



CALIFORNIA ASSOCIATION OF PUBLIC HEALTH LABORATORY DIRECTORS

LITTLE HOOVER COMMISSION INFORMATIONAL HEARING

August 28, 2008

TESTIMONY OF THE CALIFORNIA ASSOCIATION OF PUBLIC HEALTH LABORATORY DIRECTORS TO THE LITTLE HOOVER COMMISSION

The California Association of Public Health Laboratory Directors (CAPHLD) appreciates the opportunity to testify during this informational hearing. CAPHLD represents the forty local public health laboratories in California and was founded over a half century ago. These local public health laboratories represent the science centers for local government and are mission-critical to local public health jurisdictions in the control of emerging and reemerging communicable diseases, outbreaks, both naturally occurring and man-made and environmental health challenges of this century.

CAPHLD supported the Little Hoover Commission's major recommendation of reorganizing the Department of Health Services by creating a separate Department of Public Health. CAPHLD believed the Little Hoover Commission's recommendation for the creation of a scientific public health board a prudent addition to the reorganized structure of a new Department of Public Health. We further endorsed the Little Hoover Commission's recommendation that one member of the scientific public health board be a public health laboratory director. Unfortunately this recommendation was not considered.

Today's world of public health utilizes high technology coupled with scientific and professional expertise to manage serious public health problems ranging from emerging pathogens, contaminated water and food to bioterrorism. This requires the infusion of many disciplines into the equation to solve today's public health challenges. The inclusion of many disciplines into a cohesive advisory body can only enhance the abilities of the new Department of Public Health.

Regarding a Commission's stated past concern, "The State must significantly bolster technical, scientific, and physical capacity to make sure the best available tools and talents are protecting Californians"; we applaud our elected officials for addressing this need through funding of the LabAspire program. Unfortunately, just as the infrastructure was put in place and candidates were enrolled in the program, we understand the program is encountering bureaucratic program reduction and may be curtailed. CAPHLD continues to recommend that in order to adequately protect the citizens of California from some of the world's most dreaded diseases, the LabAspire program needs to be returned to full funding. We must close the gap in the need to adequately educate and train public health laboratory professionals.

Previously, CAPHLD recommended a greater commitment to public health microbiologist training activities, both financial and mentorship at the State level. We were pleased to see progress in this area, but again, recent budget cuts in the training program at the State level

damages the progress recently made to insure an adequate and stable supply of trained public health laboratory scientists.

A major workforce issue facing the nation today involves not only the scientists at the staff and supervisory level, but at the director level as well. Recent onerous federal requirements have created a national security issue. Unnecessary, unrealistic, and turf driven requirements for *local* public health laboratory directorships coupled with a national shortage of qualified individuals under these requirements have led to the work force shortage. Returning to the previous system of directorship qualification and training will result in a large sustainable pool of exemplary public health laboratory professionals to direct our laboratories for decades. The issue is mentioned in the following from the Association of Public Health Laboratories (APHL).

“.....Current laboratory directors are not optimistic about the adequacy of the candidate pool that will be available to fill future vacancies in directorships. More than two-thirds of the directors indicate that this candidate pool either is not adequate or only marginally adequate in size to meet the future demand for directors. Respondents identify two pressing barriers to recruiting adequate candidates: (1) the ability to offer sufficient salary to compete for qualified candidates; and (2) CLIA provisions that force organizations to exclude good candidates because they do not meet formal education requirements (e.g. doctoral degree and board certification) or experience requirements (e.g. management experience, technical experience). These recruitment barriers are encountered in both state and local laboratory settings, but are viewed as most severe at the local level. Formal degree programs and on-the-job training are generally viewed as the two most effective education and training modalities for the acquisition of knowledge and skills needed by future PHLDs...” Excerpts from the February 2002 APHL report “Who Will Run America's Public Health Labs? Educating Future Laboratory Directors”

CAPHLD has been able to obtain a draft federal bill to rectify the *local* public health laboratory directorship workforce shortage. Unfortunately, that while we have support from the Health Officers Association of California (HOAC) and the County Health Executives Association of California (CHEAC), recent statements from the leadership within the Department of Public Health indicate the Department is not supportive of our collective efforts and in fact may be actively working against the solution.

