A Review and Analysis of the Clinical Laboratory Improvement Amendment of 1988: Compliance Plans and Enforcement Policy

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Abstract: In 1988, Congress passed the Clinical Laboratory Improvement Amendment (CLIA), thereby extending coverage of the Clinical Laboratory Improvement Act of 1967 to include quality standards for all laboratory-based testing. The CLIA was enacted to ensure the accuracy, reliability, and timeliness of patient test results, regardless of the location where the tests were performed. This article assessed trends in the enforcement policy of the CLIA through an examination of the Laboratory Registry, an annual publication of those individuals or entities that have had sanctions imposed on them by the Centers for Medicare and Medicaid Services. We reviewed the CLIA, including its oversight, regulations that were promulgated based on it, and its enforcement procedures. We obtained the Laboratory Registries for 1993–2001. Sanctions were categorized into groups per the enforcement regulations (42 C.F.R. § 493.2 2000). The data indicated an increasing use of more lenient sanctions from 1997 to 2001, and a gradual increase in fraudulent activity for that same period. One possible explanation for this finding is that implementation of compliance plans by participating clinical laboratories had a mitigating effect on enforcement policy. Compliance plan guidance from the OIG provides an opportunity for laboratory service providers to be proactive in their attempts to decrease errors, and thus improve accuracy and reliability by documenting laboratory policies, procedures, and objectives.

Key words: CLIA regulations, clinical laboratory, compliance, enforcement, sanctions

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The Clinical Laboratory Improvement Act, enacted by Congress in 1967, regulated hospital-based laboratories and laboratories that engaged in interstate commerce.[1] Physician office labs (POLs) were excluded from federal standards. Accordingly, less than 10 percent of all clinical laboratories were required to meet federal quality standards.[2] In 1988, Congress passed the Clinical Laboratory Improvement Amendment (CLIA) to establish quality standards for all laboratory-based testing to ensure the accuracy, reliability, and timeliness of patient test results, regardless of the location where the tests were performed. Under the CLIA, a laboratory is defined as a facility for the examination of materials derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of 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.[3]

The health care industry uses clinical laboratory testing for three major purposes: diagnosis, screening, and patient monitoring. The diagnostic component of laboratory testing plays a significant role in determining a patient's condition. The screening function of testing is particularly important in this era of managed care, where early intervention can prevent the onset or limit the spread of disease. Patient monitoring serves multiple purposes, including tracking disease states, identifying side effects and complications, monitoring drug levels, and assessing prognoses. Therefore, the results of clinical diagnostic laboratory testing provide important tools for verifying a health provider's working diagnosis and are important for liability issues as well.

Outpatient clinical laboratory testing accounts for 1.6 percent of medical spending. Although clinical laboratory testing thus accounts for only a small proportion of Medicare spending, these tests play a significant role in driving diagnostic and therapeutic decisions. This makes clinical laboratory testing an attractive candidate for waste, fraud, and abuse in the provider community. Therefore, the CLIA set standards for laboratory personnel, quality control, and quality assurance based on test complexity and potential harm to the patient. Nevertheless, the CLIA has been criticized as an excessive administrative burden.[4] Others argue that the CLIA has helped to assure quality and accuracy of complex laboratory testing.[5]

This article will assess trends in the enforcement policy of CLIA through examination of the Laboratory Registry (LR), a yearly publication of those individuals or entities that have had sanctions imposed on them for the calendar year preceding the date the information is made available by the Centers for Medicare and Medicaid Services (CMS). In order to lay the groundwork for this analysis of the LR, a review of CLIA program oversight, regulation, and enforcement procedures will be presented. The method of analysis will be outlined, including the coding of sanction data for each entry in the LR from 1993 to 2001. Our analysis of the LR will track the impact of two milestone events: a late 1997 requirement that CLIA certificate numbers be used on all billing claim forms submitted for payment to Medicaid; and the Office of Inspector General's release of compliance program guidelines for clinical laboratories in March 1997. The results of our analyses will be followed by observations regarding the impact of the CLIA.

