PROPOSED AGREEMENT REGARDING CLINICAL LABORATORIES

SEC. ___. CLINICAL LABORATORIES.

(a) REGISTRATION OF CERTAIN LABORATORIES.—Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended—

(1) in subsection (d)—

(A) in paragraph (2), to read as follows:

"(2) REQUIREMENTS NOT APPLICABLE.—A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be exempt from the requirements of registration and certification under this section."; and

(B) by striking paragraph (4); and

(2) in subsection (m)(1), by striking "shall only" and all that follows through the period and inserting "may not impose a fee for the issuance and renewal of certificates of waiver.".

(b) PROVIDER PERFORMED MICROSCOPY TESTING.—Section 353(d) of the Public Health Service Act (42 U.S.C. 263a(d)) (as amended by subsection (a)(1)) is further amended by adding at the end thereof the following new paragraph:

"(4) APPLICABILITY OF REQUIREMENTS TO PROVIDER PERFORMED MICROSCOPY TESTING.—

Notwithstanding any other provision of law, a laboratory that is certified under this subsection and that performs provider performed microscopy testing shall be subject only to those requirements under this section that the Secretary dotermines are relevant to the examinations and procedures performed by such laboratory.".

"PERSONNEL STANDARDS - For purposes of determining qualified laboratory personnel, purusant to the standards applicable to such personnel under this section, the Secretary shall recognize certifications provided to such personnel by private sector certifying entities. Furthermore, the Secretary shall require, withinn five years hereof, that all laboratory personnel demonstrate their qualifications, pursuant to the standards applicable to such personnel under this section, by such certifcations from private sector certifying entities or by an alternative qualification as determined by the Secretary"

(d) PROFICIENCY TESTING.—Section 353(f)(3)(D) of the Public Health Service Act (42 U.S.C. 263a(f)(3)(D)) is amended by adding at the end thereof the following new sentence: "With respect to a laboratory that successfully participates in three consecutive proficiency testing events under this paragraph, the Secretary shall, at the request of the laboratory, waive the next scheduled on-site inspec-

tion and permit the laboratory to complete a self-assessment.".

(e) CLARIFICATION OF NOTIFICATION REQUIREMENTS.—Section 353(f) of the Public Health Service Act (42 U.S.C. 263a(f)) is amended by adding at the end thereof the following new paragraph:

"(5) CLARIFICATION OF NOTIFICATION REQUIREMENTS.—

"(A) CHANGES IN METHODOLOGY.—With respect to a laboratory that is certified under this section, the Secretary may not require such laboratory to provide notice to the Secretary of any modifications in the methodology utilized by the laboratory if such methodology does not affect the specialities for which the laboratory is certified or the complexity levels for which such certification is provided.

"(B) TECHNICAL SUPERVISORS.—With respect to a laboratory that is certified under this section, the Secretary may not require such laboratory to provide notice to the Secretary of changes in the personnel who act as technical supervisors at such laboratory.".

(f) INSPECTIONS.—Section 353(g)(1) of the Public Health Service Act (42 U.S.C. 263a(g)(1)) is amended by

striking "on an announced or unannounced basis" and inserting "on an announced or, where the Secretary determines that public safety is in jeopardy, unannounced basis".

(g) WAIVED TEST REGULATION.—Not later than June 1, 1996, the Secretary of Health and Human Services shall promulgate final regulations with respect to proposed regulations concerning laboratory examinations and procedures that are not subject to the requirements of section 353 of the Public Health Service Act.

1995

Key Issues In Medicare Reform

The American Optometric Association
1505 Prince Street Suite 300
Alexandria, VA 22314
Phone: (703) 739-9200
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Optometrists understand and share Congress' commitment to slowing down the cost growth of federal health care programs. As primary eye care providers, optometrists support systemic efforts to control costs while emphasizing high quality care in Medicare and other federal health programs. As a profession that has historically maintained relationships with individual patients who pay for most of their care with out-of-pocket dollars, optometry also understands and supports Congress' efforts to induce greater competition in Medicare through reliance on expanded consumer choices and individual incentives to compare costs.

However, for market forces to truly take hold in Medicare, Congress must ensure that all providers are given the opportunity to compete fairly. And Congress must take proactive steps to ensure that patients are given access to the full spectrum of competing providers. Optometry does not seek broad mandatory contracting requirements on health plans, as some "any willing provider" proposals would require. However, to ensure that the transition to a more competitive Medicare program goes smoothly, and to ensure that all providers can compete on a level playing field in the reformed Medicare system, optometrists believe some basic standards of conduct are necessary. To ensure real and vigorous competition, on both price and quality issues, the American Optometric Association urges Congress to include provisions addressing the following three issues in any bill establishing new "health plans" for Medicare recipients.

Provider Nondiscrimination

Congress should not allow any health plan to arbitrarily discriminate against any provider based solely on academic degree, or license, or artificial guidelines such as hospital privileges, but should recognize and promote patient access to the diverse mix of health providers which have been licensed by the states under their traditional regulatory authority.

Anti-discrimination protections to prohibit plans from arbitrarily excluding whole classes of health professionals from their provider networks, would respect the licensing authority of the states and protect duly licensed providers and their patients from the unfair predatory contracting practices that have been employed by some managed care plans in the past.

Nondiscrimination provisions to prevent these kinds of unfair practices will help ensure that future Medicare patients have access to a greater range of capable providers, and that they enjoy the benefit of the increased competition that will result from the inclusion of a broader range of providers in the plan's panel negotiations.

Key Issues In Medicare Reform

Access Standards for Health Plans

Minimum contracting standards to ensure that patients have access to an appropriate mix, number, and distribution of qualified practitioners are necessary to protect patient's access to high quality health care. While a managed plan must necessarily be able to restrict its pool of available providers, these minimum access standards would ensure that patients have access to the full range of licensed health providers and that plans maintained sufficient provider capacity to guarantee prompt access to care, regardless of a patient's place of residence, their particular health needs, or the time of day.

Access standards requiring an appropriate mix, number and geographic distribution of the full range of providers would also facilitate expanded patient choice and greater competition between provider groups with overlapping clinical authority.

Out-of-Network Service Option

Quality of care and patient choice could also be augmented by requiring all plans to offer an "out-of-network option" for all covered services. While a recent study (Milliman and Robertson, Inc.; March 14, 1995) concluded that the "inclusion of out-of-network coverage ... does not, in itself, either increase or decrease claims costs", patients exercising this option could be required to a pay a reasonable additional fee to help cover any additional related administrative expense. In exchange, Medicare beneficiaries who respond to congressional incentives and enroll in managed care plans would be assured that they could always seek alternative care or continue to see a chosen provider if their expectations of a plan didn't materialize or the plan's panel of providers was later changed.

While many states have already gone far beyond these requirements and implemented "any willing provider" laws which compel managed care plans to contract with any provider who agrees to accept the plan's terms, this approach emphasizes the patient's interests, and by allowing for an additional fee, responds to the administrative concerns expressed by the managed care community.

An out-of-network option would also allow the full range of licensed health providers to continue to compete for patients regardless of the beneficiary's chosen health plan or the make-up of the plan's provider panel. If a plan used predatory contracting strategies to acquire patient share, only to later withhold care or reduce the size of its provider panel, this requirement would ensure that patients had other viable options.

Given the popularity of plans with this feature in the private sector, and the general apprehension about Medicare reform in the senior community, it would seem that the inclusion of an out-of-network option requirement would be a prudent way to gain increased support for Medicare reform, from providers and patients alike.

DRAFT LETTER -- PLEASE REVISE AS APPROPRIATE
AND REWRITE ON PERSONAL LETTERHEAD

The Honorable Robert Dole:
Majority Leader
United States Senate
c/o Ms. Sheila Burke
Room S-230, U.S. Capitol
Washington, D.C. 20510

Dear Bob:

I hope the incredible schedule you're maintaining these days doesn't completely drain you of all your good charm! We are all very proud of you back home in Russell. And while I know you've never been busier, I hope I'll get to see you back in the office sometime -- at least before your second inauguration! In the meantime, Dad and I wish you the best in the tough months ahead. We will certainly continue to be here to help you and your campaign in anyway we can.

The reason I'm writing today though is to bring to your attention some very real and important concerns optometry has with the Medicare package now pending in Congress. We fear that the current proposals would unnecessarily restrict optometry's ability to continue serving Medicare patients, as we've done effectively since you first helped us get included in the program back in 1987.

The problem is that many managed care companies do not currently include optometrists in their provider panels. And despite the profession's recognition under the traditional Medicare program, and our ever widening scope of clinical authority under state law, our efforts to educate plan administrators as to our abilities and secure positions on managed care panels have often times been rebuffed.

The enclosed letter suggests what we are up against. Many plans simply refuse to even consider including optometrists in their networks. As is the case with the enclosed letter, it often times seems that this decision is made for purely arbitrary reasons -- not on some justifiable economic basis. While some of us believe this treatment is due in part to an inherent professional bias on the part of these largely MD-dominated plans, there also seems to be a lack of understanding of modern optometry's capabilities in the managed care community. This has resulted in the widespread use of biased credentialing requirements that disproportionately impact optometry.

For instance, in some cases plans require every professional provider in their panel to have admitting privileges at a hospital, even though this is clinically unnecessary for the provision of primary eye care services. In other cases, plans have required all applicants for their provider panels to have DEA registration numbers, even though optometrists who are trained and authorized to prescribe and administer a variety of medicines in their eye health practices rarely need or are authorized to prescribe controlled substances. In Kansas this situation got so bad we had to go to the state legislature and get a law passed to ensure that DEA numbers could not be misused in this unintended fashion.

While many of us understand and have accepted the fact that managed care is here to stay, these kinds of biased credentialing requirements make it impossible in many instances for us to even compete for managed care contracts. As the enclosed letter demonstrates, when panel decisions are made on these grounds, we rarely get a chance to discuss our comparative clinical and economic attributes with plan managers.

Given this frustrating history with managed care, you can see why optometry is concerned about the pending Medicare reform legislation. The Republican plans to slow down cost growth in the system rely heavily on an expanded use of managed care. After fighting for twenty years to get the right to see Medicare patients, and spending more than twenty years expanding our scope of practice and education to be able to effectively serve seniors many primary eye health needs, optometry doesn't want to lose access to these patients overnight.

What we need is some assurances that optometrists will be given a legitimate chance to compete for spots on Medichoice plans' provider panels. Ideally, we would like to see a requirement that plans include at least some optometrists to provide primary eye care services for their enrollees. This would not only ensure that seniors electing managed care options maintained access to optometry, but it would help preserve the gains our profession made when we became defined as physicians under the program in 1987.

Provisions that would prohibit MediChoice plans from excluding optometrists based simply on their license or degree, or any of the other arbitrary factors discussed earlier, are also essential. Our ability to provide high quality, cost-effective care should be the only issue. As long as plans refuse to consider our applications simply because we are not MDs, this will not be the case. If nothing else, plans should at least be required to justify their panel selection criteria to an independent third party. This alone would help prompt plans to reconsider their current contracting policies, and give us a better opportunity to be heard when we approach plans and try to educate them as to our potential value as cost-effective, primary eye care providers.

Unfortunately, as things stand now, the only certainty for optometry in the current Medicare reform bill is that the opportunities we've traditionally had through Medicare's fee-for-service program will be reduced. On the other hand, the bill promises managed care an unprecedented opportunity to expand its reach into the $160 billion Medicare market. Since managed care plans only serve about 8% of the program's beneficiaries now, you can see why we are so concerned about securing at least some assurances that we will be given a fair and legitimate opportunity to compete for Medicare managed care contracts in the future.

I understand the American Optometric Association has already been in contact with you and many others in the Congress about this issue. They have apparently offered some suggestions about how to resolve this problem. I am sure there are other potential solutions as well. In any case, as an old friend and supporter, I would ask that you personally consider this matter. As you know, many optometrists have worked hard to support Republican candidates across the country. Most do more than just write a check. Often times we are the ones that host the fundraisers and volunteer our time and energies at the grassroots level. Overall, I believe optometrists support and more closely identify with the Republican party's agenda. And I would think most will continue to do so regardless of the outcome of this one issue. However, I know many have read about the concessions that were given to the AMA, and believe that the proposed transformation of Medicare will make a very wealthy and influential insurance community all the more so. All optometry seeks is some equal consideration.

I realize you are extremely busy. But please, on behalf of my profession, I ask you to use your position to help remedy this situation. Thank you very much for taking the time to consider my concerns.

Most sincerely,

1597S

Preferred Plan of Georgia

A TakeCare Preferred Network

January 5, 1995

Bill Morrison, O.D.
1201 Sherwood Park Drive, NE
Gainesville, Ga 30501

Dear Dr. Morrison:

Thank you for your interest in Preferred Plan of Georgia. Our organization is always looking for quality providers. However, PPOG does not accept applications from optometrist. We only contract with ophthalmologist for eye conditions for our members.

If I can be of any further assistance please feel free to give me a call at (800) 662-5665, ext. 230.

Sincerely,

Dana Y. Galbreath

Dana Y. Galbreath
Provider Relations Representative

American Optometric Association
1505 Prince Street • Alexandria, VA 22314 • (703) 739-9200
FAX: (703) 739-9497

MEMORANDUM

TO: Rep. Bob Franks

FROM: Chris Carey

DATE: October 20, 1995

RE: Medicare reform bill

Thank you for your willingness to sit down and listen to optometry's concerns about the current Medicare package. Per your request, I've attached the language we discussed on Tuesday. I'll try to briefly explain our reasons for requesting these changes, and what we believe would be the practical effects on MedicarePlus plans if these changes were adopted.

First, the second part of our proposed amendment would simply say a plan could not deny a provider the right to participate in the plan's panel simply because of their license or certification under state law. Currently, although our members are legally authorized to provide primary eye care services under state medical practice acts, many plans simply refuse to even consider an O.D.'s application for participation in their panel. From the rejection letters and reasoning given to interested optometrists in many regions, it seems this decision is made on a purely aribitrary basis. In fact, reports from our members indicate that inquiries rarely even proceed to a discussion of fees. While this language by itself would not prevent a plan from excluding or limiting their provider panels on other legitimate business or clinical grounds, we believe it would force plans to reevaluate their credentialling policies, and prevent any competing health profession who influences a plan's contracting decisions from using the rubric of managed care to unlawfully boycott optometrists.

The first paragraph of the proposed amendment would give some teeth to the anti-discrimination language discussed above. As we discussed, it is not an any-willing-provider proposal. However, it would require a plan to include a diverse mix of providers in their panels. Presumably, this would require a plan to include at least some optometrists (but not all who apply). While we understand and acknowledge your concerns about this being perceived as a mandate, we think it is not only necessary to give optometrists a real opportunity to compete for managed care contracts, but also warranted in light of the new anti-trust protections the bill proposes giving to those responsible for assembling the provider panels for the new MedicarePlus plans.

As we discussed, if a plan's medical director or another group of influential providers in the plan's panel would seek to exclude optometrists, clearly for anti-competitive reasons, the application of a "rule of reason" standard for any suit challenging this conduct would put our members at a considerable disadvantage. In protracted litigation, we believe the comparatively deeper pockets of our chief competitors, MD-degreed opthalmologists, would make the use of litigation in this area implausible. As Dr. Wolbransky mentioned, competing MD's and OD's are already working collaboratively in Medicare today. The requirement that plans include a diverse mix of providers would help ensure that these kinds of competitive and open practice patterns continue to develop in the future.

Finally, let me again thank you for your willingness to listen to our concerns. As a profession that tends to identify more closely with the Republican party, optometry has largely supported the Republican party's overall efforts to reform Medicare. And many of members will undoubtedly remain active supporters of Republican legislators in Washington, and back home in the states. However, as things stand now, the only certainty for optometry in the current Medicare reform bill is that the reimbursements they've traditionally received through the fee-for-service program will be reduced. Since managed care plans only serve about 8% of the program's beneficiaires now, you can see why optometry is concerned about securing at least some assurances that they will be given a fair and legitimate opportunity to compete for managed care contracts in Medicare's future.

I've enclosed a copy of our letter to Speaker Gingrich regarding these issues for your review. I hope this is helpful in further explaining our concerns. I look forward to working with your office on this matter in the days ahead. Again, thank you for listening.

AMENDMENT TO H.R. 2485/MEDICARE FLOOR MARK

Page 20, strike line 34, and insert the following therein --

"(A) the organization establishes and maintains adequate arrangements with a sufficient number, mix, and distribution of health professionals and providers to assure that such benefits are made available"

Page 20, line 54, strike "." and insert therein, ";, and", and following subsection (D), insert the following new subsection --

"(E) the organization does not deny any health care professional, based solely on the professional's license or certification as applicable under State law, the ability to participate in providing benefits under the product, or be reimbursed or indemnified for providing such benefits."

15775

"PATIENT PROTECTION STANDARDS

"SEC. 1853. (a) DISCLOSURE TO ENROLLEES.—A MedicarePlus organization shall disclose in clear, accurate, and standardized form, information regarding all of the following for each MedicarePlus product it offers:

"(1) Benefits under the MedicarePlus product offered, including exclusions from coverage and, if it is a high deductible/medisave product, a comparison of benefits under such a product with benefits under other MedicarePlus products.

"(2) Rules regarding prior authorization or other review requirements that could result in nonpayment.

"(3) Potential liability for cost-sharing for out-of-network services.

"(4) The number, mix, and distribution of participating providers.

"(5) The financial obligations of the enrollee, including premiums, deductibles, co-payments, and maximum limits on out-of-pocket losses for items and services (both in and out of network).

"(6) Statistics on enrollee satisfaction with the product and organization, including rates of reenrollment.

"(7) Enrollee rights and responsibilities, including the grievance process provided under subsection (f).

"(8) A statement that the use of the 911 emergency telephone number is appropriate in emergency situations and an explanation of what constitutes an emergency situation.

"(9) A description of the organization's quality assurance program under subsection (d).

Such information shall be disclosed to each enrollee under this part at the time of enrollment and at least annually thereafter.

"(b) ACCESS TO SERVICES.—

"(1) IN GENERAL.—A MedicarePlus organization offering a MedicarePlus product may restrict the providers from whom the benefits under the product are provided so long as—

"~~(A) the organization makes such benefits available~~ and accessible to each individual electing the product within the product service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

"(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

"(C) the product provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

"(i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition, and

"(ii) it was not reasonable given the circumstances to obtain the services through the organization; and

"(D) coverage is provided for emergency services (as defined in paragraph (4)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization[(; and)]

"(2) MINIMUM PAYMENT LEVELS WHERE PROVIDING POINT-OF-SERVICE COVERAGE.—If a MedicarePlus product provides benefits for items and services (not described in paragraph (1)(C)) through a network of providers and also permits payment to be made under the product for such items and services not provided through such a network, the payment level under the product with respect to such items and services furnished outside the network shall be at least 70 percent (or, if the effective cost-sharing rate is 50 percent, at least 40 percent) of the lesser of—

← insert capacity language here; paragraph

→ insert non-discrimination language here; paragraph

SAME LETTER SENT TO HOUSE AND SENATE LEADERSHIP (List Attached) BC: FRC

American Optometric Association
1505 Prince Street • Alexandria, VA 22314 • (703) 739-9200
FAX: (703) 739-9497

October 12, 1995

The Honorable Newt Gingrich
Speaker
U.S. House of Representatives
Room H-230, U.S. Capitol
Washington, D. C. 20515

Dear Speaker Gingrich:

The American Optometric Association commends you for taking a leading role in the ongoing efforts in Congress to reform and restore the short-term solvency of the federal Medicare program. As Medicare providers, we appreciate and share your commitment to slowing the rate of increase in the program's annual costs, so that we can protect and preserve the system for future generations.

More importantly, as a profession that continues to provide the bulk of the nation's primary eye care through a variety of private payment arrangements, we welcome Republican proposals to open up Medicare and provide Medicare enrollees with the same kinds of coverage options privately insured Americans now enjoy. We share your belief that the introduction of competition between providers and between competing health plans will enable Medicare to serve our nation's seniors in a more responsive and more cost-effective manner.

Nonetheless, we are writing you today to express our deep concerns about several features of the reform bills now being considered in Congress. We believe these bills, as currently written, will only serve to stifle competition and unnecessarily harm the interests of our patients and our profession. We urge you to consider our concerns and appropriately remedy the following inadequacies with the Medicare reform packages that were just recently reported out of committee.

1) Provider Non-Discrimination.

While both the House and the Senate bills envision the migration of millions of seniors to new managed care plans, neither bill provides sufficient safeguards to protect against inter-professional discrimination or collusive credentialling practices by plan administrators. The omission of significant due process standards to protect providers once they join a plan, and the failure to require plans to include an objectively determined number, mix, and distribution of appropriately licensed health professionals in their provider panels, invites abuse and threatens the patient's ability to select and maintain relationships with providers of their liking.

As they have done in recent years, Medicare managed care plans would be free to contract widely with a diverse and well distributed collection of providers initially, to gain market share, then pare back their panels later in an effort to reduce administrative costs and deter the enrollee's ready access to and utilization of services. While optometry has proven its ability to provide cost effective eye care and market our services directly to fee-for-service and self-paying, non-insured patients, under the current proposals there is no mechanism to ensure that we could negotiate in good faith for contracts with MedicarePlus organizations.

The combination of enrollment incentives, toothless due process and access requirements, and limitations on disenrollment, suggests that plans could easily lure many of our current senior patients into their networks, then arbitrarily restrict them from continuing to see us down the road. Although we know that we could continue to provide high-quality care as participating members of these plans' provider panels, our experience with managed care to date has convinced us that our clinical abilities and cost-effectiveness alone are often not enough to secure a spot on a plan's panel.