Public health along with fire and law enforcement forms the public safety triad so important in today's world of emerging pathogens and public protection. CAPHLD strongly supported a past Commission recommendation regarding the State's need to prioritize public health spending as one of the core components of public safety equal to fire and law enforcement. While it appears this is recognized by the Department of Public Health, there continues to be an erosion of funding needs for basic core communicable disease and disease control activities.

While California has undoubtedly made significant progress toward increasing public health preparedness at the local level, CAPHLD has identified gaps in preparedness in California. Regarding several lingering issues related to public health preparedness and public health laboratories - we specifically refer the Commission to the Department of Public Health funded external report *Emergency Preparedness in California's Local Public Health Departments* released in May of 2007 and available from the Emergency Preparedness Office. This

document contains several recommendations for improving the public health laboratory system at the State and local level with which CAPHLD agrees. Some of the recommendations have been instituted. However, many of the recommendations are still in discussion and have not been acted upon. One of the most notable recommendations to the Department of Public Health that has not been fully addressed was the recommendation to expand the Laboratory Response Network (LRN).

Also, during previous hearings, we stated it is paramount that attention be given to local public health laboratory facilities. Cramped public health laboratories environments lead to unsafe conditions. They are not conducive to efficiency and impact the state's limited professional staff from performing at peak efficiency, especially in outbreak situations. Most of the forty local facilities are antiquated and in need of rebuilding from the ground up in order to meet the needs of modern day disease control and weapons of mass destruction response. While it is important to have a "state-of-the-art" state public health laboratory, which we do have, the day-to-day response to outbreaks and potential weapons of mass destruction occurs *locally*.

The current system was established to provide service as close to the need as possible and as such has served the citizens well. The model for delivery of public health services in California is different from many states where the state delivers public health needs. In California, public health needs are delivered at the local level by local government. As an example, during the anthrax events of the Fall of 2001, public health jurisdictions found that for timely response, testing had to be maintained at the local level. Due to the diversity, geography, and population of the State, the current system is necessary to protect the public.

Respectfully Submitted on Behalf of the California Association of Local Public Health Laboratory Directors,

Dennis V. Ferrero, MPH
CAPHLD Executive Director
1004 Oakleaf Way
Stockton, CA 95209



California Association of Public Health Laboratory Directors

January 18, 2008

CLIA LABORATORY DIRECTORSHIP REQUIREMENTS NEGATIVELY AFFECT CALIFORNIA'S LOCAL PUBLIC HEALTH LABORATORY SYSTEM AND THE ABILITY TO PROTECT THE CITIZENS OF CALIFORNIA AND POSSIBLY THE NATION

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HISTORY OF THE CLINICAL LABORATORY IMPROVEMENT AMENDMENT (CLIA) AND HOW DIRECTOR REQUIREMENTS NEGATIVELY AFFECT THE ABILITY FOR PUBLIC HEALTH LABORATORIES TO PROTECT THE NATION

January 18, 2008

Beginning in 1987, a series of newspaper and magazine articles were published on the quality of laboratory testing. These were in the main related to cytology laboratories and some would say cytology “mills”. There were reports of false negative PAP smears with unfortunate consequences. No reports involved public health laboratories (PHLs).

Initial regulatory changes did not envision the unique responsibility of either state or local PHLs. The regulations swept all laboratories under the same regulations, even though the mission of public health laboratories in the nation is a bit apart from hospital and independent clinical laboratories. Final regulations were passed on February 28, 1992 and implemented in September of the same year.