OVERVIEW OF CLIA REGULATIONS

The history of the CLIA begins with congressional deliberations about thirty years ago. Appearing before the House Committee on Interstate and Foreign Commerce on May 2, 1967, Wilbur Cohen, Secretary of the U.S. Department of Health, Education and Welfare (HEW), and Dr. D.J. Sencer, Director of the U.S. Public Health Service's Communicable Disease Center, testified that the error rate in laboratory testing might be as high as 25 percent.[4] Despite testimony that the 25 percent figure lacked scientific support, Congress passed the CLIA of 1967.

In 1980, Dr. Joseph Boutwell, Deputy Director of the Centers for Disease Control and Prevention's Bureau of Laboratories, stated that there was a 14 percent error rate in some of the most commonly performed medical tests.[4] Dr. Boutwell eventually admitted his estimates were excessive,[6] but the retraction was less widespread in the media. News reports in 1987 and 1988 described several negative outcomes caused by laboratory errors,[4] eventually leading Congress to hold hearings and to the passage of the CLIA in 1988. The final regulations promulgated pursuant to the CLIA became effective at the end of 1992.

In combination with a 1990 Report to Congress, the Laboratory Practice Assessment Branch of the CDC conducted a literature review to assess, in part, whether laboratory errors that occurred in physicians' offices prior to the CLIA resulted in negative health outcomes.[7] However, only one hospital-based study had examined the impact of testing errors, suggesting that additional research was needed to answer questions raised by the CLIA.

CLIA PROGRAM OVERSIGHT

The CLIA program is self-funded; its financing is provided by user fees. Three agencies within the Department of Health and Human Services (DHHS)

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administer the program: CMS; the Centers for Disease Control and Prevention (CDC); and the Food and Drug Administration (FDA).[8]

The CMS has primary responsibility for managing the CLIA program. The agency registers laboratories, collects fees, administers surveys, provides surveyor guidelines and training, enforces the Act, approves proficiency testing (PT) of providers, accredits organizations, and exempts states.[9]

The CDC is in charge of a Public Advisory Committee known as the CLIAs Committee. This Committee is charged by the Secretary of DHHS to provide advice, upon request, to the CDC with respect to any regulatory changes under consideration.[10] Prior to January 2000, the CDC was also responsible for categorizing laboratory tests according to the complexity of the test.

The FDA is now responsible for approval and complexity categorization of in vitro diagnostic (IVD) devices or tests that analyze human body fluids, such as blood or urine. The Division of Clinical Laboratory Devices, located within the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health, performs the reviews.[11]

REGULATIONS

Final regulations implementing the CLIA were published on February 28, 1992, and have been in effect since September 1, 1992. These regulations are primarily based on the complexity of the test method. In effect, more complicated tests have more stringent requirements.[9] Three categories of tests have been established: waived complexity; moderate complexity, including the subcategory of provider-performed microscopy (PPM); and high complexity.

Tests that are eligible a the certificate of waiver (COW) must be simple laboratory examinations and procedures that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or that pose no real risk of harm to the patient if the test is performed incorrectly.[3] In addition, laboratories eligible for a COW must follow the manufacturer's instructions for performing the test. The training and experience required for waived tests is minimal and may be obtained through on-the-job instruction.

A laboratory may qualify for a certificate to perform tests of moderate or high complexity if it restricts its testing to waived tests or examinations, and one or more of its tests meet the criteria for moderate (including PPM procedures) or high complexity. A laboratory applying for a certificate of compliance (COC) or a certificate of accreditation (COA) to perform moderate or high complexity testing is initially issued a certificate of registration (COR). The COR is valid for no more than two years or until an inspection can be conducted to determine that the laboratory is in compliance.[3] Laboratories with a COR can conduct testing and bill Medicare and Medicaid until they are inspected. Onsite inspections usually occur within twenty-four months of filing the application (OEI 2001). A laboratory can choose to be accredited by one of six CMS-approved accrediting organizations, including:

- American Association of Blood Banks (AABB)
- American Osteopathic Association (AOA)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- College of American Pathologists (CAP)
- Commission on Office Laboratory Accreditation (COLA)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

After a laboratory meets the CLIA requirements, it is issued a COC or a COA by the appropriate certifying entity.

