
QUALITY ASSURANCE IN INDEPENDENT PHYSIOLOGICAL LABORATORIES



OFFICE OF INSPECTOR GENERAL
OFFICE OF EVALUATION AND INSPECTIONS

OCTOBER 1990

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**Richard P. Kusserow
INSPECTOR GENERAL**

EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection was to assess quality assurance in Independent Physiological Laboratories (IPLs) by examining three aspects of the industry: regulation, personnel qualifications, and equipment standards.

BACKGROUND

Medicare coverage for IPLs was established in January 1979 when the Health Care Financing Administration's (HCFA) Office of General Counsel (OGC) determined that IPL services qualified for reimbursement under Title XVIII of the Social Security Act. The OGC ruling said IPL services qualified for Medicare Part B reimbursement if (1) the laboratory meets all State and local licensure requirements, (2) the diagnostic services are ordered by a referring physician, and (3) the services are determined to be reasonable and necessary by the Medicare carrier.

Prior to the OGC ruling, HCFA policy disqualified IPLs because they had to be certified for Medicare participation and conditions for participation had not been established. These standards still have not been developed.

The HCFA defines IPLs as "...laboratories operating independent of a hospital, physician's office, or rural clinic...." Tests IPLs typically conduct include ultrasound, pulmonary function, cardiac monitoring, and a variety of other diagnostic procedures.

METHODOLOGY

We collected information from four sources: (1) State agencies and health departments, (2) health care and IPL industry experts, (3) a random selection of IPLs, and (4) Medicare carriers.

FINDINGS

The Definition of "Independent Physiological Laboratory" is Unclear

No uniform definition exists of "physiological" as it relates to IPLs. The HCFA has never clarified types of covered IPL tests, acceptable testing sites, or standards and conditions of coverage for each test, thus fostering confusion among IPLs and carriers.

No Assurance Of Satisfactory IPL Performance Exists

We found no uniform and acceptable set of national standards defining satisfactory IPL performance. Specifically, the industry lacks (1) Federal or State oversight of IPL activities,

(2) uniform testing standards or quality control measures, and (3) standards regarding operator training and qualifications.

Concerns About IPL Performance Are Pervasive

Nearly 78 percent of the respondents who voiced definitive opinions expressed serious concerns about the quality and accuracy of IPL services. The major reason cited for these concerns was lack of regulating IPL operations.

RECOMMENDATIONS

1. The HCFA should issue Medicare coverage guidelines and instructions clarifying (1) what the term "physiological" means with respect to IPLs, (2) what tests IPLs are allowed to perform, and (3) what testing sites are permissible.
2. The HCFA should promote stronger quality assurance in IPLs through regulation or certification. This could be accomplished through any one or a combination of the following options: (1) Federal regulation, (2) State regulation, or (3) an independent certification program. The cost of such regulation or certification should be financed by provider fees. Elements common to each option include a quality control program, written testing standards, and credentialing staff or equivalent standards.

COMMENTS AND OIG RESPONSE

Comments were received from both the Public Health Service (PHS) and HCFA. Although PHS expressed support for stronger quality assurance in IPLs, they felt our respondents were unaware of Food and Drug Administration safeguards to assure the safety and efficacy of diagnostic equipment. The HCFA felt our report failed to provide convincing evidence to justify our recommendations, and they have initiated an independent review of IPLs to determine if standards should be developed.

We acknowledge the Food and Drug Administration's efforts in equipment safety and effectiveness, but we believe regulation or certification of the service itself would promote stronger quality assurance. In response to HCFA's comments, we feel the continued lack of quality assurance in IPL services is untenable and urge implementation of our recommendations. However, we have modified the recommendation to allow greater flexibility in achieving this result.

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INTRODUCTION

BACKGROUND

The Health Care Financing Administration (HCFA) defines independent physiological laboratories (IPLs) "...as laboratories operating independent of a hospital, physician's office or rural clinic." Prior to January 1979, Medicare did not cover services provided by IPLs. Medicare disqualified IPLs because they lacked certification and conditions for participation of these entities had not been established. Reimbursement was prohibited whether IPLs submitted claims for their services directly to Medicare Part B carriers or the charges were included in physicians' claims.