At the onset, CAPHLD was concerned during the development of the CLIA language because the *local* public health laboratory voice was not heard. Subsequently, the initial regulation package did not allow for non-doctoral directors of any laboratories, which was in keeping with the pathologist model of private and non-profit hospital and independent laboratories. Through many discussions and meetings with Rep. Henry Waxman (LA) and his staff, CAPHLD and other interested California laboratory interests were able to obtain a “grandfather” provision. This provision allows individuals previously qualified by a state by 1992 to be forever eligible to direct a medical laboratory. This included PHLs. The thought, at that time, was that this pool of previously qualified individuals would be sufficient to see us through until we ramped up enough doctoral directors for PHLs. The grandfather provision has protected the system since 1992, but cannot sustain the need.

During the time just prior to enactment of CLIA and up to now, the reality was that we already had a significant shortage of individuals entering the basic sciences. This has led to the current dire circumstances we now face. The “grandfather” pool is made up of either retired or near retired qualified directors. Sufficient doctoral directors who are trained in public health laboratory practice are not available to fill the positions necessary to replace the exiting directors. CMS recently added board certification in addition to the doctoral requirement, which further exacerbates the problem.

CAPHLD supports the notion of having board certified doctoral individuals *who are knowledgeable* in public health laboratory practice, *and are qualified* in directing PHLs throughout the nation. The reality is that for the foreseeable future sufficient numbers are not available for varying reasons and especially are not available in some of California’s most vulnerable locations.

Fortunately, California continues to support a strong system of bachelor degreed, locally trained, state certified Public Health Microbiologists (PHMs). Sufficient qualified mid-career PHMs who will take on the responsibility of directorships, as has occurred for six decades, are available once the CLIA regulations are changed to allow this approach.

With this in mind, the presidents of CCLHO, CHEAC and CAPHLD on February 7, 2002 signed a joint letter to HHS Secretary Thompson, requesting CMS to consider regulatory change in CLIA that “would retain the right of local public health laboratories to be directed by qualified individuals as specified under *state* law.” CMS responded negatively to the request.

Then on June 20, 2005 Richard J. Jackson, MD, MPH, State Public Health Officer wrote a letter to HHS Secretary Michael O. Leavitt requesting that CMS add a new section 7) to 42 Code of Federal Regulations 493.1443 as they relate to Laboratory Director requirements. The section would read as follows: “*For local Public Health Laboratories be qualified under state law to direct a laboratory in the state in which the laboratory is located.*” Unfortunately a negative response was sent on July 29, 2005 to Dr. Jackson from Thomas E. Hamilton, CMS Director; a response that in some respects shows a lack of understanding of the system and the needs of California’s local public health system.

CAPHLD was able to engage Rep. Doris Matsui (Sacramento) (initially through G. Trochet, MD) to carry our concern to Congress and to accomplish, if necessary legislatively, the requests of CCLHO, CHEAC, CAPHLD and the State regarding the CLIA laboratory director issue. CAPHLD was able to have Rep. Matsui see this as a national security issue. If PHLs are not able to maintain CLIA certification by virtue of the director requirement they will not be open to act as Laboratory Response Network (LRN) laboratories to protect the nation from pandemics or bioterrorism.



2008 STATUS OF CALIFORNIA PUBLIC HEALTH LABORATORY DIRECTORSHIPS

In 2001 *all* of California's 40 Public Health Laboratories (PHLs), which are also all High Complexity PHLs, were directed by full-time directors. As of January, 2008, one-third of California PHL directors serve only on a part-time basis. Over half (22) of the directors have retired since 2001 and only 9 of the 22 directorships have been filled on a fulltime basis; all by directors eligible under the CLIA "grandfather" clause. In the list below, those listed as "eligible" to retire; likely will retire in five years or less. In a survey conducted three years ago most PHLs had qualified persons on staff who would have made excellent full time directors had the board certified doctoral requirement not been put in place. Only five of California PHLs have ever been directed by board certified doctoral directors in the past sixty years, yet the California public health laboratory system is respected worldwide.

