

The Influence of CLIA '88 on Physician Office Laboratories

Patricia H. Born, PhD, and Sara L. Thran, MS
Storrs, Connecticut, and Chicago, Illinois

BACKGROUND. The study objectives were to examine the influence of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) on laboratory testing activities in physician offices, and to identify relationships between the characteristics of practices and their responses to the regulation.

METHODS. The data come from a 1995 survey of physician office laboratories conducted by Mathematica Policy Research, and are supplemented by data from a 1991 laboratory survey. Primary care physician practices performing level I and level II tests in 1991 were resurveyed in 1995. Respondents were asked a series of questions pertaining to the types of laboratory tests performed in their offices, and whether CLIA '88 had any influence on the decision to change testing practices. We present descriptive statistics to examine differences across practices in response to CLIA '88. Significant determinants of the decision to drop or modify onsite testing activities are identified using multivariate analysis.

RESULTS. More than 64% of physicians surveyed cited CLIA '88 as a factor in their decision to reduce or eliminate in-office testing. The most striking effect of CLIA '88 appears to be on pediatric practices and practices in rural areas, of which more than 70% have reduced or eliminated onsite testing. Where the potential burden of compliance is smaller, as in larger practices, CLIA '88 has had less impact.

CONCLUSIONS. CLIA '88 has had significant influence on access to laboratory testing services. According to the data from the 1995 survey, almost two thirds of physicians have eliminated some or all in-office tests. Of those physicians previously conducting in-office tests, 70% have chosen to send patients and specimens to outside facilities, resulting in greater inconvenience for patients and delays in diagnosis and treatment. These delays, and the potential for patient noncompliance stemming from the inconvenience of obtaining tests, have serious implications for the quality of medical care.

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The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) established new regulatory requirements for physician office laboratories (POLs). Among the events leading to the enactment of CLIA '88 was the appearance of an article in *The Wall Street Journal* describing the allegedly deplorable situation of gynecologic cytology examinations (Papanicolaou [Pap] tests) done in laboratories.¹ The article focused on errors that resulted in missed or delayed diagnoses of carcinoma of the uterine cervix and reported the death of a patient whose Pap test was misread. The article produced a reaction in the US Congress; committee hearings were held, and Congress enacted CLIA '88. The leg-

islation was passed despite testimony by the Department of Human and Health Services (DHHS) indicating that the additional legislation was unnecessary. The DHHS noted that a revision of the CLIA '67 regulations was already in progress, and the agency could address these issues. All the laboratories cited for unacceptable laboratory performance had been subject to existing regulations.²

The CLIA '88 statute applied to all clinical laboratories that did testing for patient care purposes. Most important, it extended CLIA '67 regulations to a large number of previously unregulated sites. With the final rules implemented in 1992, CLIA '88 mandated uniform regulation of laboratory testing in all settings, including POLs, to ensure high-quality test-

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ing for all patients. In 1994, there were an estimated 158,000 registered laboratories in the United States, of which 59% were in physician offices.³ Since the first regulation was published in May 1990, it has provoked intense controversy and required several modifications before the actual implementation date. The first rule provoked an unprecedented 60,000 written comments to the US Health Care Financing Administration (HCFA) from physicians and laboratory professionals.^{4,5} Interestingly, the debate over CLIA '88 involved little scientific evidence to indicate the extent of laboratory testing problems and their effects on public health.⁶

CLIA '88 identified three levels of tests (waived, moderate complexity, and high complexity) based on the risk of harm to patients, the likelihood of erroneous results, and the simplicity of testing. Sites performing tests in the moderate- and high-complexity categories are required to institute quality assurance programs and meet specific personnel standards and quality control requirements. These laboratories are subject to periodic onsite inspections and must engage in an approved proficiency testing (PT) program. All sites must pay registration fees, based on the level of testing complexity, and follow manufacturers' instructions to ensure the reliability of testing equipment. Sites performing only waived tests are exempt from CLIA standards, but must be registered with HCFA and maintain "good laboratory practice."

The testing categories have been slightly modified since the enactment of CLIA '88. For example, beginning in 1993, practices performing only physician-performed microscopy are not subject to routine inspection. Despite attempts to ease the burden of regulation for practices performing simple tests, a large number of previously unregulated sites were hit hard, as more than 75% of laboratory testing fell into the moderate-complexity testing category.