Coverage was established when the HCFA Office of General Counsel (OGC) determined that IPL services qualified for reimbursement under section 1861(S)(3) of Title XVIII of the Social Security Act. According to the OGC ruling, IPL services qualified for Medicare Part B reimbursement if (1) the laboratory meets all State and local licensure requirements, (2) the diagnostic services are ordered by a referring physician, and (3) the services are determined to be reasonable and necessary by the Medicare carrier.

Typical IPL services include ultrasound, pulmonary function tests, cardiac monitoring, and a variety of other diagnostic procedures. These tests differ from those performed by independent clinical laboratories (ICLs) in that bodily functions are tested (e.g., blood flow, lung capacity, heart rate) rather than bodily fluids or tissues (e.g., blood, urine, Pap smear). The IPL procedures require the patient's presence whereas clinical laboratory tests are performed on a sample taken from the patient. Typically, procedures are performed in a variety of locations including freestanding centers, office space rented from physicians, and mobile units.

Ultrasound devices are used to depict a patient's internal organs by sending high-energy sound-waves into the body producing echoes as they encounter differences in tissue structures. The data produced by the echoes can be transmitted into an image, which can be shown on a video screen or recorded on tape. Images can be recorded in color as well as black and white. Health care practitioners use ultrasound in a wide range of specialties, such as cardiology, gynecology, and vascular surgery. Typically, the tests are conducted by specially trained individuals known as ultrasonographers or, more commonly, sonographers.

Cardiac monitoring is a diagnostic technique which records a patient's cardiac activity during extended periods of time. This procedure can pinpoint cardiac irregularities, or even a heart attack, of which the patient may not be aware. Cardiac recorders are small, lightweight devices with electrodes fastened to the patient's body. All cardiac activity is recorded on tape which can be evaluated by a cardiologist or sent to an IPL which specializes in cardiac analysis.

Regulation of clinical testing began with Title XVIII of the Social Security Act which imposed standards and conditions of coverage on clinical laboratories under the Medicare and Medicaid programs. In 1967, Congress passed the Clinical Laboratory Improvement Act (CLIA) to regulate the interstate activities of independent clinical laboratories (ICLs). Congress strengthened CLIA in 1988 with amendments which mandated standards in certain kinds of testing. In 1981, Congress passed the Consumer-Patient Radiation Health and Safety Act. This law established minimum standards for State accreditation of radiologic educational programs and State certification or licensure of persons who conducted tests using radiant energy.

No Federal laws exist which regulate the performance of noninvasive physiological testing. Several Federal laws and State statutes have been enacted to regulate clinical and radiant testing. The IPLs which engage in such tests are subject to regulation of those aspects of their operations. However, the regulation does not extend to any noninvasive physiological tests conducted by IPLs.

This inspection was originally suggested by HCFA. They raised concerns about the performance of IPLs because of the lack of regulations and what they perceived as inconsistent practices by carriers regarding IPL operations.

A May 1989 OIG report entitled, "Financial Arrangements Between Physicians and Health Care Businesses" (OAI-12-88-01410), details effects of physician ownership and compensation arrangements with health care entities, including IPLs. This study indicated that IPLs operated with little or no regulation or standards imposed by either government or the IPL industry itself. As a result, many health care experts and organizations expressed concerns about IPLs and the quality of their diagnostic testing services. Accordingly, we decided to conduct a study focused on regulation of IPLs.

During 1987, Medicare paid approximately \$290 million in Part B reimbursements for noninvasive diagnostic testing. Although IPLs perform a variety of procedures, three tests—Holter monitoring, abdominal ultrasound and peripheral vascular studies—accounted for about two-thirds of these reimbursements. In 1987, a total of 1,674 IPLs had Medicare provider numbers.

PURPOSE

The objectives of this inspection were

- to determine the nature and extent of regulatory practices regarding IPLs and the services they provide;
- to determine the qualifications of personnel who conduct tests and the perceived effect on the accuracy of testing if such qualifications appear to be lacking; and

- to assess the integrity of testing in IPLs by examining practices and standards related to physiological equipment.

METHODOLOGY

We obtained information from a variety of sources. These sources included State agency and health department officials, health care and IPL industry experts, a random selection of IPLs, and Medicare carriers.

We collected information from 68 State agency and health department representatives in all 50 States and the District of Columbia. These contacts were designed to determine the existence of any present or planned State laws affecting IPL operations. In some cases, we were referred to additional agencies in the State.