PPM tests are a subset of moderate complexity tests. These examinations must be personally performed by certain types of health care practitioners, including physicians, mid-level practitioners under the supervision of a physician, or dentists.[3] To obtain a certificate for PPM procedures, the procedure must also be categorized as of moderate complexity and must be performed using a microscope.

Laboratories that perform moderate or high complexity testing must monitor patient tests, conduct quality assurance and control processes, assess personnel qualifications, and pay required fees. Laboratories are revisited every two years to verify continued compliance with the CLIA standards (OEI 2001). Under the CLIA, laboratories must also participate in proficiency testing (PT) and enroll in an approved PT program. Approved PT programs provide laboratories with samples that must be treated in the same manner as other patient specimens. The samples must be examined or tested by the laboratories' regular personnel using their regular methods.[3]

The CMS is also responsible for monitoring regulatory compliance but has delegated the conduct of compliance inspections, referred to as surveys, and the management of information required for applications, to state health departments. Currently, there are two states that are exempt from CLIA certification, New York and Washington. Those states require a state certificate or license. Waived laboratories as well as laboratories with a PPM certificate are not routinely surveyed, unless complaints are filed.

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ADDITIONAL REGULATIONS

Federal law requires the disclosure of certain information for clinical laboratory services that are payable by Medicare. These requirements include the disclosure of ownership interests, investment interests, and compensation arrangements to DHHS, and the disclosure of test results to patients.[12,13] Furthermore, Federal law imposes standards for billing. Laboratory results may only be released to the patient, the physician who ordered the tests, and providers who are currently treating or providing assistance to the patient. Reports must be written using acceptable, standardized terminology, and the laboratory must maintain them in a record that allows for ready identification and access.[3]

BILLING

The list of billing regulations is extensive and includes requirements for mandatory Medicare assignment, information regarding where payment must be billed on assignment in order to obtain payment by Medicare (with the exception of rural clinics and POLs), and limitations on who may receive Medicare payment (42 U.S.C. § 395 2001). Under the regulations, Medicare payments must be made to the person or entity that performed or supervised the performance of the test. However, certain exceptions exist including: payments to a physician who shares a practice with the physician who performed or supervised the test; and payments to a referring laboratory for a test performed at another laboratory when the referring lab is a wholly owned subsidiary of the entity performing the test, both the referring lab and the entity performing the test are wholly owned by a third entity, or not more than 30 percent of the clinical diagnostic testing for which the referring laboratory submits bills in any year is performed by another laboratory.[12]

Beginning January 1, 1998, all Medicaid State Agencies (MSAs) were advised to deny payment to all clinical laboratories that submitted bills for services not covered by a CLIA certificate and for all claims for services rendered outside the effective dates of a CLIA certificate.[14,15] Prior to this notification, MSAs denied payments only to nonphysician laboratories that omitted the CLIA certificate number on bills were found to be billing for services not covered by a CLIA certificate, or that submitted claims for services outside the effective dates of the CLIA certification.

ENFORCEMENT

The Office of Inspector General of the DHHS is mandated to protect the integrity of the DHHS programs (OEI 2001). Its mission is carried out through a program of audits, investigations, inspections, sanctions, and fraud alerts (OEI 2001). OIG lists specific practices that are covered by anti-kickback laws, including a number of activities that it considers "suspicious," such as laboratories that send their phlebotomist to physician offices to collect specimens, laboratories that offer to perform tests below the fair market rate in return for the facility's agreement to send all or most of its tests, laboratory waivers of charges to managed care patients in order to induce physicians to continue to use the lab for nonmanaged care patients, and free pickup and delivery of biohazardous waste products. Enforcement procedures are outlined in Title 42, part 493, subpart R of the *U.S. Code of Federal Regulation*. The enforcement procedures indicate that CMS has the ability to impose immediate sanctions on any laboratory that performs clinical diagnostic tests on human specimens when those laboratories are not in compliance with one or more of the conditions for Medicare coverage of their services.[3] A range of possible sanctions has been developed in response to the Clinical Laboratory Improvement Act of 1967 as amended by the CLIA, including principle or intermediate sanctions; alternative sanctions; civil suit; criminal sanctions; and additional Medicare sanctions. These sanctions are described in more detail in Table 1.

The regulatory enforcement procedures also describe general considerations for enforcement policy, including their multiple purposes: to protect the public from health and safety hazards that might result from laboratory activities; to protect the health of individuals from laboratories that practice substandard testing methods; and to motivate laboratories to comply with CLIA requirements to provide accurate and reliable test results. The procedures describe the bases for decisions to impose various types of sanctions, list alternatives to sanctions, and specify what appellate rights are available.[3]

The basis for the decision to impose sanctions derives from findings obtained in the course of inspections to certify or validate compliance with Federal requirements, through the review of materials submitted by the laboratory, and through participation in proficiency testing.[3] CMS may impose "alternative sanctions" in lieu or in addition to "principle sanctions," with the exception of laboratories that have a COW. CMS may also impose alternative sanctions (other than civil monetary penalties) after the laboratory has had an opportunity to respond, but prior to a hearing.[3]

CMS considers a variety of factors in determining the choice of one or more possible sanctions. These factors include whether the deficiencies pose immediate jeopardy; the nature, incidence, severity, and duration of the deficiencies or noncompliance; whether

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the same condition-level deficiencies have been identified repeatedly; the accuracy and extent of laboratory records as well as their availability to the State, CMS, or its agents; the overall compliance history of the laboratory; the corrective and long-term compliance outcomes that CMS hopes to achieve; whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies; and any recommendation by the State agency whether sanctions would be an appropriate remedy.[3]

CMS may impose a single sanction for each condition-level deficiency or a single sanction for all condition-level deficiencies. Laboratories that are dissatisfied with the imposition of a sanction are entitled to request a before an Administrative Law Judge (ALJ). The ALJ's decision can, in turn, be appealed to the Department Appeals Board. Furthermore, any laboratory that is dissatisfied with the decision to impose a civil monetary penalty or to suspend, limit, or revoke its CLIA certificate, may, within 60 days after the decision becomes final, file a petition for judicial review with the U.S. Court of Appeals for the circuit in which the laboratory has its principal place of business.[3]

SPECIFICATION OF SANCTIONS

The range of activities that may implicate the CLIA is expansive and may overlap with state law. For example, in March and April 2002, the California Department of Health Services (CDHS) and CMS commenced regulatory actions against Specialty Laboratories, Inc. (SLI), a leading hospital-focused clinical laboratory that performs testing nationwide. CDHS notified SLI of its intent to impose sanctions including the following: (1) a directed plan of correction; (2) random onsite monitoring; and (3) a civil money penalty based upon

TABLE 1

Sanctions Available to Enforce CLIA Regulations

Type of Sanction	Action
Principle or Intermediate	Suspension, limitation, or revocation of any type of CLIA certificate
Alternative	
(May impose one or more in lieu of or in addition to imposing a principle sanction, except on a laboratory that has a certificate of waiver, since those laboratories are not inspected for compliance with condition-level deficiencies)	Directed plan of correction State onsite monitoring Civil monetary penalty
Civil suit	
(May bring suit in appropriate U.S. District Court)	Enjoin continuation of any activity of any laboratory that continuation of the activity would constitute a significant hazard to the public health
Criminal	An individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined
Additional	
(Laboratories that participate and have approval to receive Medicare payment)	
Principle	Cancellation of the approval to receive Medicare payment
Alternative	Suspension of payment for tests in one or more specific specialty or subspecialties, performed on or after the effective date of sanction
Suspension or revocation of any type of CLIA certificate	CMS concurrently cancels the laboratory's approval to receive Medicare payment for its services
Limitation of any CLIA certificate	CMS concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate

Source: 42 C.F.R. § 493(R), Enforcement Regulations (2000, p. 989).

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deficiencies noted during laboratory inspections in June and October 2001. The sanctions were based on findings that SLI permitted unlicensed personnel to perform and supervise clinical laboratory testing in violation of California law. After SLI filed additional documentation and additional inspections by CDHS, CDHS notified SLI that it was in substantial compliance with California clinical laboratory law. CDHS then imposed civil monetary sanctions of US$344,000 plus US$20,430 for the cost of its investigations. CDHS also imposed onsite monitoring for three years (including unannounced inspections).

In contrast, CMS notified SLI that it concluded that its response to deficiencies detected in the inspections conducted by CDHS did not constitute a "credible allegation of compliance." As a result, CMS imposed certain sanctions, including notice of revocation of SLI's CLIA certificate, cancellation of its approval to receive Medicare and Medicaid payments for services performed on or after February 22, 2002, a civil penalty of US$3,000 per day for each day during the sanction period, and a directed plan of correction by which CMS could notify SLI's customers of its noncompliance and the nature and effective date of any sanctions imposed. SLI filed an appeal in April 2002, and three months later, CMS notified SLI that it had deemed the company in compliance with the CLIA as of June 19, 2002, that the company's ability to bill Medicare and Medicaid had been reinstated, and that all actions against its CLIA certificate were rescinded. SLI paid a monetary fine of US$351,000.

One of the most important aspects of the CLIA is proficiency testing (PT) of individuals performing tests. The CLIA 1988 regulations established performance standards-criteria defining accuracy and permissible error rates for PT for the first time. One of the most common deficiencies in PT cited in CLIA inspections is the failure to act on PT reported errors, and consequently it is one of the main methods besides inspection whereby CMS decides the quality of a particular laboratory. CMS certifies various agencies to offer PT programs on its behalf. PT is required for moderate and high complexity tests but not for waived tests. The regulations are very specific about the analysis of PT samples, and inspectors ensure that PT samples are handled in the same manner as patient samples. Every step in the PT process must be documented and records must be kept for two years. Originally, the sanctions outlined by CMS for unsuccessful PT performance were generally considered rather punitive, including loss of the ability to perform an analyte or entire subspecialty, but CMS has more recently emphasized training and education over sanctions.

LABORATORY REGISTRY

The LR is an annual publication from the CMS that lists individuals or entities that generally, but not necessarily, possess a CLIA certificate and have had sanctions imposed on them for the preceding calendar year.[3]

COMPLIANCE PROGRAM GUIDANCE

The OIG purports that through a partnership with the private sector, significant reductions in fraud and abuse may be achieved.[16] Accordingly, health care providers were requested to join a nationwide campaign to eliminate Medicare and Medicaid fraud and abuse. The campaign emphasized the importance of the voluntarily development and implementation of compliance plans.[17]

The OIG has specified the minimally acceptable criteria for a compliance program. Programs should include seven fundamental elements: (1) written standards of conduct in addition to policies and procedures that promote compliance; (2) the appointment of a chief compliance officer; (3) education and training programs for employees; (4) a process to receive complaints; (5) a system to respond to allegations of illegal and improper activities, including enforcing appropriate disciplinary actions against employees who violate internal compliance policies, applicable statues, regulations or requirements of Federal, State, or private health plans; (6) the use of audits or other evaluative techniques to monitor compliance; and (7) the investigation and remediation of identified problems.[16] Implementing a compliance program does not provide a laboratory with immunity from criminal, civil, or administrative prosecution, but the compliance plan would likely be a relevant factor in negotiations with the OIG.[16]

In October 1998, OIG released the Provider Self-Disclosure Protocol, a program for health care providers to voluntary report fraudulent activity that affects Medicare, Medicaid, or other Federally funded health care programs. Although disclosure does not protect the provider from civil or criminal action, reporting wrongdoing could be a mitigating factor that OIGs will consider when it provides recommendations to prosecuting agencies.[18]

REGULATION AS A POLICY SOLUTION

Regulation is an appropriate policy solution in a variety of circumstances, including circumstances that involve a variety of market failures or for distributional reasons to provide greater equity of opportunity or outcomes.[19] Regulation may be appropriate in situations that involve traditional market failures including externalities, natural monopolies, and information asymmetries. It may

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TABLE 2

Sanctions Category Key for LR, 1992–2001

Category	Sanction Types
Criminal	Convicted of Medicare fraud
	Prison term
	Civil settlement
	Fines
Principle	Suspension/revocation of CLIA certificate
	Denial/withdrawal of accreditation
	Limitation of CLIA certificate
Additional	Cancel Medicare/ Medicaid payments
	Limit Medicare/Medicaid payments
Alternate	Directed plan of correction
	State onsite monitoring
	Civil monetary penalty

Source: Author's assignment of sanctions per 42 C.F.R. § 493(R), Enforcement Regulations, 2000.

also be appropriate when existing markets are thin, preferences-related problems exist, or problems with uncertainty are present.

The CLIA was passed in 1988 to protect the public from potential harm and to decrease the potential for fraud and abuse in therapeutic and diagnostic decisions. It was thus enacted in part to address information asymmetry, a form of market failure, between patients and health care providers regarding the appropriateness of a laboratory test. Furthermore, the physical harm that results may not be substantial for any individual patient depending on the particular laboratory test, but aggregated across many persons, the total economic harm to the health insurers, including the government, may be substantial. In addition, patients cannot be taught through disclosure and labeling whether a particular test is warranted as most lack the requisite medical knowledge to make these decisions. Thus, providing information directly to patients would be ineffectual. Therefore, certification and licensing are probably the preferable approach, although care should be made to prevent "rent-seeking" behavior through the development of cartels or other collusive practices that restrict competition.

Insofar as the CLIA addresses information asymmetry, criminal sanction may be inappropriate. Criminal laws are costly, and enforcement is often imperfect. For these reasons, a civil law approach may be preferable.

METHODS

We obtained the LRs for calendar years 1993–2001 for review. The year 1993 was chosen as the first year for study since it was the first full year of the CLIA's implementation. Information regarding sanctions was extracted from the LR for each entry/entity and coded for examination in Microsoft Excel. The detailed enforcement procedures included in the *U.S. Code of Federal Regulations* guided our understanding of the factors to be considered when sanctions were imposed. Sanctions were categorized into groups per the enforcement regulations[3] and are presented in Table 2.

The types of sanctions were standardized by converting groups into annual frequencies. The annual frequency data for each type of sanction within each category were compared across each year from 1993 to 2001. The standardized data was then analyzed for trends.

RESEARCH FINDINGS

The total numbers of entries per year ranged from a low of 22 in 1993 to highs of 154 and 152 in 2000 and 2001, respectively, an approximate 600 percent increase. Figure 1 shows the complete list of yearly totals for entries/entities from 1992 to 2001.

Figure 2 graphically depicts the percentage of each type of CLIA certificate of complexity obtained in 1997. In 1997, the COW and the PPM certificate holders together comprised 68 percent of the 157,607 total labs that were regulated.[20]

The percentage of COW and PPM certificate holders continued to increase each year, eventually rising to 76

FIGURE 1

Total Number of Entries in the LR, 1992–2001

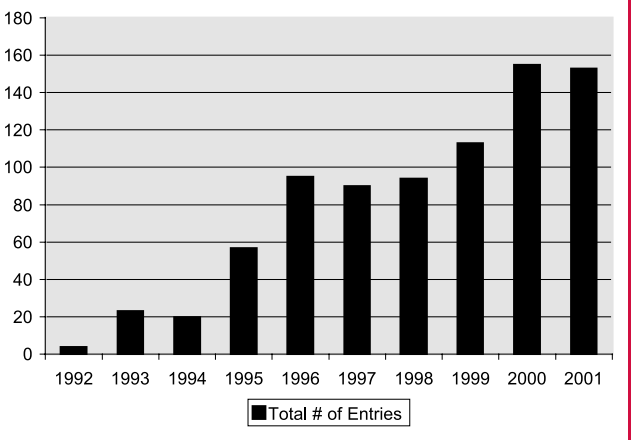

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FIGURE 2

Percentage of Each Complexity Type of CLIA Certificate, 1997

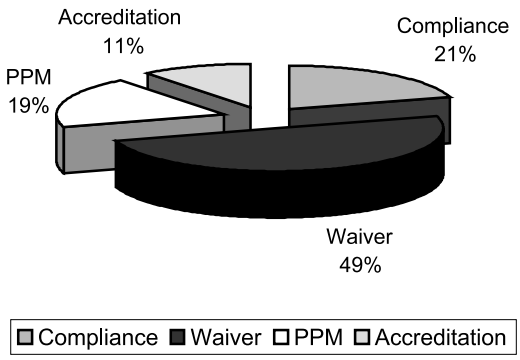
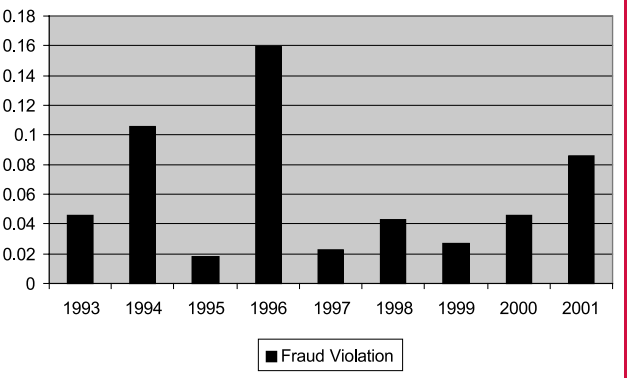


FIGURE 4

Percentage of Violations Due to Fraud from 1993 to 2001



percent out of the 170,996 total labs that were regulated in 2001. The breakdown of CLIA certifications by percentage is shown in Figure 3.[20]

Noncompliance was generally the most common reason for an LR entry/entity to have sanctions imposed on them. Nevertheless, fraud violations represented a substantial percentage of sanctions in certain years. The percent of fraud violations reached almost 16 percent of all entries in 1996, dropped to a little more than 2 percent in 1997, but rose again to 8.5 percent by 2001. Figure 4 shows the percentage of total sanctions imposed from 1993 to 2001 that resulted from fraudulent activities.

Figure 5 shows the annual frequency composition of the four sanction categories described in Table 2 from 1993 to 2001. The results showed a roughly equivalent use of all four categories of sanctions in 1993, with principle and additional sanctions comprising about 60 percent. However, in 1995 a dramatic decrease in the use of alternate and criminal sanctions occurred and principle and additional sanctions rose to 95 percent. With the exception of 1996, criminal sanctions as a percentage of total sanction use essentially become insignificant by 2001. In addition, the use of alternative sanctions use saw an almost 700 percent increase from its low of 3.5 percent of total sanctions in 1997, to almost 27 percent in 2001.

Next, the annual frequency sanction data were further segmented into "high-rated," i.e., more severe, sanctions, consisting of fraud convictions, prison sentences, fines, cancellation of Medicare payments, and