In fact, even though we are as accustomed to practicing primary eye care, and more numerous and more widely distributed than our chief competitors, MD-degreed ophthalmologists, we are often precluded from even applying for participation in many plans. Very simply, as it stands today, despite our authority under state law to practice primary eye care, many managed care companies refuse to even talk to optometrists when forming their provider panels. These discriminatory policies are not a result of economics or the so-called market at work, as fees are never even discussed or compared. The only plausible explanation for this reality seems to be professional bias on the part of the plan. Not coincidently we feel, the medical directors who control clinical policy decisions and many of the board members of these organizations are medical doctors.

To prevent Medicare reform from becoming a vehicle for the codification of these kinds of anti-competitive practices, and to ensure that Medicare patients aren't unnecessarily forced to change providers, we ask that you place some specific provider non-discrimination and panel capacity requirements on MedicarePlus plans. While we understand that the concept of managed care necessarily requires plans to restrict the number of providers they utilize, plans should not be allowed to arbitrarily prohibit an entire class of licensed health care professionals from participating in their networks. Without the inclusion of prospective due process protections that would require plans to justify their contracting decisions to an independent arbitrator, the proposals' current provisions pertaining to "access standards" for MedicarePlus plans are inadequate to prevent the continuation of this inter-professional discrimination. In fact, by clearly stating that a plan could restrict the providers in its panel, without spelling out any limitations or conditions on the exercise of this privilege, the legislation your party has proposed would only serve to sanction these discriminatory practices throughout the Medicare market.

In order to retain the good will and continued support for Medicare reforms in the optometric community, we respectfully request that you insert some meaningful non-discrimination protections in the bill before proceeding to floor votes. Many of our member optometrists have already contacted you and your colleagues to explain the importance of these provisions to them personally. We would be happy to bring in additional doctors of optometry to describe the obstacles they currently face in this regard if you so desired.

2) Anti-trust Exemptions for Provider Service Organizations.

Finally, in light of the preceding discussion on the need for non-discrimination provisions, we ask that you reconsider your proposal to provide "provider service organizations" special treatment under the anti-trust laws. As other consumer and competing insurance groups have already pointed out, the recent proliferation of physician sponsored health plans in the market and the dearth of anti-trust enforcement actions taken against such plans to date makes the need for these exemptions specious at best.

What is clear, however, is the fact that these proposed changes would greatly strengthen organized medicine's already significant advantages over other licensed health professionals. If enacted, these provisions would insulate PSN's from effective anti-trust scrutiny, as any public or private complaint about a PSN's pricing or contracting practices (with regard to a MedicarePlus product) would be destined to result in extended litigation under a rule of reason analysis. Given the comparatively deeper pockets of MDs, other health professionals, such as optometrists, would essentially lose the one tool they now have at their disposal to enforce the rules of fair competition. The most disturbing language concerns the protection, from per se review, of conduct taken by a plan or by its individual member providers in the establishment of the plan's panel. This amounts to an open invitation for MD-dominated PSNs to boycott other competing health professionals. And given the current omission of prospective non-discrimination contracting standards, and our profession's collective experience with managed care products now on the market, we believe many plans will seize this opportunity to protect their own.

Fortunately, the Leadership still has time to correct these flaws before the Medicare package is brought to the floor for a vote. We too want to make this bill "better and better" as it moves through the legislative process. We hope that you will work with us to do just that with regard to these two very critical issues for optometry. We look forward to hearing from you soon.

Sincerely,

Jeffrey G. Mays
Washington Office Director

JM:cc
1575S/1579S

News from: AMERICAN COLLEGE OF RADIOLOGY acr

Contact: Michael J. Bernstein (703) 648-8910
Keri J. Sperry (703) 648-8912

For Release:
October 30, 1995

Radiology Association Says Weakening Self-Referral Law Hurts Patients, Wastes Money

The American College of Radiology (ACR) opposes the provisions passed in the House of Representatives Medicare reform bill that remove the limits on physician self referral because patients deserve better.

The ACR is a major national medical specialty association composed of about 30,000 radiologists, radiation oncologists and radiological physicists.

The ACR has long held that physician self-referral arrangements lead to inappropriate utilization of medical services and that the justification for development of these abusive and unethical arrangements is largely contrived.

Studies from prestigious scientific publications, such as the *New England Journal of Medicine* and the *Journal of the American Medical Association*, have repeatedly found that where referring physician arrangements exist, the normal economic forces of competition do not apply. The ACR believes these investigations clearly show that this type of market control has led to increased utilization and higher prices.

In addition to the ethical concerns, the Congressional Budget Office (CBO) estimates that these proposed changes will cost taxpayers $400 million over seven years. Combined with another provision that weakens the government's ability to prosecute fraud and kickback scams, CBO has estimated that the overall cost will be $1.1 billion.

Many groups oppose these self-referral practices, including the American Medical Association. The AMA's current ethical policy states that "in general, physicians should not refer patients to a health care facility which is outside their office practice and at which they do not directly provide care or service when they have an investment interest in that facility." Unfortunately, despite its ethical policy, the AMA has supported the legislation to weaken self-referral laws.

The ACR strongly believes that exploitive and unethical practices should not be condoned under the guise of competition or deregulation. Easing limits on self referral will waste tax dollars and ultimately hamper rather than encourage competition.

Patients deserve better. Provisions to weaken self referral laws must be opposed.

Rationale for Amending "NEW EXCEPTION FOR SHARED FACILITY SERVICES"

While stripping the shared facility services exception found in the House bill is preferred for the conference report, the following changes to this section would be a must inclusion to prevent huge — "747 variety" — loopholes that would allow abusive arrangements to proliferate. Physicians and business entrepreneurs will undoubtedly attempt to use any such exception to permit joint ventures that have been properly excluded to date the current self-referral laws. These changes to the House proposal should help to curtail those who will attempt to abuse any shared facility exception.

The most telling omission in the House's current legislation is the fact that a shared facility is permitted even when the medical building contains other facilities providing the same services. The language noted under the general section for "shared facility services" would eliminate this loophole.

In addition, the definition of "shared facility" needs to incorporate language specifying that a "shared facility" should be a separate legal entity, in which revenues are shared in a manner that does not take into account the volume or value of referrals made by the shared facility physicians.

Finally, it is extremely important that any shared facility exception to the physician self-referral laws not supersede the current kickback statute. Consequently, incorporated by reference are the requirements for space and equipment rental and lease revisions in the kickback act and for the "sale of practice" provision of the "safe harbor" regulations for the kickback act as promulgated by HHS.

AMENDMENT OFFERED BY

FOR H.R. 2425

Beginning on Page 224, line 18, and ending on page 227, line 10, to amend as follows:

(d) NEW EXCEPTION FOR SHARED FACILITY SERVICES.—

(1) IN GENERAL.—Section 1877(b) (42 U.S.C. 1395nn(b)), as amended by section 15201(b)(3)(C), is amended—

(A) by redesignating paragraphs (4) through (7) as paragraphs (5) through (8); and

(B) by inserting after paragraph (3) the following new paragraph:

"(4) SHARED FACILITY SERVICES.—In the case of a designated health service consisting of a shared facility service of a shared facility—

"(A) that is furnished—

"(i) personally by the referring physician who is a shared facility physician or personally by an individual directly employed ~~or under the general supervision of~~ by such a physician,

"(ii) by a shared facility in a building in which the referring physicians furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services, and where the building contains no other facility providing the same services, and

"(iii) to a only to patients of a shared facility physician; and

"(B) that is billed by the referring physician or a by the group practice of which the physician is a member.".

(2) DEFINITIONS.—Section 1877(h) (42 U.S.C. 1395nn(h)), as amended by section 15201(b)(6), is amended by inserting before paragraph (4) the following new paragraph:

"(1) SHARED FACILITY RELATED DEFINITIONS.—

"(A) SHARED FACILITY SERVICE.—The term 'shared facility service' means, with respect to a shared facility, a designated health service furnished by the facility to patients of shared facility physicians.

"(B) SHARED FACILITY.—The term 'shared facility' means an a separate legal entity, including but not limited to a corporation, partnership, professional corporation, faculty

practice plan, or similar entity that furnishes shared facility services under a shared facility arrangement.

"(C) SHARED FACILITY PHYSICIAN.—The term 'shared facility physician' means, with respect to a shared facility, a physician (or a group practice of which the physician is a member) who has a financial relationship under a shared facility arrangement with the facility.

"D) SHARED FACILITY ARRANGEMENT.—The term 'shared facility arrangement' means, with respect to the provision of shared facility services in a building, a financial arrangement—

"(i) which is only between physicians who are providing services (unrelated to shared facility services) in the same building,

"(ii) in which the overhead expenses of the facility are shared, in accordance with methods previously determined by the physicians in the arrangement, and where revenues are shared in a manner that does not take into account the volume or value of referrals made by the shared facility physicians, among the physicians in the arrangement,~~and~~

"(iii) which, in the case of a corporation, is wholly owned and controlled by shared facility physicians,

"(iv) which meets the space and equipment rental and lease provisions set forth in section 1877(b) (42 U.S.C. 1395nn(e)(1)(A) and (B)), and

"(v) which, when one or all of the shared facility physicians cease to maintain their medical practices or no longer are members of the group practice, is sold or transferred in accordance with the "sale of practice" regulations set forth at 42 CFR Part 1001.".

"(E) with a contract with a State to provide services under the State plan under title XIX (in accordance with section 1903(m)) or a State MediGrant plan under title XXI; or

"(F) which is a MedicarePlus organization under part C or which provides or arranges for the provision of health care items or services pursuant to a written agreement between the organization and an individual or entity if the written agreement places the individual or entity at substantial financial risk for the cost or utilization of the items or services which the individual or entity is obligated to provide, whether through a withhold, capitation, incentive pool, per diem payment, or any other similar risk arrangement which places the individual or entity at substantial financial risk.".

(d) NEW EXCEPTION FOR SHARED FACILITY SERVICES.—

(1) IN GENERAL.—Section 1877(b) (42 U.S.C. 1395nn(b)), as amended by section 15201(b)(3)(C), is amended—

(A) by redesignating paragraphs (4) through (7) as paragraphs (5) through (8); and

(B) by inserting after paragraph (3) the following new paragraph:

"(4) SHARED FACILITY SERVICES.—In the case of a designated health service consisting of a shared facility service of a shared facility—

"(A) that is furnished—

"(i) personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician,

"(ii) by a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services, and

"(iii) to a patient of a shared facility physician; and

"(B) that is billed by the referring physician or a group practice of which the physician is a member.".

(2) DEFINITIONS.—Section 1877(h) (42 U.S.C. 1395nn(h)), as amended by section 15201(b)(6), is amended by inserting before paragraph (4) the following new paragraph:

"(1) SHARED FACILITY RELATED DEFINITIONS.—

"(A) SHARED FACILITY SERVICE.—The term 'shared facility service' means, with respect to a shared facility, a designated health service furnished by the facility to patients of shared facility physicians.

"(B) SHARED FACILITY.—The term 'shared facility' means an entity that furnishes shared facility services under a shared facility arrangement.

"(C) SHARED FACILITY PHYSICIAN.—The term 'shared facility physician' means, with respect to a shared facility, a physician (or a group practice of which the physician is a member) who has a financial relationship under a shared facility arrangement with the facility.

"(D) SHARED FACILITY ARRANGEMENT.—The term 'shared facility arrangement' means, with respect to the provision of shared facility services in a building, a financial arrangement—

"(i) which is only between physicians who are providing services (unrelated to

shared facility services) in the same building,

"(ii) in which the overhead expenses of the facility are shared, in accordance with methods previously determined by the physicians in the arrangement, among the physicians in the arrangement, and

"(iii) which, in the case of a corporation, is wholly owned and controlled by shared facility physicians.".

(e) NEW EXCEPTION FOR SERVICES FURNISHED IN COMMUNITIES WITH NO ALTERNATIVE PROVIDERS.—Section 1877(b) (42 U.S.C. 1395nn(b)), as amended by section 15201(b)(3)(C) and subsection (d)(1), is amended—

(1) by redesignating paragraphs (5) through (8) as paragraphs (6) through (9); and

(2) by inserting after paragraph (4) the following new paragraph:

"(5) NO ALTERNATIVE PROVIDERS IN AREA.—In the case of a designated health service furnished in any area with respect to which the Secretary determines that individuals residing in the area do not have reasonable access to such a designated health service for which subsection (a)(1) does not apply.".

AMENDMENT OFFERED BY

FOR H.R. 2425

Page 220, Strike line 1 through page 220, line 4, and insert the following:

"(C) Outpatient physical or occupational therapy services.

"(D) Radiology and other diagnostic services.

"(E) Radiation therapy services.".

Page 220, Strike line 11 and all that follows through Page 220, line 20.

(C) in paragraph (2), by striking "or who have such a compensation relationship with the entity".

(6) In subsection (h)—

(A) by striking paragraphs (1), (2), and (3);

(B) in paragraph (4)(A), by striking clauses (iv) and (vi);

(C) in paragraph (4)(B), by striking "RULES.—" and all that follows through "(ii) FACULTY" and inserting "RULES FOR FACULTY"; and

(D) by adding at the end of paragraph (4) the following new subparagraph:

"(C) MEMBER OF A GROUP.—A physician is a 'member' of a group if the physician is an owner or a bona fide employee, or both, of the group.".

SEC. 15202. REVISION OF DESIGNATED HEALTH SERVICES SUBJECT TO PROHIBITION.

(a) IN GENERAL.—Section 1877(h)(6) (42 U.S.C. 1395nn(h)(6)) is amended by striking subparagraphs (B) through (K) and inserting the following:

"(B) Parenteral and enteral nutrients, equipment, and supplies.

"(C) Magnetic resonance imaging and computerized tomography services.

"(D) Outpatient physical or occupational therapy services.".

(b) CONFORMING AMENDMENTS.—

(1) Section 1877(b)(2) (42 U.S.C. 1395nn(b)(2)) is amended in the matter preceding subparagraph (A) by striking "services" and all that follows through "supplies)—" and inserting "services—".

(2) Section 1877(h)(5)(C) (42 U.S.C. 1395nn(h)(5)(C)) is amended—

(A) by striking ", a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy," and inserting "and a request by a radiologist for magnetic resonance imaging or for computerized tomography", and

(B) by striking "radiologist, or radiation oncologist" and inserting "or radiologist".

SEC. 15203. DELAY IN IMPLEMENTATION UNTIL PROMULGATION OF REGULATIONS.

(a) IN GENERAL.—Section 13562(b) of OBRA–1993 (42 U.S.C. 1395nn note) is amended—

OFFICE OF LEGISLATIVE & INTER-GOVERNMENTAL AFFAIRS FAX COVER SHEET

# of Pages: Cover + 26 **DATE:** 10/20/95

TO:
Chris Jennings

Fax: (202) 456-7431

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FROM:
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Peter Hickman
HCFA/OLIGA

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REMARKS:
Attached material on CLIA:

1. Example Deficiencies and Implications for Patients (7 pages)
2. HHS briefing package on CLIA (fact sheets + charts) (13 pages)
3. Myths & Facts about CLIA (distributed by Rep. Dingell's office) (6 pages)

HEALTH CARE FINANCING ADMINISTRATION
Washington, D.C.

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)
AND PHYSICIAN OFFICE LABS (POLs)

EXAMPLE DEFICIENCIES AND IMPLICATIONS FOR PATIENTS

The following examples are taken from reports by CLIA surveyors, describing actual deficiencies found in POLs. These examples represent common problems in POLs, discovered through CLIA surveys and proficiency testing. Many of these problems would have gone undetected without CLIA and would likely reappear if CLIA is repealed. Congress is currently considering legislation that would exempt POLs from all CLIA requirements (except for Pap smears).

IMPROPER STORAGE OF TEST SPECIMENS AND MATERIALS

Example 1:

Specimens collected for gonorrhea cultures were stored in a refrigerator or freezer for up to 30 days. However, gonorrhea bacteria are very sensitive to cold and will die if kept below body temperature. If handled properly, the specimens would have been placed in a special medium so that the test process would begin immediately. No positive test results for gonorrhea were reported by this laboratory.

Implication for patients: Possible complications from undetected and untreated gonorrhea include sterility, pelvic inflammatory disease, urethritis, amniotic infection syndrome, and premature births. Untreated infections may also lead to further spreading of the disease.

Example 2:

All chemistry specimens for an enzyme test were frozen for up to two weeks. The laboratory ignored the test instructions, which warned that freezing specimens would cause falsely low test values.

Implication for patients: Physicians use enzyme tests to screen for heart disease, liver disease, and muscular and bone disorders. A falsely low value for a cardiac (heart) enzyme can result in failure to detect a heart attack. A false liver enzyme level may conceal hepatitis, cirrhosis, congestive heart failure, pancreatitis, or infectious mononucleosis. In each case, inaccurate testing may result in failure to provide appropriate treatment for these serious conditions.

Example 3:

A lab refrigerated specimens for rapid strep testing for four days before the test was performed. However, the instructions for the test used by this laboratory warned that specimens should be refrigerated for no more than three days before testing.

Implication for patients: Rapid strep tests are used to confirm suspected streptococcus A infections ("strep throat"). Failure to perform the test promptly defeats the purpose of the "rapid" test, which allows treatment with antibiotics to begin immediately. Using specimens that are too old to be properly tested may also cause inaccurate results. Failure to detect and treat a contagious strep infection (due to a "false negative" result) may allow the infection to spread, and can lead to rheumatic heart disease. Inappropriate use of antibiotics (due to a "false positive" result) can also affect patients' health, and may facilitate the growth of drug-resistant bacteria, which present a serious public health problem.

Example 4:

The instructions for a hemoglobin A1C test specified that specimens are stable for up to seven days, if refrigerated. However, when interviewed, a lab's staff stated that specimens are stable for 8-10 days. Testing in this laboratory was completed within 10-12 days.

Implication for patients: Hemoglobin A1C tests are commonly used to monitor diabetic patients, providing physicians a measure of the patient's blood glucose (sugar) level over a period of time. This information is used to help determine the patient's insulin dosage. If specimens are not tested within the test manufacturer's recommended time, the results may be falsely low, affecting the patient's treatment. Inappropriate treatment for diabetes (e.g. too much or too little insulin) can lead to coma or death.

Example 5:

A laboratory left a urine culture specimen in an incubator for 11 days, rendering it unacceptable for testing. Such samples are generally incubated for 24-48 hours before testing. There was no evidence that the laboratory was aware of the error, which would invalidate any test results. In fact, no test results were reported for this patient, of which the lab was also unaware.

Implication for patients: Undetected and untreated urinary infections can cause uremic poisoning, kidney damage, and renal failure.

Example 6:

A gynecologist who had been in practice for over 30 years used the office radiator to incubate fungal cultures. Most fungal cultures should be incubated at room temperature or 30 degrees centigrade with 40-50% humidity. Radiators have fluctuating temperatures and excessive heat may kill the fungus by drying out the culture media.

Implication for patients: Failure to accurately diagnose and treat fungal infections may cause unnecessary discomfort and, in patients with diabetes or impaired immune systems, can lead to more serious infections.

Example 7:

An obstetrician/gynecologist performed glucose tolerance tests on pregnant women using equipment that had no records of calibration, maintenance, or quality control procedures. An inspection of the lab found quality control materials that were frozen and outdated.

Implication for patients: Inaccurate glucose test results in pregnant women can lead to misdiagnosed gestational diabetes, which may endanger the life of the mother and the baby.

Example 8:

A laboratory stored "dexacola" (a sugar drink used in glucose tolerance testing for diabetes) in the same refrigerator as potentially infectious biological specimens.

Implication for patients: Patients were unintentionally exposed to infectious agents.

INADEQUATE LABELING AND TRACKING OF TEST SPECIMENS AND RESULTS

Example 1:

Lab staff labeled a patient specimen with the name "Brown" and ordered a test for this patient. However, during a survey of the lab, they said the patient's name was actually "Brownville". When this name could not be found in the lab's computer records, staff concluded that it must be "Browntown", since a patient by that name had been seen in the office that week. (While this incident is real, the names are fictitious.)

Implication for patients: Identification of patient specimens was based on a process of elimination. This procedure -- or lack thereof -- offered no guarantee that the test results reported for a patient actually belonged to that patient, or that treatment was based on the proper test results.

Example 2:

"Post-it" notes (which fall off easily) were used to label patient specimens while awaiting testing. No other identification appeared on the specimens.

Implication for patients: There was no certainty that patient specimens were identified correctly.

FAILURE TO FOLLOW MANUFACTURER'S INSTRUCTIONS IN PERFORMING TESTS

Example 1:

A laboratory performing strep testing never had a positive strep result. The test kit included three bottles of chemical reagents, with instructions to add them in the order of bottles 1, 2, and 3. However, the laboratory's staff was adding them in the order of bottles 1, 3, and 2. They had inadvertently switched the bottles and did not take the time to read the bottle labels as they performed the test. Quality control checks were never performed and all test results were negative.

Implication for patients: Rapid strep tests are used to confirm suspected streptococcus A infections ("strep throat"). Failure to detect and treat a strep infection, based on a "false negative" result, may allow the infection to spread, which can lead to rheumatic heart disease and death.

Example 2:

A physician's wife conducted lab tests in her husband's office laboratory. She used her own blood as the quality control material for cholesterol tests, since her cholesterol level was routinely checked by her doctor. However, cholesterol levels fluctuate as much as 40% over time, based on overall health, physical condition, and activities (e.g. exercise, diet, alcohol consumption, infections, time of day or year, pregnancy, medication, etc.). Thus, an individual's cholesterol level cannot be relied on as control material.

Implication for patients: Failure to accurately diagnose and treat high cholesterol can lead to arteriosclerosis (hardened arteries), strokes, coronary heart disease and heart attacks.

USE OF MALFUNCTIONING TEST EQUIPMENT AND MATERIALS

Example 1:

Function checks that signal whether an instrument is operating properly showed that a testing instrument was not in good condition. Hematology controls (samples of known value tested before patient specimens to ensure the test is capable of producing accurate results) were run up to 26 times before obtaining an acceptable reading. However, the laboratory ignored these quality control alarms and ran tests on patient specimens, some of which produced abnormal results.

Implication for patients: Hematology tests are routinely used to diagnose anemia, bleeding disorders, infections, dehydration, or inflammation, and to monitor cancer patients on chemotherapy. There was no way of knowing whether the results produced by this lab were accurate.

Example 2:

A laboratory continued to test patient specimens even though its chemistry analyzer needed repair and its water source was contaminated. The lab also used quality control materials and chemical reagents beyond their expiration dates. In addition, the lab's system for identifying specimens failed to clearly link them with the correct patient.

Implication for patients: All patients tested during this period should have been retested. However, because of the lab's faulty tracking system, patients could not be identified and no retesting was done. Patients received questionable test results and were not informed of this fact.

Example 3:

A laboratory performed testing on an instrument that was not calibrated because they had lost the equipment's calibrator strip. The staff also ignored built-in alarms indicating instrument failure, and did no quality control tests to check the instrument's condition. Based on results obtained from this instrument, four patients were diagnosed and treated for iron deficiency anemia.

Implication for patients: There was no way to determine whether the test results were accurate. Unnecessary treatment for iron deficiency anemia (iron supplements, blood transfusions, etc.) can be harmful to patients, as well as adding financial costs.

FAILURE TO DETECT CLEARLY INACCURATE TEST RESULTS

Example 1:

A laboratory failed to detect test results that were much lower than the normal expected range for a chemistry test that measures potassium levels. The error was not investigated and incorrect results were reported to the patients. The fact that the lab was performing the test incorrectly was not discovered until it failed proficiency testing (required by CLIA).

Implication for patients: Potassium tests are commonly used to monitor treatment for hypertension (high blood pressure), which without medication can lead to coma, stroke, or death. Inaccurate lab testing that shows falsely high or low potassium levels can result in failure to provide appropriate treatment and increased health care costs.

Example 2:

Patients treated with coumadin (a blood thinner) for heart disease are regularly monitored for the ability of their blood to clot (using "protime" and "partial prothrombin time" laboratory tests). At one HMO satellite office, all test results

were typical of patients not on coumadin (i.e. shorter clotting times), including for those who actually were taking the drug. When these patients were retested by the HMO's other satellite office, the results were higher (i.e. longer clotting times), as expected for patients on coumadin therapy.

Implication for patients: Test results cannot be accurately interpreted without regard to the patient's history (e.g. age, gender, medication usage, etc). This lab failed to discover that its tests were producing inaccurate results because it did not consider whether the results were appropriate for the particular patients involved. As a result, inappropriate treatment may have been prescribed.

Example 3:

A laboratory doing lipid profile testing (cholesterol and triglyceride tests) reported results so excessively unusual that they were clearly meaningless. Some percentage results were recorded as greater than 100%, and some cholesterol results were as high as 31,000 mg/dl (normal ranges are typically between 140 and 220 mg/dl). The lab also reported potassium levels (critical for patients with high blood pressure) and platelet counts (essential in blood clotting) that were obviously inconsistent with life.

Implication for patients: Test results were reported without regard to their quality, making accurate diagnosis and treatment of patients impossible.

Example 4:

A laboratory failed to accurately interpret "sensitivity tests" that show which antibiotics will be effective in treating a bacterial disease. These tests involve measuring the distance between bacteria growth and a particular antibiotic so that physicians can choose the most appropriate drug. However, many laboratories merely look for an absence of bacteria growth around an antibiotic (rather than measuring the distance between them), and reporting the bacteria as "sensitive" to the drug. Without a standard measurement procedure, the result may be inaccurate or misleading.

Implication for patients: If bacteria are incorrectly reported as "sensitive", patients may be treated with an ineffective antibiotic that only serves to create a stronger, more deadly bug. When bacteria are falsely reported as "resistant" (the opposite of "sensitive"), patients may receive a stronger and more expensive drug than necessary, which may be harmful to both their health and their pocketbooks.

Example 5:

A laboratory performing syphilis tests reported negative results for 800 consecutive tests. They very seldom had a positive syphilis result. The surveyor inspecting the lab believed there were errors in the lab's testing procedure and questioned the lab's supervisor about the testing results. The supervisor stated

that people in her area were less promiscuous than people in the surveyor's home town (a large city), which explained the lack of positive results.

Implication for patients: Failure to accurately diagnose and treat syphilis can lead to dementia, blindness, and sterility. Failure to identify contagious syphilis carriers also has serious implications for public health.

RELIANCE ON SUBSTANDARD TESTING PERSONNEL

Example 1:

A laboratory director failed to recognize that testing personnel hired under contract were performing far below acceptable standards. For example, the staff failed to follow test manufacturers' instructions and often failed to do quality control checks to ensure accurate results. When control tests were performed and indicated equipment failures, patient specimens were tested anyway.

Implication for patients: None of the test results produced by this substandard laboratory could be relied on as valid. While the testing personnel were hired under contract to the lab, the laboratory director was responsible for ensuring that quality standards for the laboratory were met.

CLIA FACT SHEET

WHAT IS CLIA?

- The Clinical Laboratory Improvement Amendments of 1988 superseded the original Clinical Laboratory Improvement Act of 1967. CLIA '88 set uniform quality standards for all clinical labs and was passed with broad bipartisan support.

- CLIA applies to all labs that conduct tests on human specimens for health purposes -- for example, tests on tissue, blood, urine and other samples to detect cancer, HIV, diabetes, and other diseases.

CLIA PROVISIONS ARE BASED ON COMPLEXITY OF TESTS

- CLIA provisions are based on the complexity of tests, not the type of lab where the testing occurs. Thus, labs performing similar tests must meet similar standards, whether located in a hospital, doctor's office, or other site.

- CLIA established three categories of tests: waived tests, moderate complexity tests, and high complexity tests. Waived tests -- simple tests with small chance of error or risk -- are exempt from virtually all CLIA rules.

PROVISIONS FOR MODERATE AND HIGH COMPLEXITY TESTS

- Personnel and proficiency testing: CLIA sets minimum qualifications for all persons performing or supervising lab tests. Labs must also participate in an approved proficiency testing program.

- Quality control: Labs must have systems for monitoring testing processes and equipment to ensure proper operation and accurate results.

- Cytology testing: CLIA sets special rules for cytology testing including workload limits, specialized proficiency testing and personnel standards, and quality control procedures.

REGISTRATION, INSPECTIONS AND FEES

- CLIA was designed as a self-funded program.
  - All clinical labs must register with HHS and pay a nominal certificate fee.
  - Most labs performing moderate or high complexity tests are inspected every two years, with fees assessed to cover inspections and other program costs.

- Labs exempt from routine federal inspections include those performing only waived tests, labs in which specified practitioners do only certain microscopic tests, labs accredited by approved accrediting organizations, and labs in states that approve or license clinical labs under standards at least as stringent as CLIA.

PROFILE OF PHYSICIAN OFFICE LABS (POLs) AFFECTED BY THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)

MOST LABS REGISTERED UNDER CLIA ARE PHYSICIAN OFFICE LABS.

- Of the 152,000 clinical labs registered under CLIA in 1995, 89,000 (almost 59%) are POLs, most of which had no quality oversight prior to 1992.
- In contrast: 8.8% of all registered labs are in nursing facilities, 5.8% in hospitals, 4.8% in home health agencies, and 3.8% are independent labs. Smaller categories include labs in HMOs, schools, dialysis units, and other facilities.
- In 1993, POLs billed the Medicare program approximately $ 2.7 billion for diagnostic laboratory tests.

59% OF PHYSICIAN OFFICE LABS FACE MINIMAL REGULATION UNDER CLIA.

- Virtually all CLIA requirements are waived for 35% of POLs. These labs do only simple tests deemed by HHS to have very small chance of error or risk to patients.
- An additional 24% of POLs are exempt from routine inspections under CLIA. These labs conduct certain moderate complexity tests ("provider-performed microscopy") performed by physicians or other practitioners as part of a patient exam.

OTHER PHYSICIAN OFFICE LABS DO MORE COMPLEX TESTS, SOME AT HIGH VOLUME.

- The remaining 41% of POLs conduct moderate and/or high complexity tests, which, if done incorrectly, would place patients at significant risk.
- These POLs do a broad range of tests with most certified for more than one laboratory specialty.
- 17% of these POLs conduct more than 10,000 tests per year.
- Only moderate and high complexity POLs are subject to all of CLIA's quality standards, with stricter standards for high complexity tests.

SURVEYS & PROFICIENCY TESTING IMPROVE QUALITY IN LABS.

- Initial CLIA surveys identified more deficiencies in POLs than in other clinical labs. For example:
    - 35% of POLs failed to adequately assess whether tests were producing accurate results, compared to 23% of hospital labs and 13% of independent labs.

- 28% of POLs failed to follow test manufacturers' instructions, compared to 20% of hospital labs and 11% of independent labs.

- 9% of POLs failed to check whether materials used to culture and identify disease-causing bacteria worked, compared to 4% of hospital labs and 2% of independent labs.

- 8% of POLs failed to ensure reliable identification of patient specimens, compared to 4% of hospital labs and 3% of independent labs.

▸ A study published in the Journal of the American Medical Association in 1993 suggests the consequences for patients of improperly performed lab tests.

- The study showed that patients were significantly more likely to have a second heart attack or stroke following a prothrombin time (blood-clotting) test in a low-volume POL than patients tested by a higher-volume POL or a commercial lab.

- These results were believed to be at least partly related to inaccurate test results in the low-volume POLs, which led doctors to prescribe inappropriate dosages of anticoagulant drugs.

▸ Proficiency testing (PT) directly measures testing performance, as well as providing invaluable feedback to POLs. It is widely recognized as a key ingredient for maintaining quality testing in labs.

- In 1994, POLs were far more likely than hospital or independent labs to fail proficiency tests for hemoglobin, cholesterol, microbiology, prothrombin time, and potassium. For example, 8% of POLs had PT failures for hemoglobin, almost 10 times that of hospital and independent labs. Hemoglobin testing is performed by more than 30% of all POLs, and is the second most common POL laboratory test.

▸ By identifying and overseeing the correction of deficiencies, CLIA has already improved the quality of testing in POLs.

- In 2,186 POLs that had undergone a second CLIA survey by August 1995, serious deficiencies decreased 26% between their first and second inspections.

- Total deficiencies decreased 23%, with a 51% drop in the average number of deficiencies per lab.

▸ HHS' educational approach to surveys and PT promotes cooperation with providers while ensuring minimum quality standards for laboratory tests.

PHYSICIAN OFFICE LABS DO MANY DIFFERENT KINDS OF TESTS.

- Most common moderate and high complexity tests done by physician office labs:

  - Triglycerides (used to evaluate risk of heart attack or stroke)
  - Blood urea nitrogen (used to evaluate kidney disease)
  - Uric acid (detects gout and other disorders)
  - High density lipoprotein (HDL) cholesterol (used to evaluate risk of heart disease or stroke)
  - Group A Strep antigen (detects strep throat and other strep infections)

- Most common waived tests done by physician office labs:

  - Urine pregnancy tests
  - Dipstick urinalysis (detects urinary infections and other diseases)
  - Glucose (detects diabetes, helps evaluate other diseases)
  - Occult blood (detects colon cancer)
  - Hemoglobin (detects anemia and other blood disorders)
  - Cholesterol (detects coronary artery disease, risk of heart attack or stroke)
  - Hematocrit (detects anemia and other blood disorders)

STEPS TAKEN BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO REDUCE CLIA BURDEN ON PHYSICIAN OFFICE LABS

WAIVERS

- Virtually all CLIA requirements are waived for labs doing only simple tests deemed by HHS to have very small chance of error or risk to patients.

- Waiver labs are only required to:

  - o register with HHS and pay a nominal certificate fee;
  - o follow manufacturers' instructions for performing tests; and
  - o permit inspections for investigation of bona fide complaints.

- 35% of all physician office labs are currently waiver labs, and others may qualify as HHS clarifies the waiver application process and criteria for waived tests.

EXEMPTION FROM ROUTINE INSPECTION FOR OTHER PHYSICIAN OFFICE LABS

- In 1993, HHS regulations defined a sub-category of moderate complexity tests that are exempt from routine inspections under CLIA. These tests -- now called "provider-performed microscopy" (PPM) -- are commonly performed in physician office labs as part of a patient exam.

- A new rule published in April 1995 expands the sub-category to many more labs by allowing mid-level practitioners (in addition to physicians) to perform PPM tests. Three new tests were also added to the PPM list.

- 24% of physician office labs do only PPM tests (or PPM and waived tests), and others may qualify based on the new expanded rule.

FLEXIBLE OPTIONS FOR ACCREDITATION AND STATE PROGRAMS

In addition to the waiver and PPM exemptions, CLIA is flexible in providing options for how standards may be met.

- Over 8,000 physician office labs accredited by private organizations are deemed to meet all CLIA requirements. Organizations currently approved by HHS for this purpose include the Commission on Office Laboratory Accreditation (COLA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and four other accreditors.

- Labs located in states that approve or license labs under standards at least as stringent as CLIA are exempt from CLIA rules. Washington state is currently recognized for this purpose, exempting almost 1,300 physician office labs. (New York is also exempt but its physician office labs are not, because they are not inspected by the state program.) Applications from other states are under review.

GRANDFATHER PROVISIONS AND PHASE-INS FOR EXISTING PERSONNEL

- Regulations published in 1992 and April 1995 allow many lab employees who were already performing or supervising moderate or high complexity tests to continue to do so based on their training and experience.

- Personnel standards were phased in gradually to assure adequate time for lab staff to qualify. Most physicians already met all required qualifications.

OTHER BURDEN REDUCTIONS IMPLEMENTED BY HHS

- All routine inspections are scheduled ahead of time, rather than unannounced.

- Labs need not reapply for a new certificate each survey cycle. They need only confirm their status and note any changes they have made.

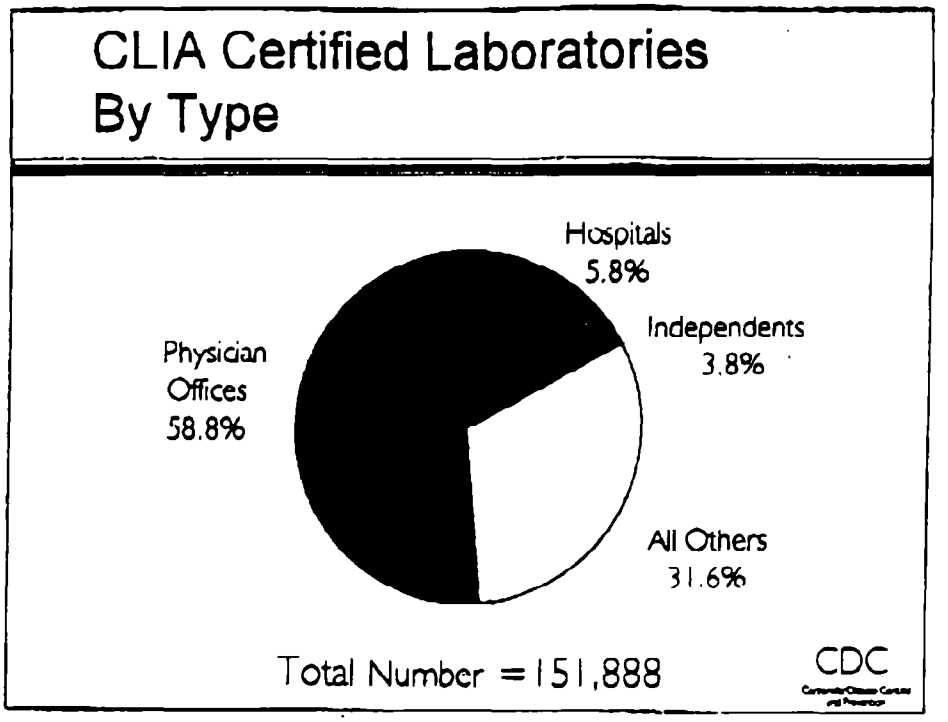
- HHS has developed an educational program for new physicians to qualify as lab directors.

- Implementation of quality control and proficiency testing requirements was phased in over time.

FURTHER PROVISIONS TO EASE CLIA BURDENS ON PHYSICIAN OFFICE LABS ARE UNDER DEVELOPMENT WITHIN HHS.

- HHS is revising its survey procedures so that labs with excellent compliance records and no proficiency testing failures will be inspected on-site every four years instead of every two years, as previously required.

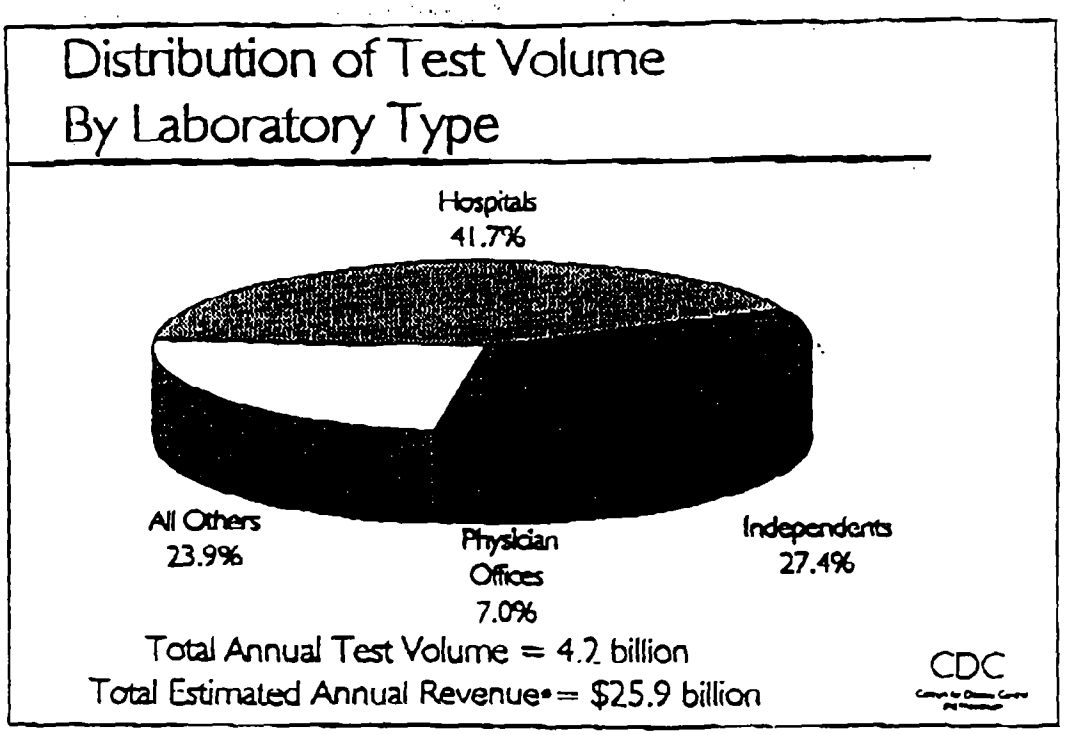
- HHS will be proposing a new sub-category for moderate complexity tests that use "accurate and precise technology" (APT) and come with detailed manufacturer instructions. These tests will be subject to only random inspections and less stringent rules than other moderate complexity tests.



Key Points

- the majority of clinical laboratories in the U.S. are physician office laboratories, a group that was largely unregulated prior to CLIA '88
- the group "All Others" includes a diverse group of testing sites including community clinics, nursing facilities, health fairs and mobile units
- the testing sites included in the "All Others" group were also largely unregulated prior to CLIA '88

Source: HCFA OSCAR System (as of 01/30/95)



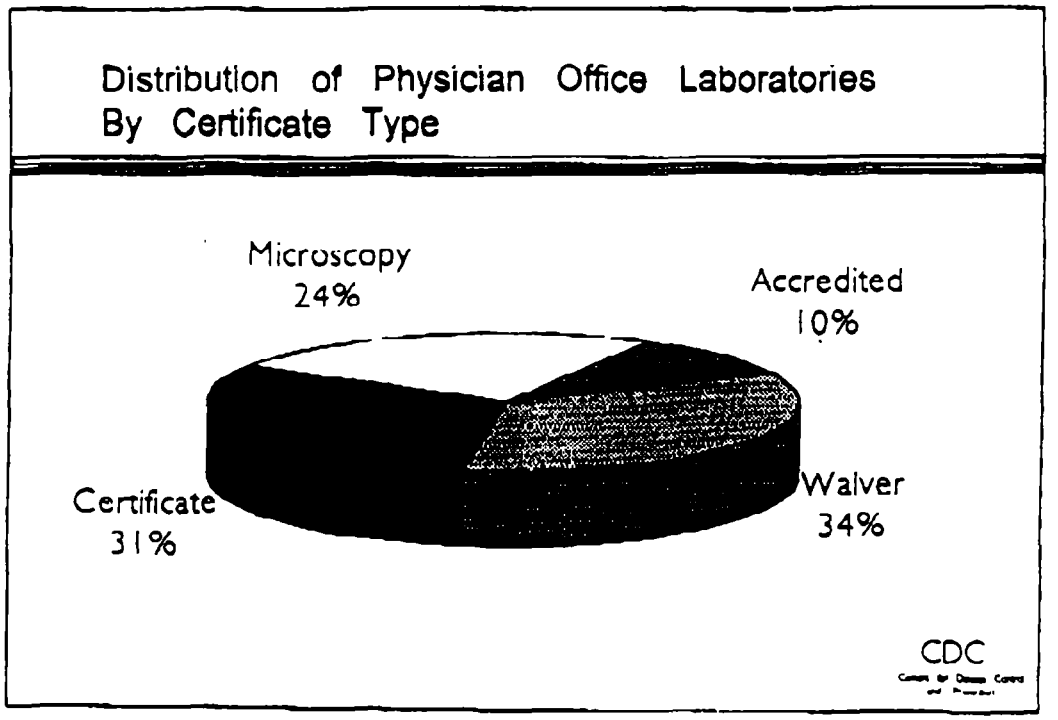
Key Points

- although physician office laboratories are not performing the majority of testing in the U.S., they still perform in excess of 294 million tests annually

Source: CLIA Baseline - a Random Sample of HCFA 109 Forms

Data analyzed independently by CDC.

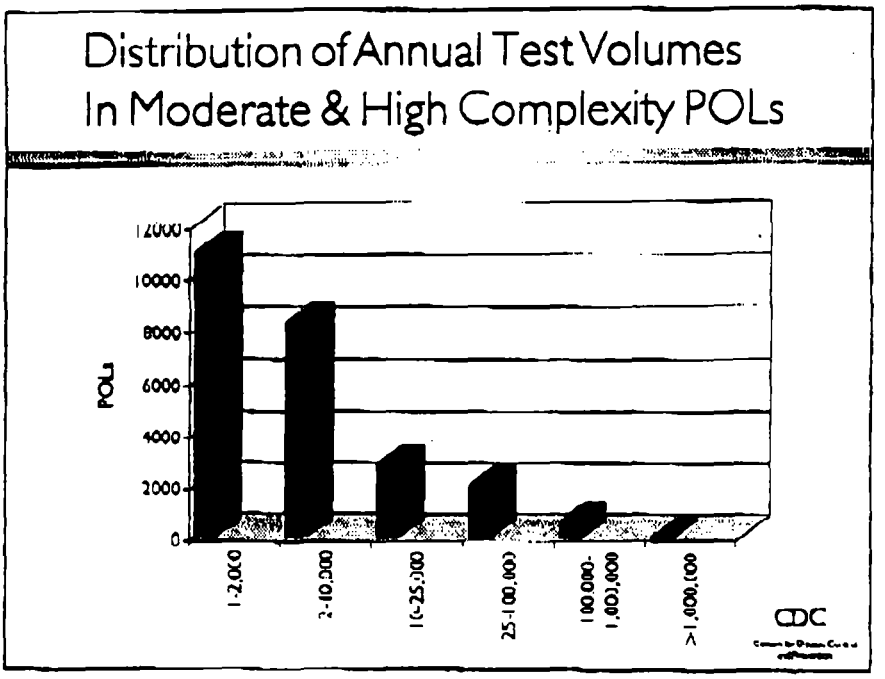
*Revenue estimate based on 1993 Medicare data and test volume information from the CLIA Baseline Sample of HCFA 109 Forms.



Key Points

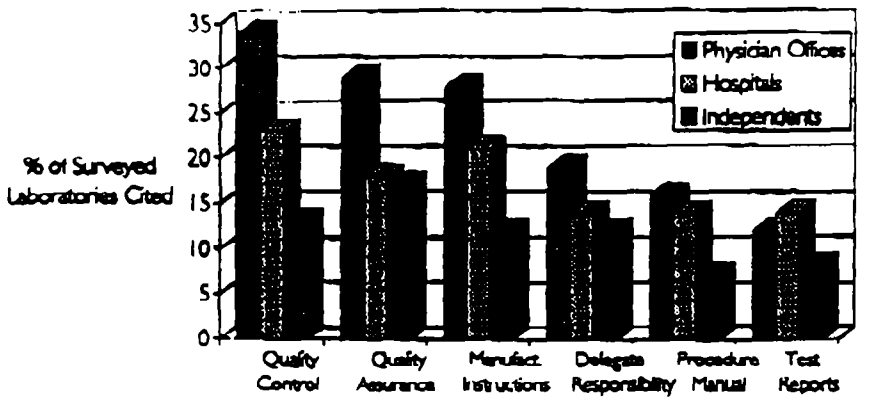
- Regulatory relief has been provided to 58% of physician office laboratories by certificate of waiver and provider performed microscopy CLIA provisions.
- Many physician office laboratories (10%) are accredited by nonprofit professional organizations.

Source: HCFA OSCAR System (as of 03/02/95)



Source: HCFA ODIE and CLIA Reports (as of 03/31/95)

Most Common Deficiencies Cited

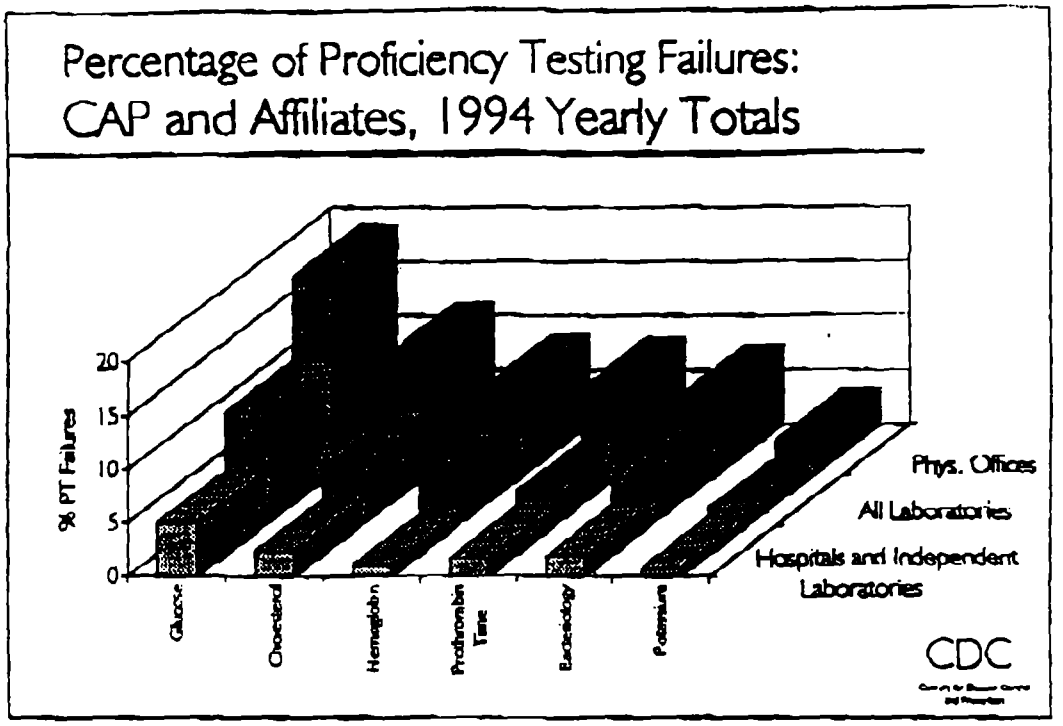


CDC

Key Points

- **Quality Control:** The laboratory must perform and document control procedures using at least 2 levels of control materials each day of testing
- **Quality Assurance:** Each laboratory must establish and follow written policies for a comprehensive quality assurance program ... to evaluate the ongoing and overall quality of the total testing process.
- **Manufacturer's Instructions:** The laboratory must follow the manufacturer's instructions for the test system operation and test performance.
- **Responsibilities:** The laboratory director must specify in writing the responsibilities and duties of each consultant and each person engaged in the performance of all phases of testing ...
- **Procedure Manual:** The laboratory must have a procedure manual describing the processes for testing and reporting patient results.
- **Test Reports:** The test report must indicate the name and address of the laboratory, the test performed, the test result, and the units of measurement.

Source: HCFA OSCAR System (as of 03/06/95) and the Code of Federal Regulations.



Key Points

- for all sentinel analytes, physician office laboratories had higher proficiency testing failure rates than hospitals and independent laboratories
- for all sentinel analytes, physician office laboratories had higher proficiency testing failure rates than the failure rates observed for all participants

Source: Proficiency Testing Data from College of American Pathologists & Affiliates for 1994 and the HCFA OSCAR System

Data analyzed independently by CDC.

IMPROVEMENT IN PHYSICIAN OFFICE LABORATORIES BETWEEN FIRST AND SECOND CLIA INSPECTIONS

Table 1

CONDITION-LEVEL DEFICIENCIES* IN PHYSICIAN OFFICE LABS (POLs)
FIRST VS SECOND SURVEY CYCLE

(N=2,186 POLs with both first and second surveys completed as of August 16, 1995)

	First survey	Second survey	% decrease
POLs with condition level deficiencies	175 (8%)	129 (6%)	26%
Average # condition level deficiencies per POL surveyed	.12	.09	25%

* Condition level deficiencies are sufficiently serious to lead to revocation of a lab's CLIA certificate unless corrected within a designated period of time.

Source: Health Care Financing Administration CLIA data base.

Table 2

TOTAL DEFICIENCIES IN PHYSICIAN OFFICE LABS (POLs)
FIRST VS SECOND SURVEY CYCLE

(N=2,186 POLs with both first and second surveys completed as of August 16, 1995)

	First survey	Second survey	% decrease
POLs with deficiencies	1,886 (86%)	1,449 (66%)	23%
Average # deficiencies per POL surveyed	5.5	2.7	51%

Source: Health Care Financing Administration CLIA data base.

This document was developed and distributed by Representative Dingell's office

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) AND PHYSICIAN OFFICE LABS (POLs)

MYTHS AND FACTS

MYTH #1: When CLIA was passed, Congress was only concerned about the quality of Pap tests in large commercial laboratories.

FACT: While a high error rate for Pap tests was a major concern underlying the passage of CLIA in 1988, Congress was motivated by other factors as well. These included concern about the proliferation of physician office labs (POLs), most of which were subject to no quality standards at all. Several hearings on CLIA were held in both the Senate and the House, including testimony on inaccurate lab testing in physician offices. These hearings and other legislative history clearly show that oversight of POLs was an important goal of CLIA.

MYTH #2: CLIA requires "massive amounts of paperwork".

FACT: All clinical labs must fill out a four-page application form when they first register with HHS.

- The form asks for such information as:
  - + the lab's name, address, director's name, and hours of operation;
  - + the type of facility (e.g. physician office, hospital, home health agency);
  - + whether the lab is accredited by a private accrediting organization;
  - + the type of certificate it is applying for (e.g. waiver or regular certificate);
  - + the number of individuals involved in lab testing and annual volume of tests the lab performs.
- Many of these items are completed by checking off boxes on the form.
- Labs doing only waived tests or "provider-performed microscopy" (59% of POLs) only fill out a few sections of the application form, which take approximately 20 minutes to complete.
- Labs doing moderate or high complexity tests must also check off the laboratory specialties or subspecialties in which they perform tests, and give the annual test volume for each.
- The application form is only filled out once. To renew a CLIA certificate, most POLs need only confirm their status on a customized statement sent to them by HHS, noting any changes in name, address, laboratory specialties, etc., in the last two years. For other POLs, information is updated during their on-site inspection, which involves no additional paperwork.

FACT: Several other paperwork requirements (applying only to non-waived tests) can be met through standard documentation maintained by any medical practice. For example, recordkeeping requirements can be met using patients' medical records, and manufacturers' instructions for testing equipment may qualify as procedure manuals.

MYTH #3: CLIA imposes "hefty fees" on physician office labs.

FACT: Most physician office labs pay only nominal fees, since most are small and many perform only waived tests.

- All labs pay an application fee when they first register with HHS, and to renew their CLIA certificate every two years. Labs doing only waived tests pay $100 every two years, while those doing only "provider-performed microscopy" pay $150 every two years. **These labs (59% of all POLs) pay no other CLIA fees.**

- Other labs performing moderate or high complexity tests pay $100 to $600 in certificate fees, with most POLs paying only $100 every two years. Moderate and high complexity labs also pay compliance fees to cover inspections and other program costs. These fees vary by state and by the lab's annual volume of tests.

- A special compliance fee category was created for small labs, particularly POLs, that perform less than 2,000 tests a year. These labs pay a "flat" compliance fee of $300. 55% of POLs subject to compliance fees fall into this low-volume category and pay a total of $400 every two years ($100 for the certificate fee and $300 for the compliance fee).

MYTH #4: Physician office labs can no longer perform urine pregnancy tests without meeting burdensome requirements.

FACT: Simple urine pregnancy tests are waived tests, which are exempt from virtually all CLIA rules. Labs performing only waived tests are only required to:

- register with HHS and pay a nominal certificate fee ($100 for a two year period);

- follow manufacturers' instructions for performing tests; and

- permit inspections for investigation of bona fide complaints.

MYTH #5: Rapid strep tests (classified under CLIA as moderate complexity tests) can be accurately performed by an untrained person with minimal instruction.
(Some sources say members of Congress were taught in minutes to perform this test; another says seventh graders could do so after reading the package insert.)

FACT: While the steps involved in performing a rapid strep test may seem relatively simple, other factors make the tests more complex and risky than they appear.

- For example:
  - + Specimens are often mishandled or stored improperly, rendering test results unreliable. While testing must occur within a set timeframe after obtaining a strep specimen, some POLs have been found to refrigerate specimens for longer periods. A practitioner who is unaware of such errors is likely to base treatment decisions on inaccurate results.
  - + Surveys have shown that personnel in POLs often fail to follow test manufacturers' instructions, such as the proper sequence for performing the steps of a test. In rapid strep tests, adding the chemical reagents in the wrong order will produce "false negative" results. Quality control and proficiency testing samples (required by CLIA) can be used to detect whether reagents have been added in the wrong order.
  - + Errors are often made in interpreting rapid strep tests, especially when the tests yield borderline results. Lab personnel who are not trained in the use of these tests are more likely to interpret them erroneously.
- Incorrectly handled, performed, or interpreted rapid strep tests may produce "false negative" or "false positive" results.
  - + Prompt treatment of strep infections provides rapid relief of symptoms and decreases risk of contagion to others. When tests yield "false negative" results, these benefits are unavailable. Failure to treat some types of strep infection can lead to rheumatic fever and subsequent heart damage, which can cause serious impairment or death. Such infections are also much more expensive to treat if undetected until a more advanced stage.
  - + "False positive" results also subject patients to risk and lead to increased costs. For example, frequent use of penicillin (which is more likely with unnecessary use) can cause patients to develop resistance to the drug. Such resistance impairs the drug's effectiveness in treating subsequent infections, requiring use of more expensive or more powerful antibiotics later on.
- In categorizing lab tests under CLIA, HHS consults with the Clinical Laboratory Improvement Advisory Committee (CLIAC), composed of physicians, lab professionals, and other scientists. CLIAC has repeatedly considered and rejected proposals to waive rapid strep tests from CLIA rules, based on the serious risks involved when such tests are performed incorrectly or by untrained personnel, and on variation in the quality of the test kits made by different manufacturers.

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) AND PHYSICIAN OFFICE LABS (POLs)

MYTHS AND FACTS ABOUT ACCESS TO LABORATORY TESTS

MYTH #1: CLIA has reduced patients' access to laboratory tests.

FACT: There is no evidence that this has occurred. In fact, a new study by the Inspector General of the Department of Health and Human Services (HHS) concludes that CLIA has had no effect on the availability of laboratory services.

- The volume of lab testing, number of tests per patient, and expenditures for lab tests have increased since CLIA was passed in 1988.
  - + In 1988, Medicare paid for 232 million lab tests compared to 403 million tests in 1993.
  - + In 1988, Medicare Part B enrollees received an average of seven lab tests per patient, compared to 12 tests per patient in 1993.
  - + Medicare expenditures for lab tests more than doubled since CLIA was passed, rising from $2.8 billion in 1988 to $5.9 billion in 1993.
- CLIA has not affected physicians' ability to obtain laboratory services for their patients, including in rural areas.
  - + None of 232 physician practices randomly surveyed by the Inspector General, including rural practices, reported any trouble securing laboratory tests for their patients. All had access to a clinical laboratory and 98% made use of more than one lab.
  - + While the mix of entities providing lab services is different in rural areas than in urban areas, the Inspector General's report concludes that rural residents' access to lab services is equivalent to that of non-rural residents.
- The total number of physicians operating in-office labs has not changed since CLIA was passed in 1988.
  - + The number of office labs operated by physicians in solo practice declined by an estimated 22% between 1988 and 1994, reflecting an on-going trend away from solo practice and toward larger group practices.

- + This decrease, however, was offset by an increase in the number of physicians operating labs in group practices. While the total number of group practice labs did not change between 1988 and 1994, the average number of physicians per group increased. Overall, the number of physicians operating office labs has remained unchanged.

- o When physician office labs have closed, they have often done so for reasons unrelated to CLIA, while other physicians have opened new office labs since 1988.

  - + The Inspector General's study explored the reasons why physicians closed office labs between 1988 and 1994. Such closures were not attributable to any single cause, and included both governmental and non-governmental factors. These included low reimbursement rates, changes in the medical marketplace, self-referral restrictions and OSHA requirements, as well as CLIA.

  - + Marketplace influences may have had the greatest impact on POLs, including mergers and sales of physician practices, and contracts with HMOs and other managed care entities. Such contracts often mandate use of specific laboratories and will not pay for testing done in physician offices. Widespread purchase of physician practices by hospitals has also affected POLs. In almost all such cases, the Inspector General found, the hospital required that all moderate and high complexity testing be sent to the hospital's laboratory.

  - + The Inspector General projected its survey results to physicians nationwide, based on those in active practice in 1988 who were still practicing in 1994. Within this group, approximately 17,000 POLs closed between 1988 and 1994, including POLs that ceased testing altogether (not necessarily due to CLIA) and those that merged with other lab testing sites. During the same period, these physicians opened almost 15,000 new POLs, producing a net change of about 2,000 POLs. The Inspector General believes this change was offset by additional POLs opened by physicians who have entered practice since 1988.

MYTH #2: **CLIA causes hardship for patients by forcing them to travel to outside labs for testing ordered by their doctor. This is especially burdensome for elderly and disabled patients, and those living in rural and underserved areas.**

FACT: It is unusual for patients to be sent from a doctor's office to another facility for clinical lab testing.

- o Most physician offices are able to collect specimens from patients whether or not they operate a clinical laboratory on-site. For tests not performed on-site, the specimens are usually picked up by couriers and delivered to an outside lab for analysis. The results of such tests are usually returned to the referring physician in 24 hours or less, who often informs patients of the results over the phone.

MYTH #3: **Referring moderate and high complexity tests to outside laboratories causes delays that lead to inappropriate diagnosis and treatment.**

FACT: By setting minimum quality standards that help ensure testing accuracy, CLIA promotes proper treatment rather than hindering it.

- Incorrectly handled, performed, or interpreted laboratory tests may produce "false negative" or "false positive" results.
  - + "False negative" results not only cause treatment delays, but may subject patients to risk of serious impairment or death. Medical conditions are also often more expensive to treat if undetected until a more advanced stage.
  - + "False positive" results may lead to inappropriate treatment and further diagnostic tests, exposing patients to unnecessary risks, anxiety, and costs.
- Some moderate and high complexity tests take considerable time to complete regardless of where they are performed. For example, cultures to diagnose bacterial diseases take at least 24 hours to produce an accurate result. These tests, if conducted properly, involve no more "delay" when sent to an outside lab than when done on-site in a POL.
- Nine moderate complexity tests, performed by physicians and other practitioners as part of a patient exam, are included in a special sub-category called "provider-performed microscopy" (PPM). Labs performing only these tests are exempt from routine inspections under CLIA. 24% of POLs perform only PPM tests (or PPM and waived tests), for which results are immediately available. Additional POLs do PPM tests along with other moderate or high complexity tests.

Copies of the HHS Inspector General's report -- "CLIA's Impact on the Availability of Laboratory Services" -- are available by calling the Inspector General's office at (202) 619-1142.

FOR IMMEDIATE RELEASE
October 27, 1995

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Laboratory Coalition Warns About House Medicare Provision

House Medicare Reform Legislation could have Tragic Consequences for the Public

Washington, D.C. -- Members of the Coalition to Preserve Safe Patient Testing (Coalition), representing the nation's major laboratory groups, today warned that a provision in the House Medicare reform legislation could have tragic consequences for the public.

The provision, which would exempt physician office laboratories from any safety and quality standards, reverses many of the reforms contained in the Clinical Laboratory Improvement Amendments (CLIA) which President Reagan signed into law in 1988.

"CLIA was intended to address serious concerns related to the accuracy and reliability of laboratory testing, particularly in Pap smear testing and physician office laboratories," reported Amy Melnick, spokesperson for the Coalition.

"CLIA set basic minimum standards for all laboratory testing regardless of where the tests are performed," added the Coalition's spokesperson. "If physician office laboratories are exempted, they would be able to perform complex tests to detect HIV, heart disease, cancer and genetic abnormalities without any regulation or oversight. The coalition is deeply concerned about the implications for patient care."

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In response to concerns expressed by physicians and other groups that CLIA was unnecessarily burdensome, changes have been made in the program to facilitate in-office testing. Fifty-nine percent of the 89,000 physician office laboratories are in CLIA categories that have minimal regulation and fees. Tests which require a high degree of accuracy, are difficult to perform, or which put patients at risk if performed inaccurately are subject to more stringent regulation.

"The Coalition supports these recent changes and would consider further streamlining of CLIA regulations through legislative reform," the Coalition's spokesperson said. "However, a wholesale exemption of physician office laboratories is simply bad policy. We believe that the original intent of CLIA must be protected. We must ensure that all laboratory testing, wherever it is performed, is done accurately and according to good scientific practices. Patients deserve this protection."

The organizations in the Coalition to Preserve Safe Patient Testing represent bioanalysts, doctoral scientists, clinical laboratory scientists, laboratory managers and supervisors, medical technologists and physicians working in hospitals, independent laboratories, physician offices and industries nationwide as well as owners and directors of clinical laboratories. Coalition members are committed to retaining the basic minimum federal standards for clinical laboratory testing such as quality control, quality assurance, personnel standards, proficiency testing and site neutrality that CLIA ensures.

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