We obtained information from a wide variety of health care experts and organizations. We based selections on their knowledge of the IPL industry. Included among these contacts were a number of manufacturers of noninvasive diagnostic equipment typically used in IPLs.

Health care organizations and associations providing information and material included the American College of Cardiology, the American College of Radiology, the Joint Commission on Accreditation of Healthcare Organizations, the National Electrical Manufacturers Association, and the American Institute of Ultrasound in Medicine. (See the appendix for a complete listing of organizations and associations contacted.)

We contacted a sample of IPLs to ascertain the day-to-day operations of these entities, concentrating on types of diagnostic tests performed, where performed, and kinds of equipment used. Other areas reviewed included any regulation of their operations by a State or other governmental agency, staff qualifications and training, and quality control practices.

A total of 35 IPLs in 8 randomly-selected Medicare carrier service areas were contacted. The eight carriers selected were Travelers of Connecticut; Empire Blue Shield of New York; Nationwide of West Virginia; Blue Shield of Florida; Blue Shield of Michigan; Blue Shield of Kansas City; Blue Shield of Arkansas, and Occidental of California. The carriers accounted for approximately 30 percent of total Medicare payments for Part B services in 1986. We also contacted each carrier to determine if it had any special policies to monitor the activities of the IPLs in its coverage area.

FINDINGS

The Definition of “Independent Physiological Laboratory” is Unclear

No uniform definition exists of “physiological” as it relates to IPLs. The HCFA has never clarified types of covered IPL tests, acceptable testing sites, or standards and conditions of coverage of each test. This has fostered confusion among IPLs and carriers.

We encountered a diverse array of entities operating as IPLs. These ranged from large corporations conducting a multitude of diagnostic testing to sole ownership enterprises performing an occasional EKG. Equipment ran the gamut from a \$100 blood pressure cuff to almost a million-dollar magnetic resonance imaging (MRI) device. A wide variety of IPL types were categorized by testing sites. Moreover, despite HCFA’s definition of an IPL as a laboratory operating “...independent of a hospital, physician’s office, or rural health clinic...”, we found a number of IPLs conducting tests in hospital settings and in physicians’ offices. The HCFA’s guidelines provided no direction on *where* the tests could be performed or exactly what was meant by the phrase, “...operating independent....”

On the advice of a medical consultant, we intended to exclude from this study any diagnostic services which were invasive or potentially harmful to a patient. Thus, we proceeded on the basis that invasive and radiant tests, such as blood tests and x-rays, were not “physiological” tests and would not be included in our study. However, we learned that many IPLs were conducting these tests. We included ultrasound as a noninvasive test even though a form of radiation is used in the procedure. The type of radiation used, however, is “non-ionizing” and is considered to be harmless to the patient.

In 1979, when OGC determined that IPL services qualified for coverage, the only requirements were the three stipulations referred to previously (see Introduction). In its decision, OGC did not offer a definition of the term, “physiological.” It did, however, cite two noninvasive services as examples of the types of tests for which payment could be made: electrocardiographs (EKGs) and electroencephalograms (EEGs). The OGC opinion further noted, “Carriers shall advise all affected independent laboratories that HCFA is studying the type of services furnished by these independent laboratories and that standards and conditions for coverage of some or all of these services may be published by regulation.”

To date, an elaboration of those “standards and conditions” has not been delineated, either in regulations or in HCFA guidelines. As a result, considerable confusion exists with regard to defining an IPL, tests permitted, and IPL qualifications.

One carrier indicated it would issue an IPL provider number to an entity which did clinical and radiant testing. Another said it would attempt to categorize the entity as a physician’s office and issue a provider number accordingly.

One carrier asked its HCFA regional office to clarify the kinds of tests which IPLs could perform. The carrier noted that IPLs in its service area were conducting the following tests: doppler flow studies, ultrasounds, EKGs, EEGs, pulmonary function tests, MRIs, and computerized axial tomography (CAT) scans.

The regional office responded that a specific list of such services has never existed, other than the reference to EKGs and EEGs. The response further noted: "The responsibility for defining the tests included has been left to the Medicare carriers. A practical definition might be that any test which is a clinical laboratory or radiological test cannot be considered as a physiological test. To that extent, we would disagree with your inclusion of cat scans as being physiological, since we consider them to be a radiological procedure."