FIGURE 3

Percentage of Each Type of CLIA Certificate, 2001

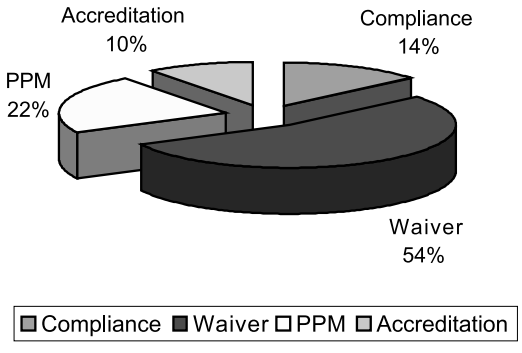


FIGURE 5

Sanction Frequency by Category from 1993 to 2001

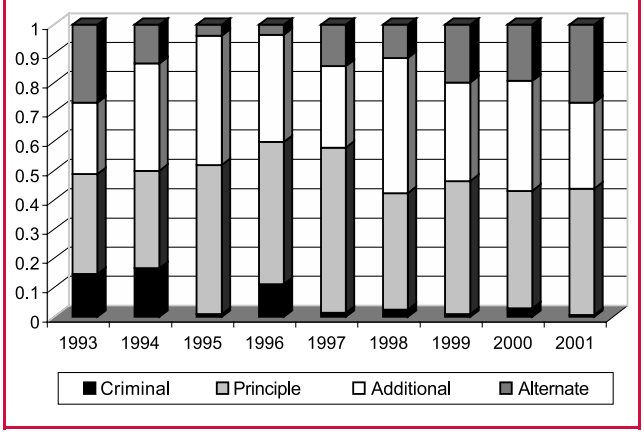


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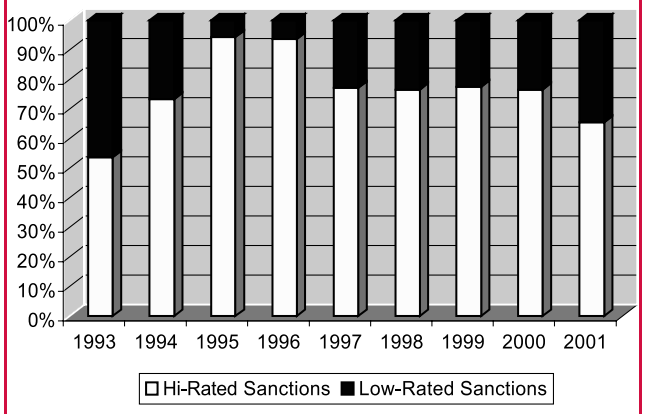
FIGURE 6

Frequency of High-Rated and Low-Rated Sanction Types 1993–2001



suspension/revocation of CLIA certificate, or "low-rated," i.e., less serious, sanctions consisting of limited Medicare payments, a limited CLIA certificate, imposition of a plan of correction, onsite monitoring, and a civil monetary penalty. Figure 6 shows that the high-rated sanctions were used about 54 percent of the time in 1993 and the low-rated about 46 percent. This ratio changed significantly in 1995 and 1996 when low-rated sanctions were utilized about 6 percent of the time and high-rated sanctions accounted for the remaining 94 percent. The use of low-rated sanctions rose almost 250 percent the next year, to nearly 23 percent. The utilization of low-rated sanctions remained relatively level from 1997 to 2000, but increased in 2001 to approximately 35 percent.

CONCLUDING OBSERVATIONS

The 1997 directive requiring inclusion of a laboratory's CLIA certificate number in all bills sent to Medicaid was followed by an increase in the number of entries in the LR from 1998 to 2000. The relationship between the Medicaid directive and the increase in LR entries cannot be directly established; however, the increases came after the number of entries in 1997 had seen a decrease from 1996. The ability to crosscheck certificate numbers and billing codes to screen laboratory providers for appropriate testing complexity level, valid certificate authorization periods, and the existence of a certificate likely made investigations much easier to conduct.

This same database could also have been used to develop provider profiles to identify potential violators. There were over 157,000 laboratories registered with CMS in 1997, and about 68 percent of the those labs held a COW or PPM; these laboratories were not required to undergo proficiency testing or biannual inspections unless a complaint had been filed against them. The additional screening capability that the directive provided enabled CMS to monitor these lower complexity certificate holders (COW and PPM) with greater ease than was previously possible. It is possible that the increase in LR entries/entities from 1998 to 2001 derived primarily from the inclusion of low certificate complexity users that had not previously been closely tracked. Unfortunately, the LR data do not provide the specific complexity level of the particular entry/entity, and therefore it is not possible to segment the data by certificate level.

Compliance plan guidance from the OIG provides an opportunity for laboratory service providers to be proactive in their attempts to decrease errors, and thus improve accuracy and reliability by documenting laboratory policies, procedures, and objectives. Of course the plan also serves to mitigate possible adverse actions from CMS or OIG should future noncompliance become an issue. Unfortunately, the use of compliance plans by clinical laboratories (following the release of guidelines in early 1997) is not documented in the LR. However, the impact of compliance plans on clinical laboratories in the LR appears to be significant.

When we segmented the reasons for sanctions from the LR, we found a positive trend in the percentage of fraudulent activities from 1997 to 2001. When this trend was compared to the information contained in the LR regarding the types of sanctions that had been imposed, we found a corresponding increase in the use of more lenient sanctions during the same period. One possible explanation for this finding is the purposeful implementation of compliance plans by participating clinical laboratories. These trends reveal an increased use of the more lenient sanctions, such as the alternative sanctions or the group of low-rated sanctions.

CLIA enforcement policy can be characterized as aggressive as it includes opportunities for the imposition of significant sanctions designed to combat the practices of obvious and intentional fraud, waste, and abuse, but these policies also provide the groundwork for a cooperative environment that improves safety as well as test accuracy and reliability for those clinical laboratories that implement a proper, thorough compliance plan.

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