In our study, we examined the influence of CLIA '88 on physician office laboratories under the assumption that some practices were better equipped to comply with the regulation. To the extent that practices are unable to absorb the monetary and time costs of compliance, we expected that CLIA '88 would cause some to reduce, modify, or eliminate clinical laboratory testing in their offices. The response has important implications for the quality of patient care, since these changes could severely impede access to timely, convenient testing.

Many other factors, including changes in labora-

tory testing technology and in public and private payer reimbursement policy, influence the decisions of practices to conduct testing in-house. Most notably, managed care organizations have instituted a variety of operating procedures and financial incentives that may influence decisions as these practices become more involved with managed care patients. Changes in physician practice structure, such as the movement toward larger group practices, also suggest changes in these practices' ability to perform certain activities.⁶

METHODS

We used the data from the 1995 Survey of Physicians' Office Laboratories,⁷ in which respondents were asked a variety of questions regarding their laboratory testing activities. The survey also collected information on practice characteristics, including specialty, practice type, and location, to assess any differential influence of the regulation on testing activities across practices.

The survey was conducted by Mathematica Policy Research and sponsored by the American Medical Association (AMA), the Medical Group Management Association, the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, the College of American Pathologists, and the American College of Obstetricians and Gynecologists. Nearly 800 physician practices responded to the survey, for an overall response rate of 77.4%.

The 1995 survey sample was limited to those primary care POLs who performed level I or II tests in the 1991 survey. This survey was conducted by Mathematica Policy Research and sponsored by the AMA, the American Hospital Association, the Health Industry Distributors Association, and the Health Industry Manufacturers Association. The most compelling reason for resurveying respondents to the 1991 survey was the availability of pre-CLIA data on these POLs, permitting an assessment of changes in the types of tests performed and the reasons behind these changes. Also, using a sample of POLs known to be previously conducting tests reduced the time and expense of sample screening.

A total of 1468 POLs conducting levels I and II tests were surveyed in 1991 using a combination of self-administered and telephone surveys; the response rate to this survey was 58.7%. Of these,

1181 were primary care practices selected for the 1995 survey. Forty practices were randomly selected for instrument pretesting and excluded from the final survey sample. Practices that were no longer active or could not be verified as active (after two mailings and several telephone attempts) were excluded from the sample. Of the remaining 1033 practices, a total of 581 completed self-administered questionnaires (by mail or fax) and 216 completed telephone interviews.

This sample design precluded the possibility of finding POLs that opened as a result of CLIA, although this is not likely to have been widespread. According to recent Centers for Disease Control and Prevention data, physicians now perform 294 million tests per year (7% of the total), while pre-CLIA projections were for 2.7 billion tests in POLs.⁶

SAMPLE CHARACTERISTICS

Table 1 presents the characteristics of the 797 practices that responded to the 1995 survey. All survey results are weighted for the oversampling of large practices in 1991 and nonresponse to the 1991 and 1995 surveys. Over two thirds of the practices surveyed were operated by solo practitioners, and nearly half were general or family practices. The average number of physicians in the practices surveyed was 1.66.

Because the 1995 survey was a resurvey of physician practices surveyed in 1991 who were performing in-office laboratory tests in 1991, additional data from the 1991 survey can be used to further explain practices' responses to CLIA '88. The last two columns in Table 1 indicate the variation across practices in revenues received from laboratory services and the practices' experience with proficiency testing.

RESULTS

CHANGES IN TESTING ACTIVITY AND TESTING COMPLEXITY

To determine the extent to which physicians have changed their laboratory testing practices, respondents were asked if they had reduced or eliminated in-office laboratory testing because of CLIA '88 or for other reasons. Approximately 7% of the practices reported having reduced or eliminated testing for reasons other than CLIA '88. Most striking is that more than 64% of the practices surveyed eliminated

some or all in-office laboratory testing because of CLIA '88 (Table 2).

Also indicated in Table 2 is how CLIA '88 has changed the level of complexity of laboratory testing among these practices. Physicians were asked to indicate the categories in which they perform testing, including waived, physician-performed microscopy procedures (PPM), and moderate-complexity and high-complexity tests.* Because the initial sample of physicians in 1991 were performing only complex or moderately complex tests, we can conclude that the physicians who reported in 1995 that they were performing tests only in the waived or PPM categories have reduced the complexity of their testing operations.