Our study encountered a bewildering variety of entities. Some actual examples:

- One of the IPLs we interviewed conducted ultrasound tests, mammographies, and tests involving nuclear medicine.
- A representative of a chain of diagnostic testing centers advised us that his centers were structured as physicians' offices rather than IPLs in order to bypass restrictive laws in the States where his centers were located.
- One durable medical equipment company had to obtain an IPL provider number because it occasionally performed EKGs. In 1988, the company had performed only four EKG tests.
- One IPL defied description. It acted as a "middleman" by obtaining referrals from physicians and contracting out those referrals to an IPL. The company itself maintained no staff or equipment.

We attempted to characterize each of the 35 IPLs contacted according to types of tests performed, testing locations, and physician-directed or not. We classified the types of tests into four categories: (1) one type of noninvasive test only (such as a cardiac monitor), (2) both invasive and noninvasive tests conducted, (3) both radiological and noninvasive tests conducted (such as mammogram and ultrasound), and (4) multiple noninvasive tests (such as ultrasound and pulmonary function).

SUMMARY OF IPL CONTACTS	
TYPES OF TESTS	NUMBER OF IPLS
One type only	15
Invasive & noninvasive	5
Radiological & noninvasive	7
Multiple noninvasive	8
TESTING LOCATIONS	
Stationary	21
Mobile only	6
Mobile & stationary*	5
Hospital settings	3
ORGANIZATION	
Physician-directed	17
Non physician-directed	18
* Includes equipment leased to physicians' offices, tests conducted by IPL staff in leased space, and tests analyzed in IPLs after being performed in physicians' offices.	

No Assurance Of Satisfactory IPL Performance Exists

Our study found that no uniform and acceptable set of national standards defining satisfactory IPL performance exists. Specifically, the industry lacks: (1) Federal and State regulation of IPL activities, (2) uniform testing standards or quality control measures, and (3) standards regarding operator training and qualifications. We discuss these weaknesses in further detail below.

Lack of Federal and State Regulation

No Federal laws exist affecting the performance of noninvasive physiological testing and there is virtually no legislation among the States. Several State respondents indicated their legislatures were considering measures to regulate noninvasive physiological testing.

We also asked State respondents three questions: (1) Should IPLs be regulated? (2) Should IPL staff be certified? (3) Should IPL equipment be subject to mandatory quality control checks? More than 80 percent of those responding answered "yes" to all three questions. One typical comment was, "We regulate barber shops in this State. Why not IPLs?"

As of July 1989, three States (Kentucky, Maryland, and West Virginia) had enacted legislation affecting the performance of noninvasive physiological testing, exclusive of pulmonary function testing. A summary of applicable provisions follows:

- Kentucky — all medical laboratories must be licensed and are subject to periodic inspection. Each laboratory must establish a quality control program acceptable to the State. Personnel qualifications may be prescribed at a later date.
- Maryland — cited elsewhere in this report, the Maryland law regulates equipment rather than facilities. This law regulates only equipment costing more than \$600,000, no matter where the testing is conducted.
- West Virginia — similar in most respects to the Kentucky law. However, West Virginia requires that laboratory staff must be licensed and certified.

The only guidelines HCFA has issued regarding IPLs are the provisions relating to service coverage and a prohibition against durable medical equipment (DME) companies from owning IPLs. (This prohibition stems from conflict-of-interest situations in which IPLs were performing oximetry tests for financially related DME companies. Oximetry test results are needed before oxygen can be prescribed for a Medicare beneficiary.)

Only one of the eight carriers contacted has a systematic plan for monitoring the IPLs in its service area. This carrier conducts an integrity check on IPL owners before issuing a provider number; after the IPL has been operating for 6 months, a review of their services is automatically scheduled. The other carriers review an IPL's activities only in response to a specific complaint or in reaction to a question arising during processing an IPL's claim.

Two carriers require IPL directors to be physicians. One carrier requires IPL staff to be certified in accordance with local laws.

Lack of Uniform Testing Standards or Quality Control Measures

We contacted a wide variety of health care organizations and experts representing professional societies aligned with specific forms of diagnostic testing, equipment manufacturers, credentialing organizations, and public interest groups. Thirteen experts said noninvasive physiological testing—no matter where the testing was performed—lacked uniform testing standards or quality control measures.