1. **Alameda County** Part-time Director; retired
2. **Berkeley City** Part-time Director; eligible to retire
3. **Butte County** Part-time Director; retired
4. **Contra Costa** Full-time Director; eligible to retire
5. **El Dorado County** Full-time Director
6. **Fresno County *** Full-time Director; directs two PHLs and is eligible to retire
7. **Humboldt County*** Part-time Director; eligible to retire
8. **Imperial County** Part-time Director; employed full-time elsewhere
9. **Kern County** Part-time Director; retired
10. **Kings County** Full-time Director; eligible to retire
11. **Long Beach City** Full-time Director
12. **Los Angeles Co.*** Full-time Director; eligible to retire
13. **Madera County** Full-time Director; directs two PHLs and is eligible to retire
14. **Marin County** Full-time Director; eligible to retire
15. **Mendocino County** Part-time Director; eligible to retire
16. **Merced County** Part-time Director; eligible to retire
17. **Monterey County** Full-time Director; eligible to retire
18. **Napa County** Part-time Director
19. **Orange County*** Full-time Director, eligible to retire
20. **Pasadena City** Full-time Director
21. **Placer County*** Full-time Director, eligible to retire
22. **Riverside County** Full-time Director; eligible to retire
23. **Sacramento County*** Full-time Director; eligible to retire
24. **San Bernardino Co.*** Full-time Director; eligible to retire
25. **San Diego County*** Full-time Director; eligible to retire
26. **San Francisco C&C** Full-time Director; eligible to retire
27. **San Joaquin County*** Full-time Director; eligible to retire
28. **San Luis Obispo Co.*** Full-time Director; eligible to retire
29. **San Mateo County** Full-time Director; eligible to retire
30. **Santa Barbara Co.** Full-time Director
31. **Santa Clara County*** Full-time Director
32. **Santa Cruz County** Part-time Director; retired
33. **Shasta County*** Part-time Director; retired
34. **Solano County** Full-time Director; directs two PHLs and is eligible to retire
35. **Sonoma County*** Full-time Director; directs two PHLs and is eligible to retire
36. **Stanislaus County** Part-time Director; retired
37. **Sutter County** Part-time Director; retired
38. **Tulare County*** Full-time Director; eligible to retire
39. **Ventura County** Full-time Director; eligible to retire
40. **Yolo County** Full-time Director; eligible to retire

* Laboratory Response Network (LRN) "Reference" PHL. LRN "Reference" Laboratories have special national security responsibilities to protect the nation during national emergencies e.g. biological and chemical terrorist attacks and outbreaks such as pandemic and avian influenza.

For further information contact:

Dennis V. Ferrero, MPH, CAPHLD Executive Director dferrero.caphld@yahoo.com



KEY POINTS REGARDING LEGISLATIVE RELIEF FROM BURDENSOME AND UNNECESSARY CLIA DIRECTORSHIP REQUIREMENTS AFFECTING LOCAL PUBLIC HEALTH LABORATORIES

1. The proposed bill provides relief for *local* Public health laboratories (PHLs).
2. The proposed bill allows states to set standard for *local* PHLs.
3. States can choose to retain current CLIA standard.
4. Both executive organizations representing the local public health departments in California, the California Conference of Local Health Officers (CCLHO) and County Health Executives Association of California (CHEAC) and the State have requested the change in CLIA directorship requirements in writing.
5. Many local PHLs are at risk of closure nationally solely due to unnecessary CLIA directorship requirements.
6. Sec. 493.1453 of the CLIA regulations already require high complexity laboratories directed by directors not holding a doctoral degree and board certification to have a clinical consultant. All PHLs in the nation have clinical consultants; most of which are the local jurisdiction's physician health officer.
7. CMS' response to California that PHLs need the same personnel qualifications at the Director level as clinical laboratories does not equate to quality. California requires staff level Public Health Microbiologists to have a bachelor's degree, specific training in a PHL *AND* state certification. This level of expertise is *NOT* required in CLIA regulations for the professional staff in clinical laboratories, so the argument does not equate to California's high PHL standards.
8. The bill addresses a national security issue. All California PHLs are part of CDC's Laboratory Response Network (LRN) to protect the nation from emerging, reemerging and bioterrorism threats and if they close due to CLIA, they won't be part of the LRN.
9. This bill will lead to change that will strengthen the local PHL network nationally.
10. Since local PHLs have a narrow specialized testing responsibility and are staffed by bachelor degreed, trained, and state certified staff who are periodically evaluated, superior control of testing results is already in place at the testing level in California.
11. Empirical evidence tells us that increased academic requirements at the director level *do not* relate to increased quality testing.
12. Empirical evidence tells us that the academic requirements *and* training of the professional bench or testing level personnel is what relates to improved quality.