Another finding was differences across specialties: Physicians in family practice or pediatrics were more likely than other specialists to have reduced onsite testing activities because of the CLIA '88 regulations, and internists were more likely to have completely eliminated onsite testing because of CLIA '88. Interestingly, when compared with all other specialties, obstetrician-gynecologists were the most likely to have reduced testing complexity.

The regulatory requirements of CLIA '88 are likely to be a much greater burden on the solo practitioner than on practices with more than one physician, where costs, personnel, and administrative activities can be shared. Compared with groups of physicians in the same specialty, the solo practitioner was more likely to eliminate or reduce testing activities or reduce the complexity of tests performed. Furthermore, multispecialty groups were less likely to change their testing activities than were single-specialty groups, suggesting that any increase in requirements associated with a larger scope of tests are greatly offset by the ability to share the burden with other physicians in the group.

The location of a POL may be correlated with the decision to alter testing practices, because the alternatives to onsite testing may vary across locations.

* All the practices surveyed in 1995 had been performing level I and level II testing in 1991. These classifications do not correspond exactly to the current categorization of moderately and highly complex tests. In 1991, tests in level I were generally those that were deemed to pose a nonnegligible risk of harm to the patient if done incorrectly, with little chance that the test would yield erroneous results, and did not require extensive knowledge for performance or interpretation. Level II tests included those tests that require extensive knowledge to perform or interpret, and if done incorrectly, may have a substantial risk of harming patients and a significant risk of yielding incorrect results.⁹

TABLE 1

Characteristics of 797 Practices Responding to 1995 Survey, by Key Measures of Testing Activity from Baseline Survey (1991)

Characteristic	% of Respondents (n=797*)	Performed Proficiency Testing, %	% Practice Revenues from Testing
<i>Specialty</i>			
Family practice	44.4	39.5	14.1
Internal medicine	26.8	45.8	16.6
Pediatrics	16.2	19.4	9.3
Obstetrics/gynecology	12.5	23.9	10.5
<i>Practice Type</i>			
Solo practice	67.6	30.5	12.9
Single-specialty group	25.8	42.6	14.3
Multispecialty group	6.0	68.7	17.1
<i>Location</i>			
Nonmetropolitan	24.0	51.8	13.6
Metropolitan $\geq 1,000,000$	39.7	31.4	12.7
All Physicians	100.0	36.0	13.5

* Average no. of physicians in practice: 1.66.

Source: 1995 Survey of Physicians' Office Laboratories⁷ and 1991 CLIA Impact Study.¹⁰

TABLE 2

Percentage of Physicians Reporting Changes in Laboratory Testing Activities Because of CLIA '88

Variable	Eliminated Some Testing, %	Eliminated All Testing, %	Reduced Complexity of Testing, %
All physicians (n=797)	54.8	9.4	38.9
<i>Specialty</i>			
Family practice	61.0	8.7	39.3
Internal medicine	40.7	13.9	31.1
Pediatrics	65.3	7.3	31.9
Obstetrics/gynecology	51.7	5.8	63.3
<i>Practice Type</i>			
Solo practice	55.1	12.2	43.4
Single-specialty group	53.8	3.2	31.4
Multispecialty group	48.0	5.2	21.2
<i>Practice Location</i>			
Nonmetropolitan	66.8	5.9	38.7
Metropolitan			
<1,000,000	55.7	10.2	39.1
$\geq 1,000,000$	46.5	10.8	38.9

Source: 1995 Survey of Physicians' Office Laboratories.⁷

The figures in Table 2 indicate that 72.7% of rural practices reported having dropped some or all testing because of the CLIA '88 regulations. This proportion is significantly greater than the corresponding proportion among practices in the metropolitan areas, although rural practices were less likely to have completely eliminated in-office testing. The likelihood of decreasing testing complexity did not vary by practice location.

MULTIVARIATE ANALYSIS

The decision to change testing activities appears to depend on practice characteristics. For this reason, we estimated probit models based on the assumption that practice location, practice size, practice type, physician specialty, proportion of revenues from laboratory testing, and past experience with PT explain the decision to change testing activities. Using this methodology, we were able to obtain estimates of the independent influence of each characteristic. (Results of analysis are not shown but are available from the author on request.)

Practices in obstetrics and gynecology and internal medicine were found to be significantly less likely than pediatric practices to reduce or eliminate in-office testing. For example, the probability of drop-

ping tests is 21% lower for obstetrician-gynecologists than for pediatricians.