Ultrasound tests, in particular, were singled out as lacking uniform performance standards or quality control measures. Some typical comments were:

“There is no standardized protocol for doing ultrasound tests.”

“Other than ultrasound, there are fairly well documented quality control procedures.”

“There is no independent standard that each manufacturer (of ultrasound equipment) can be measured against.”

“Ultrasound is more of an art than a science.”

Several respondents blamed the Food and Drug Administration (FDA) for failing to establish standards for ultrasound testing. One expert noted, “FDA has no image quality standards on ultrasound equipment.”

The 1976 amendments to the Federal Food, Drug, and Cosmetics Act empowered FDA to regulate medical equipment devices. One function granted FDA was to develop performance standards for new medical devices. The amendments permitted FDA to regulate new equipment for marketing if the equipment was substantially equivalent to preenactment devices. Such equipment may be marketed subject to the same regulatory controls as their preenactment predecessor devices.

Several General Accounting Office (GAO) studies as well as a recent OIG study, “Home Testing Devices: FDA Clearance and Monitoring Activities” (OAI-12-89-01360), found that, although performance standards for medical devices had not been developed, FDA has safeguards in place to assure the safety and effectiveness of equipment. Primarily, FDA uses its own draft guidance instructions to manufacturers and voluntary standards to evaluate the performance of medical devices.

During the inspection, we encountered a number of examples of performance standards which we considered laudable. For example:

- The American College of Radiology Task Force on Standards Setting developed a 14-point performance standard on mammography screening. Not only does the standard stipulate technical equipment requirements, but it also cites goals, indications, contraindications, frequency guidelines, and qualifications for both technicians and technologists.
- A Maryland law governing equipment costing in excess of \$600,000 mandates that every operator of such equipment establish a “Quality Assurance Program” detailing appropriate use and monitoring of the equipment. The Maryland law cites appropriate elements of the Program as including “...documentation of informed consent, checks for allergies, appropriate medical history prior to testing...” The law also requires equipment operators to hold monthly meetings to evaluate identified problems regarding their services.
- A midwestern IPL conducting more than 20 different ultrasound procedures produced an operating manual which details patient preparation procedures, clinical indications, expected results, contraindications, and technical requirements for each test.

Whenever feasible, we obtained copies of written performance guidelines. These guidelines ranged from detailed instructions on how tests were to be conducted to employee leave requests. In no case were these guidelines prepared as a result of State or other regulation. All had been prepared voluntarily. For example, the American College of Cardiology has promulgated standards on a number of diagnostic cardiovascular tests. However, no requirement exists for any IPL to adopt these standards. Clearly, if the IPL felt no compulsion to prepare performance guidelines and standards or adopt existing ones, it did not do so.

As with performance standards, the quality control measures established by the IPLs we contacted were strictly voluntary. If an IPL did not want to implement quality control procedures or special techniques to verify accuracy, it did not do so. All the IPLs we contacted, however, did engage in at least one quality control procedure. The range and extent of such procedures appeared to vary considerably from IPL to IPL.

Lack of Operator Training Standards and Qualifications

At the 35 IPLs we contacted, 18 of 45 equipment operators or technologists were neither registered by an accrediting organization nor registry-eligible (meeting all qualifications for registration except passage of an examination). Additionally, 15 of these IPLs did not require their technologists to take continuing education courses annually.

The IPLs are not required to hire registered technologists. With limited exceptions (noted below), no laws or required standards exist denoting minimum educational or training standards for operators of medical equipment devices. The owner of a midwestern IPL stated, "Some IPLs can just drag people off the street and train them. Personnel qualifications should be the same no matter where the test is done—IPL, hospital, or wherever."

Pulmonary function testing is the only noninvasive physiological test subject to extensive regulation. Twenty-four States along with Puerto Rico have legislation requiring pulmonary and respiratory technologists to be licensed by the State in which they practice and certified by the National Board for Respiratory Care, the national credentialing body in that field.

In the two most frequently performed IPL tests—ultrasound and cardiac monitoring—virtually no standards exist for training, educational requirements, qualifications, or accreditation. Every IPL is left on its own with respect to staff qualifications and requirements. If an IPL chooses not to establish any qualifications or criteria for its employees, it is free to do so.

While only Utah and West Virginia have laws affecting sonographers (who operate ultrasound equipment), a number of other States are considering legislation. The Utah law, which will become effective April 1991, requires sonographers to be licensed by the State and certified by a nationally recognized credentialing body. The West Virginia law, passed in April 1989, requires all "lab technicians and lab technologists" to be licensed and certified. Although this law mandated implementation in 90 days, a State official advised us that full implementation may be delayed due to monetary problems.

No uniform national standards exist regarding training or qualifications of technicians who do ambulatory electrocardiography (AECG) analysis. Further, no recognized credentialing bodies offer certification examinations in AECG monitoring. One credentialing organization does offer a “self assessment” examination; however, this is offered solely on a voluntary basis.

Concerns About IPL Performance are Pervasive

Interviews with health care experts, IPL operators, and State respondents confirmed that concerns about the quality of IPL services are pervasive. Nearly 78 percent of all respondents who voiced definitive opinions expressed misgivings about IPL performance. One expert’s comment was typical: “Regulation is needed to assure the patient receives quality testing.”

Among other reactions received from representatives of health care organizations and associations were:

“There should be some standards to protect the public.”

“It’s easy to get false negatives.”

“Regulation would help to curb improper practices.”

“You need quality control, and it should be mandatory.”

Owners and operators of IPLs had similar comments. In general, these respondents felt that the lack of regulation of IPL operations fostered a climate which allowed some IPLs to skimp on quality control if it suited them to do so. Some of the comments expressed were:

“Regulation would stop people who have no regard for quality.”

“There are lots of bad apples out there.”

“We need to keep incompetent people out of the business.”

“Some IPLs have poor techniques. It would not hurt to have some oversight.”

Although quality and accuracy of testing were the concerns most frequently expressed, related issues were also voiced. These issues included safety of testing, reliability of equipment, and qualifications of physicians and staff who operate equipment. Several respondents mentioned potential hazards associated with IPLs which conducted tests using radiation and nuclear medicine.

A number of experts deplored what they perceived as a lack of attention devoted to equipment checks and preventive maintenance. One IPL owner noted, “Some companies use very old

equipment.” Another interviewee stated, “Doctors generally buy cheap equipment and use poorly trained staff to operate it.”

Three respondents were critical of the qualifications of physicians who conducted tests. One expert said, “One-third of all imaging procedures are performed by non-qualified physicians.” Another stated, “Doctors should be credentialed in the specialty in which they do testing.”

Of 17 health care experts who expressed an opinion, 15 favored minimum educational and training standards and mandatory credentialing for technologists who operate physiological testing equipment. Typical comments were:

“Poorly trained, uncredentialed laboratory techs are one of the major problems affecting the quality of physiological testing.”

“If an IPL had only registered people, it would indicate they are concerned about quality.”

“If a tech is considered competent, but is not credentialed, then there is something missing in his training.”

RECOMMENDATIONS

1. **The HCFA should issue Medicare coverage guidelines and instructions for IPLs.** The instructions should clarify (1) what the term “physiological” means with respect to IPLs, (2) what tests IPLs are allowed to perform to be included in the IPL category, and (3) what testing sites are permissible. These directives will enable carriers to treat IPLs in a more uniform and consistent manner.

2. **The HCFA should promote stronger quality assurance in IPLs through regulation or certification.** This recommendation can be accomplished by any one or a combination of the options listed below. However, any proposal addressing quality assurance in IPL services should include these elements: (1) a quality control program, (2) written testing standards, (3) credentialing of staff or equivalent experience and training, (4) continuing education or training, and (5) onsite inspection visits. These elements are implicit in each of the options listed below. The cost of such regulation or certification should be financed by provider fees.
 - a. ***Federal Regulation***

The HCFA could seek legislation to impose national certification standards on IPLs along the lines of laws governing ICLs. Such standards would address minimum staff qualifications and training as well as mandatory quality control equipment checks. Periodic onsite inspection visits would be required. These visits could be done by the same State agencies which survey ICLs. Costs could be offset by assessments against the inspected entities. Any IPLs which fail to meet minimum standards would be barred from Medicare participation. (If merited, these standards also could be extended to physicians who conduct a large number of diagnostic tests in their offices.)

 - b. ***State Regulation***

The HCFA could seek legislation to require, as a condition of Medicare participation, that IPLs be regulated by States. The legislation could establish a set of minimum standards but still allow States considerable flexibility in determining the details of their quality assurance programs, with enforcement conducted by each State. Perhaps the programs now in effect in Maryland, Kentucky, and West Virginia could be used as a basis for structuring these standards.

 - c. ***Independent Certification***

In conjunction with industry groups, the HCFA could recognize an independent oversight organization to monitor and certify IPLs. (Legislation may be needed to effect this approach.) Certification would be required before an IPL could participate in Medicare. The Joint Commission on

Accreditation of Healthcare Organizations (JCAHO) favors this approach. According to the JCAHO, IPLs have many characteristics in common with ICLs; many of the standards established for ICLs could also apply to IPLs. The JCAHO standards used for hospital clinical, radiant, and physiological testing could be used as a model for an independent oversight program.

COMMENTS

We received comments on the draft report from both the Public Health Service (PHS) and HCFA.

The PHS expressed support for stronger quality assurance in IPLs and included a number of general and technical comments. Primarily, PHS questioned whether our respondents were fully aware of FDA's procedures and safeguards designed to assure the safety and effectiveness of diagnostic equipment, in particular, ultrasound devices. The FDA has been striving to achieve quality assurance in diagnostic equipment by promoting voluntary performance standards. In association with a standards organization, FDA has developed a manual on ultrasound equipment performance. In response, we feel our respondents were not singling out FDA for criticism; rather, they were expressing frustration with a health care system which they perceive as being less than perfect. As we indicated previously, we acknowledge FDA has safeguards in place to assure the safety and efficacy of equipment.

We have made certain revisions with regard to PHS' technical comments concerning FDA procedures. The PHS had no comments on the recommendations.

The HCFA felt our report failed to provide convincing evidence to justify our recommendations. Although HCFA declined to implement the recommendations, they have initiated an independent review of specific kinds of IPLs to determine if standards should be developed. Moreover, HCFA indicated a willingness to consider the need for legislation if their findings supported such action.

In response to HCFA's comments, we believe the absence of quality assurance in IPL operations is untenable. Medicare beneficiaries have a right to expect a basic level of quality performance and, at the present time, such assurance with respect to IPLs does not exist. We have, however, modified our recommendations to provide more flexible mechanisms for quality assurance, particularly for options involving State governments or an independent certifying entity.

We wish to thank PHS and HCFA for their comments, and we are pleased by their expressions of interest in our study.

APPENDIX

INSPECTION CONTACTS

1. American Association for the Continuity of Care
2. American Association of Retired Persons
3. Acuson, Inc.
4. Advanced Technology Laboratories
5. American Association for Respiratory Care
6. American Association of Medical Assistants
7. American College of Cardiology
8. American College of Radiology
9. American Imaging Association
10. American Institute of Ultrasound in Medicine
11. American Medical Technologists
12. American Registry of Clinical Radiography Technologists
13. American Registry of Diagnostic Medical Sonographers
14. American Society of Echocardiography
15. American Society of Internal Medicine
16. CCI/NBCVT (formerly Cardiovascular Credentialing International/National Board for Cardiovascular Testing)
17. Citech (Center for Information on Technology for Health Care)
18. Center for the Advancement of Ambulatory Monitoring
19. Circadian
20. Credentialing Commission

21. Diagnostic Health Services
22. ECRI (formerly Emergency Care Research Institute)
23. Federation of State Medical Boards
24. Food and Drug Administration
25. Health Industry Manufacturers Association
26. Hewlett-Packard
27. Joint Commission on Accreditation of Healthcare Organizations
28. Keith Mauney & Associates
29. Marquette Electronics, Inc.
30. Medical Technology Practice Pattern Institute
31. National Board of Respiratory Care
32. National Commission for Health Certifying Agencies
33. National Electrical Manufacturers Association
34. National Organization for Competency Assurance
35. National Society for Cardiovascular Technologists
36. Nuclear Associates
37. Office of Licensing & Certification Programs, State of Maryland
38. Public Citizen Health Research Group
39. Radiation Measurements, Inc.
40. Society of Diagnostic Medical Sonographers
41. Society of Vascular Technology
42. Ultramed, Inc.