CURRENT CLIA REGULATION

Laboratories Performing High Complexity Testing

Sec. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of Sec. 493.1443 of this subpart and provides overall management and direction in accordance with Sec. 493.1445 of this subpart.

Sec. 493.1443 Standard: Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

- (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and
- (b) The laboratory director must--**
- (1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and
(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or
- (2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and
- (i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or
(ii) Have at least 2 years of experience directing or supervising high complexity testing; or
- (3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and--
- (i) Be certified and continue to be certified by a board approved by HHS; or
(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least--
(A) Two years of laboratory training or experience, or both; and
(B) Two years of laboratory experience directing or supervising high complexity testing.
(C) On December 31, 2002, individuals must meet the qualifications specified in paragraph (b)(3)(i) of this section;
- (4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or
- (5) On or before February 28, 1992, be qualified under State law* to direct a laboratory in the State in which the laboratory is located;** or
- (6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.
[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994; 62 FR 25858, May 12, 1997; 63 FR 55034, Oct. 14, 1998]

*** California requires PHL directors in CA be a certified Public Health Microbiologist (Bachelor's minimum, specified training in a Public Health Laboratory AND pass a rigorous Public Health Microbiologist exam and have 4 years of experience in a Public Health Laboratory.**

REQUEST FOR REMEDY FROM THE STATE OF CALIFORNIA

SEP-08-2005 11:49

TULARE CO HLTH DEPT LABS

559 685 2586

P.11



SANDRA SHEWRY
Director

State of California—Health and Human Services Agency Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

June 20, 2005

The Honorable Michael O. Leavitt, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt:

I urge you to consider revising Clinical Laboratory Improvement Act of 1988 (CLIA) regulations to allow local public health laboratories to be directed by qualified individuals as specified under state law. This would assure that public health laboratory services continue to be available to local health departments without compromising quality.

CLIA regulations mandate that all laboratory directors must possess a doctoral degree and postdoctoral board certification. A grandfather clause in federal law allows those qualifying as laboratory directors on or before February 28, 1992, to continue to direct a laboratory in the state in which they qualified. Unfortunately, not enough qualified and experienced doctoral-level persons are available to direct the nation's local public health laboratories. California law regulating public health laboratories has a nondoctoral director requirement that has served California citizens well for over 50 years.

Unless the CLIA regulations are revised, California's 61 local public health departments may soon be in a state of crisis due to the shortage of qualified laboratory directors. Local public health departments and laboratories protect the public against communicable diseases, assure the safety of our food and water, respond to bioterrorism and chemical threats, and address the many other public health needs of our communities. Because of our state's large geographic size and population, California's existing state law mandates the availability of local public health laboratory services so that local health departments can respond quickly to public health threats. California currently has 39 local public health laboratories.

To understand the difficulties faced by public health laboratories as a result of the laboratory director requirements, consider the following:

- Since 1992, only one new laboratory director with a doctoral degree has entered California's public health laboratory system.
- Based on a confidential survey conducted by the California Association of Public Health Laboratory Directors, within five years or less, at least one-half of current

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SEP-08-2005 11:39AM

From: 559 685 2586

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The Honorable Michael O. Leavitt
Page 2
June 20, 2005

laboratory directors in California's local public health laboratories will retire, and almost all will do so within ten years.

- Eighty percent of local public health laboratories in California currently have directors that do not possess a doctoral degree, but all have met the quality performance standards of CLIA 1988 and continue to do so.
- