in the CLIA program, 43 State agencies reported that they have found sites conducting laboratory tests without a CLIA certificate.

### **Some State Processes Augment Safeguards in the CLIA Program, Although Vulnerabilities Remain**

Some State laboratory licensure requirements may mitigate vulnerabilities in the CLIA program. About half of the States report having a State laboratory licensure program in addition to the CLIA program. Of these, ten State programs survey some or all waived and provider-performed microscopy laboratories, and 14 programs require initial onsite surveys earlier than the CLIA requirement of 24 months.

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## RECOMMENDATIONS

The purpose of this report is to identify vulnerabilities in the CLIA enrollment and certification processes. We believe that CMS needs to take some action to reduce the vulnerabilities identified in this report. We recognize that resources are limited and that implementing some of the following recommendations may require additional funding.

### **Regarding waived and provider-performed microscopy laboratories, we recommend that CMS:**

- C Provide educational outreach to directors of waived and provider-performed microscopy laboratories regarding CLIA requirements.
- C Require laboratories applying for waived and provider-performed microscopy certificates to identify which test systems they will use.
- C Establish a mechanism whereby Medicare claim denials can be used to inform State laboratory surveyors about laboratories billing outside their certificate.
- C Use periodic paper self-assessment tools to help ensure compliance for laboratories that are not routinely visited.
- C If CMS's pilot project finds similar problems to those found in the Ohio and Colorado studies, we encourage CMS to conduct random onsite inspections of some waived and provider-performed microscopy laboratories each year.

### **Regarding surveyed laboratories, we recommend that CMS:**

- C Review waived and provider-performed microscopy testing at moderate and high complexity laboratories during routine surveys.
- C Shorten the time between application and initial onsite visits to new laboratories.
- C Formally require accreditation agencies to inform CMS about laboratories conducting tests in specialties not accredited by the agency.
- C Establish a workgroup to develop methods to identify uncertified laboratories.

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## AGENCY COMMENTS

We appreciate the assistance and cooperation we received from CMS staff while conducting this study. We received comments from them on this report and they concurred with our recommendations. The text of their comments can be found in Appendix A.

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# INTRODUCTION

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## PURPOSE

To identify vulnerabilities in the Clinical Laboratory Improvement Amendments program enrollment and certification processes.

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## BACKGROUND

The information presented in this report was collected during the inspection titled: *CLIA Regulation of Unestablished Laboratory Tests*, (OEI-05-00-00250). That inspection's purpose was to examine how the Centers for Medicare and Medicaid Services (CMS) regulate laboratories conducting unestablished laboratory tests. During the course of that inspection, we found information not only about unestablished tests, but also about vulnerabilities in CLIA enrollment and certification processes that apply to all laboratories. This report was written to outline those vulnerabilities, and includes additional analyses of the original data gathered.

In 1988, Congress enacted the Clinical Laboratory Improvement Amendments (CLIA). The CLIA established “quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.” The CMS is responsible for implementing CLIA, including laboratory registration, fee collection, onsite surveys and enforcement. The CMS contracts with State agencies and private accreditation agencies to carry out the provisions of the Clinical Laboratory Improvement Amendments.

Under current law, all laboratories must be certified under CLIA to perform testing on human specimens.<sup>1</sup> In addition, Medicare and Medicaid require CLIA certification as a condition of payment. The CLIA regulations define a laboratory as:

*[A] facility for the . . . examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.*

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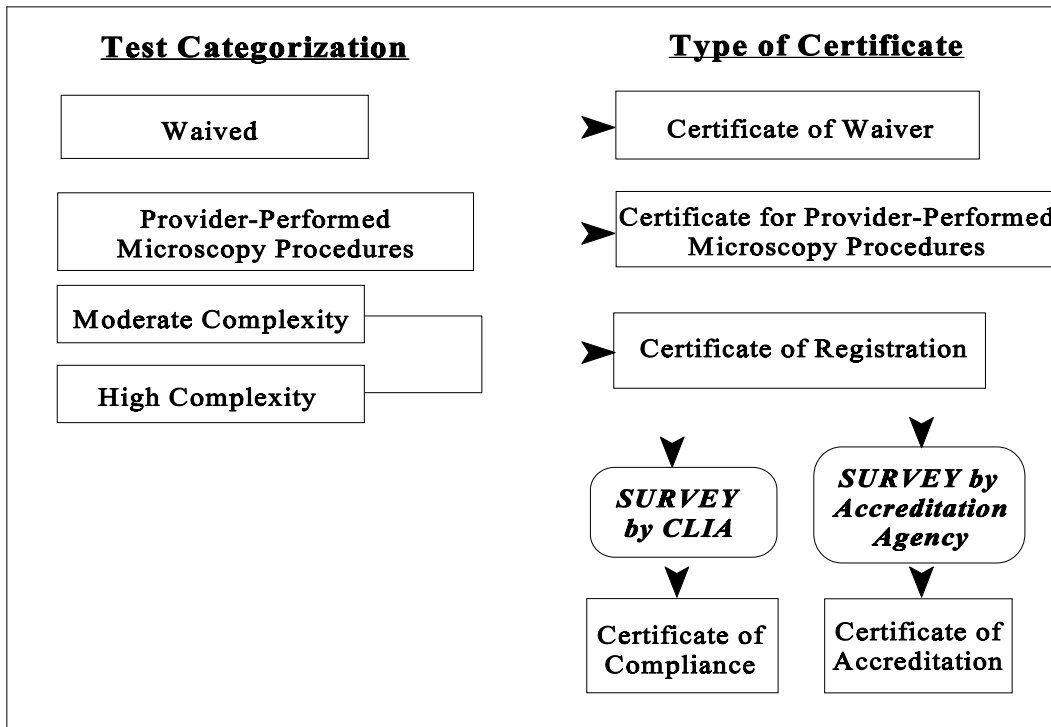
<sup>1</sup>The regulations allow for some exceptions, including forensic laboratories, research laboratories that “do not report patient-specific results,” drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration, and some Federal laboratories.

Laboratories enroll in the program by completing an application and paying a certificate fee to CMS. Fees are based on certificate type, annual volume and types of testing reported on the application. All laboratories are required to keep CMS informed of major changes in testing, laboratory ownership or directorship. All CLIA-certified laboratories must also comply with all State laws governing laboratories.

## Types of CLIA Certificates

Each laboratory must have a certificate appropriate for the complexity of the testing conducted. All laboratory test methods have been categorized by the Food and Drug Administration<sup>2</sup> (FDA) into the following four categories based on testing complexity: high complexity, moderate complexity, provider-performed microscopy and waived. The type of CLIA certificate issued relates to the complexity of testing conducted at the laboratory (see Figure 1).

**Figure 1: Relation of test categorization to CLIA certificate type**



Source: OEI Process Analysis, 2001

As of July 2000, nearly 170,000 laboratories were registered under CLIA.<sup>3</sup> About 86,500 laboratories (53 percent) have been issued a Certificate of Waiver. Certificates of Waiver

<sup>2</sup>The Centers for Disease Control and Prevention held this responsibility until January, 2000.

<sup>3</sup>This includes about 5,800 laboratories in New York and Washington which are exempt States. These States meet CMS requirements to survey and certify laboratories under their State program. The States must pay a fee and show CMS that the State program meets or exceeds the requirements for laboratories under CLIA.



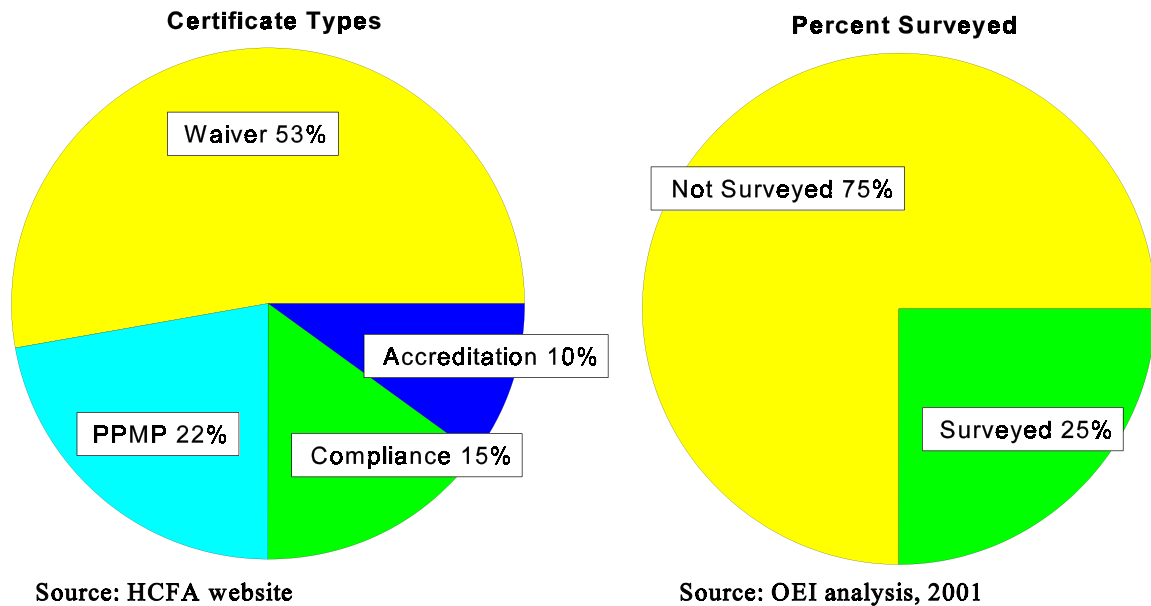
are issued to laboratories that use specific test methods approved by the FDA for this category. A test may be categorized as a waived test if it is approved by FDA for home use, or if it is determined to have an insignificant risk of erroneous result, including those that:

- C “are so simple and accurate as to render the likelihood of erroneous results negligible, or
- C the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.”<sup>4</sup>

Under the Clinical Laboratory Improvement Amendments, waived laboratories are only required to follow manufacturers’ instructions for waived tests and to limit testing to methods approved by the FDA as waived. These laboratories may be surveyed if complaints are filed against them, but waived laboratories are not routinely surveyed.

Approximately 36,000 laboratories hold Certificates for Provider Performed Microscopy Procedures. These certificates are issued to physicians and other approved providers who meet CLIA requirements to perform specific moderate-complexity microscopy procedures. Laboratories with these certificates may also conduct waived tests. These laboratories are required to have written procedures for the tests they perform. All provider-performed microscopy laboratories must have a quality assurance system to evaluate test method accuracy and a system to assure competency of testing personnel.

**Figure 2: CLIA Laboratories**



<sup>4</sup>Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, sec. 353(d)(3)(B) and sec. 353(d)(3)(C) (1988).

All provider-performed microscopy tests must be performed by a physician or other qualified provider as defined in CLIA regulations. No other laboratory employee is permitted to conduct these tests. As with waived laboratories, laboratories with a provider-performed microscopy certificate may be surveyed if complaints are filed, but are not otherwise routinely inspected by CLIA surveyors.

The remaining 41,500 laboratories conduct moderate or high complexity testing. When these laboratories initially apply for CLIA certification, they are issued a Certificate of Registration and a CLIA number. Laboratories with a Certificate of Registration can conduct testing and bill Medicare and Medicaid until they are inspected. Onsite inspections occur within 24 months of filing an application and are used to verify compliance with CLIA standards. Once the laboratory has proven to surveyors that it meets all requirements, it is issued a Certificate of Compliance or a Certificate of Accreditation. These laboratories are revisited every 2 years to verify compliance with CLIA standards.

### **Surveys: State Agencies, Accreditation Agencies and CMS Regional Offices**

The majority of moderate and high complexity laboratories are surveyed by State agencies. The CMS contracts with State survey agencies to carry out the oversight provisions of CLIA, including routine visits to laboratories as required under CLIA law. State agencies also investigate complaints and maintain laboratory application and survey records in CMS databases.

Laboratories can elect to be surveyed by an accreditation agency that has been approved by CMS. The CMS has contracts with six such agencies to provide surveys of laboratories. Some accreditation agencies review all specialties and subspecialties, while other agencies only accredit some of them. Accreditation agencies tend to serve specific types of laboratories. For example, the Commission on Office Laboratory Accreditation primarily accredits physician office laboratories. Every 2 years, States conduct validation surveys of 5 percent of the accredited laboratories in their State.

The CMS's regional offices assist States in their oversight functions. Regional office staff perform onsite surveys of federally operated laboratories, State laboratories and some county laboratories. Regional office surveyors also conduct monitoring surveys of laboratories that the State has inspected to ensure the accuracy of State surveyor inspections. In addition to surveys, regional offices provide advice to States and laboratories regarding CLIA regulations, processes and procedures.

### **Specialties and Subspecialties**

The CMS has divided all laboratory tests into nine testing specialties: Histocompatibility, Microbiology, Diagnostic Immunology, Chemistry, Hematology, Immunohematology, Pathology, Radiobioassay and Clinical Cytogenetics. Six of these specialties are further divided into a total of 21 subspecialties. All laboratories, except

those applying for a Certificate of Waiver, must report their intended testing specialties and subspecialties on their CLIA application. All CLIA-certified laboratories are required to notify CMS of any changes to their specialties and subspecialties.

## Waived Laboratories and CMS's Pilot Studies

In 1999, Colorado and Ohio State surveyors received permission from CMS to conduct random inspections of about 100 waived and provider-performed microscopy laboratories in their respective States. After reviewing these State studies, CMS concluded that, “significant quality and certification problems were identified in over 50 percent of these laboratories.” Consequently, CMS has begun similar pilot projects in eight additional States to determine whether problems found in Colorado and Ohio exist elsewhere.

The number of waived laboratories and waived tests has increased significantly since the beginning of the CLIA program. In 1992, waived laboratories accounted for about 20 percent of all CLIA-certified laboratories. Today, 53 percent of all laboratories are waived. In 1992, the waived category covered nine tests such as urine pregnancy, glucose and urine dipstick or tablet analysis. Currently there are about 40 tests in the waived category. Test systems are created by manufacturers and given brand names, resulting in multiple test systems for each type of test. There were 250 waived test systems in 1995, which increased to approximately 840 test systems by September 2000.

Waived laboratories are exempted from routine site visits in CLIA law and regulations,<sup>5</sup> although States are not prohibited from requiring site visits to waived laboratories. The main reason these laboratories are not site visited is because waived tests are those that are simple, accurate and unlikely to pose harm to the patient if performed incorrectly. For laboratories conducting these simple tests, waived (and later provider-performed microscopy) categories minimized regulatory and financial burdens. Without the cost of surveys, CMS was able to set CLIA fees for waived and provider-performed microscopy laboratories very low.

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## METHODOLOGY

As noted earlier, the information presented in this report was collected during the inspection titled: *CLIA Regulation of Unestablished Laboratory Tests*, (OEI-05-00-00250). For this report, we conducted additional analyses of the enrollment and certification information gathered during the study on unestablished tests.

To estimate the extent of laboratories conducting tests not authorized by their certificates, we looked at CLIA enrollment and certification data to identify waived and provider-

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<sup>5</sup>Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, sec. 353(d)(2)(C) (1988). Laboratory Requirements, 42 C.F.R., sec. 493.1775 (1992).

performed microscopy laboratories. We compared these lists to a 5 percent sample of Medicare Part B claims billed in 1999. We examined billing by waived and provider-performed microscopy laboratories for laboratory tests that they were not authorized to perform.

We reviewed CLIA regulations, policies and procedures. We interviewed CMS central office staff and regional office staff in five regions. We contacted State agencies in all 50 States, the District of Columbia and Puerto Rico. We conducted in-person interviews with State agency staff in the District of Columbia and 11 States: Arizona, California, Delaware, Illinois, Kansas, Maryland, Missouri, New Jersey, New York, Pennsylvania and Wisconsin. The remaining 39 States and Puerto Rico completed written surveys. Overall, 52 State agencies participated in this study.<sup>6</sup>

In our interviews and written surveys, we asked questions about enrollment and certification processes and obtained information about respondents' experiences with the CLIA program. We also asked respondents for their opinions on certain CLIA enrollment and certification processes.

Similar discussions were held with representatives from the following three accreditation agencies: the College on Office Laboratory Accreditation, the Joint Commission on Accreditation of Healthcare Organizations and the College of American Pathologists. These organizations were contacted because they have deemed status from CLIA to provide survey and certification services for some laboratories. These three agencies survey over 95 percent of the accredited laboratories in the CLIA program.

We also interviewed staff at the Centers for Disease Control and Prevention (CDC) and at the FDA. These agencies play a role in advising and assisting CMS in carrying out the provisions of the CLIA law.

As part of this study, we performed a secondary analysis of results from two studies of waived and provider-performed microscopy laboratories conducted by CLIA surveyors in Colorado and Ohio.<sup>7</sup> These reports were initiated by the States and conducted with the permission of CMS.

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

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<sup>6</sup>Collectively, the respondents from the 50 States, the District of Columbia, and Puerto Rico will be referred to as "State agencies" or "States" in this inspection report.

<sup>7</sup>"Waived/Provider-Performed Microscopy Procedure Laboratory Certificate Verification Surveys" conducted by the Ohio Department of Health, Division of Quality Assurance, Bureau of Diagnostic Safety and Personnel Certification, Laboratory Certification Program. A special CLIA project to "evaluate the compliance for non routinely inspected tests in both sites that receive routine inspections and in sites without routine inspections," conducted by the Colorado Department of Public Health and Environment, Laboratory and Radiation Services Division, CLIA Program. Both studies were conducted in Fiscal Year 1999.

# FINDINGS

## Significant vulnerabilities exist in CLIA's oversight of waived and provider-performed microscopy laboratories

### Lack of onsite visits of waived and provider-performed microscopy laboratories is a program vulnerability

Waived and provider-performed microscopy laboratories, which account for 75 percent of all CLIA-certified laboratories, are not surveyed. Therefore, surveyors do not have the opportunity to identify and correct problems, and educate untrained laboratory staff at these laboratories. During routine visits of moderate and high complexity laboratories, CMS employs an educational survey process where surveyors educate non-compliant laboratories about the CLIA requirements applicable for their particular setting.

When surveyors have visited waived and provider-performed microscopy laboratories they report finding compliance problems. About 90 percent of State respondents believe that the lack of routine site visits to waived and provider-performed microscopy laboratories presents program vulnerabilities. About half of our State agency respondents report experiencing problems with waived and provider-performed microscopy laboratories in their State. Fifteen States mentioned concerns about testing at waived and provider-performed microscopy laboratories such as:

- C laboratories not following manufacturers' instructions,
- C failure to identify incorrect results,
- C testing beyond the laboratory's CLIA certificate,
- C untrained staff,
- C lack of quality controls,
- C poor equipment,
- C poor storage of reagents,
- C poor record keeping, and
- C misunderstanding of CLIA requirements.

One respondent calls the lack of site visits for waived laboratories "a huge black hole in the integrity of the CLIA program. If no one ever checks on them . . . they can essentially do whatever they want." For the most part, State respondents only have contact with waived and provider-performed microscopy laboratories over the telephone and in onsite surveys resulting from complaints. Therefore, it is difficult for surveyors to estimate the extent of problems at these laboratories.

## **In two States, about half of waived and provider-performed microscopy laboratories may be non-compliant**

State surveyors in Colorado surveyed a random sample of waived and provider-performed microscopy laboratories and found that 56 percent were out of compliance with CLIA requirements. Ohio surveyors conducted a similar survey and found 45 percent of waived and provider-performed microscopy laboratories out of compliance. Colorado and Ohio surveyors found similar compliance problems in the laboratories they surveyed. Compliance problems for waived laboratories include the following:

- C not following manufacturers' instructions,
- C not having manufacturers' instructions available for referencing when visited onsite, and
- C testing outside their certificate level.

Both States also found problems with provider-performed microscopy laboratories. Colorado found 90 percent of provider-performed microscopy laboratories lacked written procedures or could not demonstrate the accuracy of the test method or the competency of testing personnel. In both States, non-compliant provider-performed microscopy laboratories were found to have the following deficiencies:

- C expired reagents and controls,
- C no written procedures for tests conducted,
- C no quality assurance methods,
- C no proficiency testing,
- C no quality assurance of staff competency, and
- C testing outside their certificate level.

## **Some laboratories are testing outside of their waived or provider-performed microscopy certificates**

Some surveyors have found laboratories testing outside their certificates. The Ohio State agency study found that about 10 percent of waived and provider-performed microscopy laboratories were conducting tests not authorized under their CLIA certificate. A majority of our State respondents report that they have found waived and provider-performed microscopy laboratories conducting moderate or high complexity tests. Twenty-two States estimate that a small percent of all applications for Certificates of Waivers or provider-performed microscopy certificates are submitted by laboratories conducting higher complexity testing. The exact number of laboratories testing beyond their certificate is unknown.

In looking at a 5 percent sample of laboratory tests billed to Medicare, we found about 1,700 waived laboratories out of about 13,000 (13 percent) billed Medicare for non-waived tests and were denied payment for having an inappropriate CLIA certificate. Of

the 13,444 provider-performed microscopy laboratories in our sample, 11 percent were denied payment for tests they were not authorized to perform.

When a laboratory bills Medicare for tests not covered by their CLIA certificate, it may be an indicator that the laboratory is conducting higher complexity testing. Several State respondents believe that when laboratories have their Medicare claims denied for inappropriate CLIA certification, the laboratories are likely to seek out an appropriate certificate so that they can get Medicare and Medicaid reimbursement. Some Medicare carriers notify State agencies when a laboratory bills for services outside their CLIA certificate. However, no formal mechanism exists for Medicare or Medicaid fiscal agents to report laboratories billing outside their certificate level to CMS or State agencies.

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## **Despite safeguards, some vulnerabilities also exist for moderate and high complexity laboratories**

Onsite surveys and Medicare denials are the most important tools that CMS has to ensure that laboratories meet CLIA requirements. Onsite visits are used to verify that a laboratory meets all requirements and has correctly reported testing information to CMS. State agency respondents believe that Medicare and Medicaid denials of services not authorized under a laboratory's CLIA certificate are strong motivation for laboratories to correct any errors in their CLIA certification.

### **Waived and provider-performed microscopy tests conducted at moderate and high complexity laboratories are vulnerable to noncompliance**

Routine surveys of moderate or high complexity laboratories do not include reviews of waived and provider-performed microscopy testing. Therefore, any problems with these tests would not be identified and corrected through the routine CLIA survey process. Colorado surveyors found 40 percent of moderate and high complexity laboratories failed to follow manufacturers' instructions for waived tests. Surveyors had expected to find few compliance problems with waived and provider-performed microscopy tests in moderate and high complexity laboratories since these laboratories are routinely surveyed to ensure quality testing. They also found one-third of the moderate and high complexity laboratories had no written microscopy procedures or quality assurance for their microscopy methods. Laboratories with major compliance problems such as failure to follow manufacturers' instructions and lack of quality assurance may produce incorrect test results and thus impact patient health.

### **Allowing new laboratories to operate and bill Medicare and Medicaid for up to 24 months before they are surveyed may be a vulnerability**

Although onsite surveys provide some safeguards, moderate and high complexity laboratories that have newly registered for Certificates of Registration may operate

without being surveyed for up to 24 months. Laboratories are assigned a CLIA number when their application is accepted, which allows them to receive reimbursement from Medicare and Medicaid during this period.

A majority of State agencies reported that this 2 year period may be a vulnerability in the CLIA program. Specifically, laboratories may be providing incorrect results, may have poor quality laboratory practices or may be performing tests outside of their certificate. Under current policy, onsite visits to laboratories are not made until survey fees are paid. Although the CLIA regulations allow for 2 years before the initial onsite visit, some States report inspecting most laboratories in under a year, and CMS has encouraged States to inspect new laboratories three months after the initial application is complete.

### **Accreditation agencies do not report laboratories testing in specialties outside their CLIA certificate**

Over 60 percent of State agencies reported that they would not know if a laboratory was performing work in a specialty not covered by the laboratory's chosen accrediting body. Accreditation agencies are not required to notify CMS when they find a laboratory testing in specialties that they do not examine. When an accreditation agency determines that a laboratory is performing a test that is not covered by the agency, they inform the laboratory that it is the laboratory's responsibility to seek certification or accreditation for the testing from CLIA or from another accreditation agency. It is left to the laboratory to follow through and register with CLIA or another accreditation agency to review their tests. Some States reported that they check applications to identify cases where a laboratory intends to conduct testing in a specialty not accredited by the agency selected.

### **Laboratories may downgrade their certificate to avoid CLIA requirements**

According to some State surveyors, some moderate and high complexity laboratories may seek to avoid site visits by downgrading their certificate to waived or provider-performed microscopy before their scheduled survey. These laboratories can conduct moderate and high complexity tests and bill Medicare or Medicaid until they downgrade their certificates. Downgrading means that potentially out-of-compliance laboratories agree to cease moderate and high complexity testing and can avoid correction processes.

Anecdotal information from States indicates that a few laboratories have taken advantage of this vulnerability in the past and gamed the CLIA certification and Medicare reimbursement systems. A few States mentioned pursuing cases where a laboratory cycled between moderate complexity testing and waived testing. These laboratories would conduct moderate complexity laboratory tests while under a Certificate of Registration for up to 24 months before switching to waived testing. After receiving a Certificate of Waiver, the laboratory would switch back to moderate complexity testing under a new Certificate of Registration and resume moderate complexity testing without achieving compliance with CLIA requirements. While this vulnerability exists, we do not know if it is widespread.



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## **The CMS's reliance on laboratories to self-identify for enrollment appears to be a weakness**

During a recent study, we identified 160 laboratories that had offered tests without a CLIA certificate.<sup>8</sup> We specifically attempted to identify only laboratories offering unestablished laboratory tests, which are not reimbursable by Medicare. Respondents believe that laboratories conducting these types of tests bill the patient directly and do not have the same incentives that traditional laboratories have to enroll in CLIA. It appears likely that there are additional, unidentified laboratories conducting established and unestablished laboratory testing without CLIA certification.

Despite widespread belief that most laboratories voluntarily enroll in CLIA, 43 State agencies (81 percent) reported that they have found laboratories conducting testing without a CLIA certificate. The exact number of non-certified laboratories is unknown. Some respondents believe that most laboratories voluntarily enroll in CLIA because they plan to bill Medicare and Medicaid and they must have appropriate CLIA certification for the tests they bill.

Non-certified laboratories come to the attention of State surveyors in several ways. States report that they identify uncertified laboratories via complaints from the public, referrals from other State agencies and leads from local insurance companies. Some States report that they have seen advertising for non-certified laboratories. While conducting CLIA site visits, a few States routinely ask whether any additional laboratories are in the building or owned by the same company. Additionally, some States report that local Medicare or Medicaid contractors refer non-certified laboratories to the State agency.

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## **Some State processes augment CLIA's safeguards, although vulnerabilities remain**

In most States with laboratory licensure programs, laboratory regulations are identical or similar to CLIA's regulations. However, there are some exceptions. Some States have processes that go beyond CLIA regulations. Although these States are still exposed to some vulnerabilities in the CLIA program, their additional processes may mitigate CLIA program vulnerabilities to some extent.

### **Some State laboratory licensure requirements may mitigate CLIA vulnerabilities**

About half of States surveyed report having a State laboratory licensure program in addition to CLIA. Many State programs parallel CLIA, but some allow States to take

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<sup>8</sup>Department of Health and Human Services, Office of Inspector General, *CLIA Regulation of Unestablished Laboratory Tests*, OEI-05-00-00250, 2001.

additional actions that minimize CLIA program vulnerabilities. Ten State programs require surveys of some or all waived and provider-performed microscopy laboratories. Four States also require that all accredited laboratories be surveyed by their program.

Fourteen State programs require that surveyors inspect laboratories earlier than the CLIA requirement of 24 months. Five of these States reported that site visits must occur before a laboratory is allowed to test or before a license is issued. Seven States report that sites must be visited within 10, 30, 60 or 90 days of the application. Two States require annual surveys even though the CLIA program requires visits every 2 years.

Maryland is an example of a State with regulations and processes that bolster surveyors' ability to ensure compliance. Surveyors visit laboratories quicker than the 24 months permitted by CLIA. In Maryland, initial visits to laboratories are usually made within 90 days to 1 year of application. Moreover, Maryland routinely conducts initial surveys of all accredited laboratories, and routine surveys of some waived and provider-performed microscopy laboratories. Unlike most States, Maryland also reviews waived and provider-performed microscopy testing conducted at moderate and high complexity laboratories. Maryland staff report finding the same types of deficiencies in waived and provider-performed microscopy testing that were found in the Colorado and Ohio studies. They report that repeated surveys are effective in bringing laboratories into compliance. However, when laboratory staff turns over deficiencies often occur again due to lack of training and poor administrative oversight in the laboratory.

### **A majority of States require lists of tests on applications; some believe this has improved the accuracy of certificate and specialty categorization**

Lists of tests are not required as part of the standard CLIA application form. However, 36 States ask laboratories to submit a list of tests that they intend to perform and/or laboratory equipment that they intend to use as part of the CLIA application process. These test lists further supplement the list of specialties and subspecialties required by CLIA. About two-thirds of these States report that most laboratories are disclosing the full range of testing and/or equipment that they intend to use. However, because laboratories often change the testing they conduct, these lists are used as an initial indicator for State agencies. Some respondents noted that some laboratories neglect to submit the list of tests with the application. Several States indicated that the list of tests is useful to help ensure that the laboratory receives the correct certificate.

In the past, there has been opposition to requirements for laboratories to disclose information on CLIA applications about their laboratory practices, including the number and name of tests and test methodologies used. Those opposed felt that requiring laboratories to report this information would be burdensome for laboratories that conduct extensive testing.

# RECOMMENDATIONS

The purpose of this report is to identify vulnerabilities in the CLIA enrollment and certification processes. We did not initially intend to focus on waived and provider-performed microscopy laboratories. Our findings indicate that further study in this area is warranted. We believe that CMS needs to take some action to reduce the vulnerabilities identified in this report. We recognize that resources are limited and that implementing some of the following recommendations may require additional funding.

## Waived and Provider-Performed Microscopy Laboratories

We believe that CMS's pilot project to examine the compliance of waived and provider-performed microscopy laboratories in eight additional States will be integral to any regulatory or legislative changes needed to address vulnerabilities associated with these types of laboratories. With regard to waived and provider-performed microscopy laboratories, we recommend that CMS:

- C Provide educational outreach to laboratory directors of waived and provider-performed microscopy laboratories. Directors should be periodically informed about the CLIA requirements for the testing they conduct, as well as the limitations involved in the waived and provider-performed microscopy certificates. This could include establishing a newsletter, a toll-free phone number, and/or disseminating information through professional groups.
- C Require laboratories applying for waived and provider-performed microscopy certificates to identify which tests they plan to conduct and which test systems they will use. This could be a test checklist on the CLIA application.
- C Establish a mechanism whereby Medicare claim denials can be used to inform State laboratory surveyors about laboratories billing Medicare outside their certificate. Specify a threshold of the number of incorrect claims billed by a laboratory that would result in a referral to surveyors.
- C Use periodic paper self-assessment tools to help ensure compliance for laboratories that are not routinely visited. This could be a checklist of compliance requirements for waived and provider-performed microscopy laboratories.
- C If CMS's pilot project shows that the extent of problems in waived and provider-performed microscopy laboratories is similar to that found in the Ohio and Colorado studies, we would encourage CMS to conduct random surveys of some waived and provider-performed microscopy laboratories each year.

## Moderate and High Complexity Laboratories

We recommend that CMS take the following actions regarding moderate and high complexity laboratories:

- C Review the waived and provider-performed microscopy tests conducted at moderate and high complexity laboratories during routine surveys to ensure compliance with CLIA regulations.
- C Shorten the length of time allowed between application and surveys for new laboratories.
- C Formally require accreditation agencies to inform CMS about laboratories conducting tests in specialties not accredited by the agency.
- C Establish a workgroup to develop methods that can be used to identify uncertified laboratories. Methods could include collaboration with State and local licensing bodies.

## AGENCY COMMENTS

We appreciate the assistance and cooperation we received from CMS staff while conducting this study. We received comments from them on this report and they concurred with our recommendations. The text of their comments can be found in Appendix A.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator  
Washington, D.C. 20201

DATE: JUL 31 2001

TO: Michael F. Mangano  
Acting Inspector General  
Office of Inspector General

FROM: Ruben J. King-Shaw, Jr.  
Deputy Administrator/Chief Operating Officer  
Centers for Medicare and Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Enrollment and Certification Processes in Clinical Laboratory Improvement Amendments Program*, (OEI-05-00-00251)

Thank you for the opportunity to review the above-referenced report. The Centers for Medicare & Medicaid Services (CMS) appreciates the work OIG has done in outlining vulnerabilities in the Clinical Laboratory Improvement Amendments (CLIA) program regarding certificate of waiver (COW) and provider-performed microscopy laboratories (PPMP). The OIG's review of the CLIA enrollment and certification process reflects many of the same issues CMS and the Centers for Disease Control and Prevention have identified regarding COW/PPMP laboratories.

We would like to add that our ability to effectuate many of the report recommendations may be limited due to lack of resources, program priorities, and funding. We are currently evaluating whether any legal limitations exist concerning implementation of OIG recommendations.

We concur with the following OIG recommendations:

OIG Recommendation

CMS should provide educational outreach to directors of waived and provider-performed microscopy laboratories regarding CLIA requirements.

CMS Response

We concur. Although funding and program priorities may limit our ability to accomplish this, we will do all that we can to make directors of COW/PPMP laboratories more aware of CLIA requirements.

The Health Care Financing Administration (HCFA) was renamed to the Centers for Medicare & Medicaid Services (CMS). We are exercising fiscal restraint by exhausting our stock of stationery.

OIG Recommendation

CMS should require laboratories applying for COW/PPMP certificates to identify which test systems they will use.

CMS Response

We concur. The recommendation to solicit lists of tests from COW/PPMP laboratories will most likely be instituted if we can identify an efficient mechanism. The collection of test specific information from moderate and high complexity laboratories is problematic, as demonstrated by our early experiences with the HCFA-109 original CLIA Survey form, which was replaced with the HCFA-116 CLIA Application for Certification form.

OIG Recommendation

CMS should establish a mechanism whereby Medicare claim denials can be used to inform State laboratory surveyors about laboratories billing outside their certificate.

CMS Response

We concur. CMS will enlist the help of Medicare carriers to help establish a mechanism whereby Medicare claim denials can be used to inform State laboratory surveyors about laboratories billing outside their certificate.

OIG Recommendation

CMS should use periodic paper self-assessment tools to help ensure compliance for laboratories that are not routinely visited.

CMS Response

We concur. This recommendation parallels similar actions produced by our own studies. We will develop self-assessment aids for laboratories that are not routinely visited.

OIG Recommendation

If CMS's pilot project finds similar problems to those found in the Ohio and Colorado studies, we encourage CMS to conduct random onsite inspections of some waived and provider-performed microscopy laboratories each year.

CMS Response

We concur. CMS is currently planning this action as a result of our own studies.

OIG Recommendation

CMS should review waived and provider-performed microscopy testing at moderate and high complexity laboratories during routine surveys.

CMS Response

We concur. CMS is currently planning this action as a result of our own studies.

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OIG Recommendation

CMS should shorten the time between application and initial onsite visits to new laboratories.

CMS Response

We concur. Our policy is to survey new laboratories about 3 months after the application process is complete and the laboratory's certification fee is paid. Though it is somewhat early in 2001, our data already show improved compliance.

OIG Recommendation

CMS should establish a workgroup to develop methods to identify uncertified laboratories.

CMS Response

We concur. CMS will establish a workgroup to develop methods to identify uncertified laboratories in the near future.

Attachment