Single- and multispecialty group practices were both significantly less likely to drop or reduce testing than solo practitioners. The probability that a multispecialty group reduced testing was 24% less, and the probability that a single-specialty group practice reduced testing was 15% less, than the probability that a solo practitioner reduced testing. These results suggest a positive relationship between the scope of medical services provided and the decision to perform testing in-house.

Consistent with Table 2 is the finding that across specialties, obstetrician-gynecologists were 27% more likely than pediatricians to reduce the complexity of their testing activities. Single- and multispecialty group practices were also found to be significantly less likely than the solo practitioners to have reduced testing complexity. The estimated effect is greatest for multispecialty practices, indicating the potential ease with which a multispecialty practice may absorb the costs of compliance when a larger battery of tests is regularly performed.

The estimated effects for practice location revealed no significant difference across metropolitan or rural areas in the probability of reducing labo-

TABLE 3

Percentage of Physicians Using Alternatives to Onsite Testing

Variable	Collect Specimens for Outside Laboratory, %	Send Patients to Outside Laboratory, %	Combination of Both, %
All physicians (n=797)	35.3	24.8	38.9
<i>Specialty</i>			
Family practice	41.5	15.2	42.3
Internal medicine	40.0	18.4	39.5
Pediatrics	9.6	58.2	31.8
Obstetrics/gynecology	36.2	31.9	31.9
<i>Practice Type</i>			
Solo practice	32.6	27.5	39.5
Single-specialty group	38.7	20.9	37.4
Multispecialty group	59.5	15.3	25.2
<i>Practice Location</i>			
Nonmetropolitan	39.6	21.8	38.6
Metropolitan			
<1,000,000	34.4	32.3	32.7
≥1,000,000	33.1	19.3	45.6

Source: 1995 Survey of Physicians' Office Laboratories.⁷

TABLE 4

Percentage of Physicians Reporting Each Problem Associated With Reducing or Eliminating In-Office Testing Activities

Variable	Diagnosis Is Delayed, %	Outside Laboratory Is Inconvenient, %*	No Convenient Public Transportation, %
All physicians (n=797)	77.9	41.9	28.4
<i>Specialty</i>			
Family practice	79.3	50.6	25.1
Internal medicine	73.7	50.4	33.3
Pediatrics	84.5	17.9	28.9
Obstetrics/gynecology	73.1	22.7	27.6
<i>Practice Type</i>			
Solo practice	78.5	41.3	31.4
Single-specialty group	77.5	38.7	20.5
Multispecialty group	68.2	59.0	28.9
<i>Practice Location</i>			
Nonmetropolitan	79.7	60.0	23.2
Metropolitan			
<1,000,000	75.5	31.1	29.4
≥1,000,000	79.2	39.7	31.2

* Laboratory is >15 miles or >30 minutes away.

Source: 1995 Survey of Physicians' Office Laboratories.⁷

ratory testing complexity. Practice location influenced the decision to reduce or drop testing services, but was not a determinant of the types of tests performed.

The variables representing the 1991 testing experience were not significant determinants of the probability of reducing or dropping in-office testing in 1995, but are significant in the decision to reduce testing complexity in 1995. The results illustrate the potentially lighter burden of CLIA '88 for those practices already in compliance. Practices receiving a large share of revenues from testing were presumably more profitable in these activities than practices receiving a smaller share and would be less likely to abandon this profitable component of their business.

ACCESS ISSUES

To further investigate the influence of CLIA '88, we asked the physicians who had changed their testing activities to determine the effect on their patients' access to laboratory services. We used analysis of variance techniques to identify statistically significant differences in access across practice characteristics.

One consequence of reducing in-office testing is that either patients or specimens must be sent out-

side for analysis. Table 3 presents physicians' use of three alternatives: (1) collecting specimens and sending them to outside laboratories, (2) sending patients to outside laboratories for specimen collection and testing, or (3) a combination of both. Most of the practices surveyed sent at least some patients to an outside laboratory, while just more than one third continued to collect all specimens onsite but sent them to laboratories for testing.

Among the specialty groups surveyed, pediatricians were the most likely to have stopped collecting specimens in their offices. In 1995, more than 58% of the pediatricians surveyed sent patients to outside laboratories for tests that they used to perform onsite. The tests now performed offsite included a basic streptococcal test, which is frequently ordered for the evaluation of a common pediatric presentation.

Practices in small metropolitan areas were more likely than those in other areas to send their patients elsewhere for tests. Outside laboratories may be less convenient for patients in rural areas and rural practices may have opted to continue collecting specimens to avoid inconveniencing patients. Practices in large metropolitan areas may have better access to couriers, which simplifies sending specimens out of

the office. Multispecialty group practices were more likely than others to continue to collect specimens onsite, perhaps because testing is a larger part of the practice for multispecialty groups.

When physicians send patients offsite for clinical laboratory testing, patients can be inconvenienced by the additional time and cost of traveling to another location for the test. Physicians and their staff can be inconvenienced by the increased complexity in tracking specimens and test results when a third party is added to the process. These inconveniences complicate the ability to make timely diagnoses and begin treatment, and ultimately may reduce the overall quality of care. The figures in Table 4 indicate that nearly 78% of the practices reported that diagnosis or treatment was delayed when patients are sent to an outside laboratory.

Table 4 also summarizes physicians' reports on the distance to the referred laboratory and the availability of public transportation. More than 28% of the physicians surveyed reported that public transportation to the outside laboratory was not available, but this varied significantly across spe-

cialties and locations. Less than 18% of the pediatric practices surveyed reported that the outside laboratory was more than 15 miles or 30 minutes away. The convenience of an alternative site may help to explain why pediatricians were more likely than physicians in other specialties to send their patients to an outside laboratory when they stopped performing tests onsite. Physicians in non-metropolitan areas were more likely than physicians in other locations to report that the outside laboratory used most often was inconvenient.

When practices send patients elsewhere for laboratory services they face the risk that some patients will disregard physicians' orders to obtain prescribed tests at the referred facilities. Table 5 presents physicians' responses to questions aimed at determining the extent of noncompliance with orders to obtain laboratory tests at another facility. For example, more than 27% of all physicians reported having patients who had received tests in an emergency department sometime in the last year, and approximately 19% reported that this had occurred sometime in the last month. Almost 45% of

TABLE 5

Percentage of Physicians Reporting Experiences with Patient Compliance and Noncompliance in Obtaining Ordered Tests Outside the Physician's Office

Variable	Patient Obtained Test at Local ED, %		Patient Did Not Obtain Test, %	
	Previous Month	Previous 12 Months	Previous Month	Previous 12 Months
All physicians (n=797)	18.8	27.2	35.1	44.8
<i>Specialty</i>				
Family practice	22.4	28.8	33.8	43.9
Internal medicine	13.7	21.1	27.9	32.1
Pediatrics	20.3	37.4	47.6	57.7
Obstetrics/gynecology	13.8	20.1	39.7	57.7
<i>Practice Type</i>				
Solo practice	19.6	28.2	37.3	48.0
Single-specialty group	12.9	20.7	31.1	39.4
Multispecialty group	23.3	31.8	17.9	26.0
<i>Practice Location</i>				
Nonmetropolitan	25.3	36.9	34.4	46.3
Metropolitan				
<1,000,000	16.6	25.0	35.9	43.4
≥1,000,000	16.5	22.7	34.7	45.1

Source: 1995 Survey of Physicians' Office Laboratories.⁷

ED denotes emergency department.

the practices responded that, in the past year, some patients did not obtain an ordered test when they were referred to an outside laboratory, and 35% reported at least one such incident of noncompliance in the last month. These results varied little across physician categories.

DISCUSSION

The primary intention of CLIA '88 was to promote higher quality laboratory services. However, the burdens imposed on the previously unregulated POLs suggest that quality improvements may come at a substantial cost in terms of access. Moreover, there is little direct evidence today to suggest that CLIA '88 has improved the overall quality of laboratory services. In fact, a recent study of testing in primary physicians' offices suggests that improvements in analytic problems may be derived at the expense of an increase in pre- and postanalytic problems, such as in specimen management.⁶

EVIDENCE RELATED TO QUALITY

An early study of the effect of CLIA '88 on the incidence of invasive cervical cancer concluded that a reduction in false-negative Pap test results might be achieved under the regulation, but noted a concern that a corresponding increase in the price of the test would greatly reduce the access to Pap testing. Estimates of the false-negative rate vary widely, partly because it has been defined inconsistently in the literature. Ignoring effects on access, however, the authors suggested that CLIA '88 might reduce the rate of false-negative results from 15% to 5%.¹¹

One requirement of CLIA '88 is that POLs performing moderately complex or highly complex tests submit to onsite inspections. The HCFA report for the first round of CLIA laboratory inspections highlighted deficiencies in the quality of services provided by POLs, including failure to assess whether tests were producing accurate results and failure to follow manufacturers' written instructions for performing tests.³ The report noted no evidence that patients were actually harmed by these process-oriented deficiencies.

Between September 1992 and September 1993, the Commission on Laboratory Accreditation (COLA) performed onsite surveys of 562 laboratories.¹² COLA found that many laboratories that performed only one or two high-complexity tests had

discontinued these rather than face CLIA's personnel requirements. Five percent of the laboratories surveyed had serious deficiencies, the most common being related to quality control. Since quality assurance was a new concept codified in the CLIA regulations, few laboratories had any quality assurance activities in place.

EVIDENCE RELATED TO ACCESS

Several studies have addressed the influence of CLIA '88 on access to services. At the request of the HCFA, the Office of the Inspector General conducted a survey of 232 physician practices, none of which indicated that they had trouble securing laboratory tests for their patients.¹³ They found that the number of POL sites in operation had decreased 13% since 1988, and that CLIA '88 had an impact on the kinds of testing performed by POLs. However, they concluded that CLIA '88 has not affected physician ability to obtain laboratory tests and, in particular, the availability of services in rural areas has not been restricted.

Results from the AMA Socioeconomic Monitoring System (SMS) surveys of physicians indicate that the proportion of physicians performing in-office tests increased from 45% to 54% between 1989 and 1993 but fell significantly to 49% in 1995. The AMA's Socioeconomic Monitoring System surveys are telephone surveys of a random sample of nonfederal patient care physicians practicing in the United States, excluding resident physicians.¹⁴ The annual surveys reveal significant variations in the provision of in-office laboratory tests by specialty, location, and practice size that have persisted over time.

EVIDENCE RELATED TO BURDENS

The *Medical Laboratory Observer* conducted a national survey of laboratorians in 1994 to determine their experiences with CLIA '88.¹⁵ Two thirds of the survey respondents felt that CLIA '88 had failed to improve the quality of care and had adversely affected the clinical laboratory profession. Most striking was the report that the volume of paperwork, essential for passing inspection, rose dramatically during the first year of CLIA implementation.¹⁶

CONCLUSIONS

This study provides perhaps the most compelling evidence to date of the influence of CLIA '88.

Although consistent findings are obtained in smaller samples,¹⁷ our survey is based on a national sample of practices. Our results suggest that CLIA '88 was primarily responsible for the reduction of in-office laboratory testing between 1991 and 1995. While more than 70% of practices surveyed have reduced or eliminated testing during this period, we found that a vast majority of those surveyed (64%) cited CLIA '88 as the force driving this change.

The direct consequences of CLIA '88 appear most strikingly in pediatric practices and practices in rural areas, of which more than 70% have reduced or eliminated onsite testing. Our analysis highlights several significant differences across specialties, practice size, and practice location. Most notably, where the potential burden of compliance is smaller, because of prior experience with PT or within larger practices, the probability of reducing testing complexity is significantly lower.

There are many concerns about the costs and quality of laboratory testing activities that we do not address with our data. The effect of CLIA '88 to move testing activity away from POLs to larger reference laboratories has likely lowered the overall costs of providing tests. Such savings must be balanced against the increased costs of transporting patients or specimens to alternative sites, increased administrative costs associated with tracking patients and specimens through an additional step in the testing process, and the potential costs associated with delaying a diagnosis.

CLIA '88 has affected access to testing services because many physicians now send patients or specimens to outside facilities. These alternatives are often inconvenient for the patient and an overwhelming number of practices report that this results in delays in diagnosis and treatment. Patient noncompliance in obtaining prescribed tests is fairly common, with serious implications for the quality of care. Furthermore, the cost of receiving tests in an emergency room often exceeds the cost of obtaining

them at the prescribed location; patients not receiving prescribed tests may go untreated or have their treatment delayed. The lack of evidence to suggest that CLIA '88 has improved testing outcomes should be balanced against our results that suggest that CLIA '88 has adversely affected at least some dimensions of quality, such as timely access and diagnosis. Both results must be recognized in the debate more than the overall effectiveness of CLIA '88.

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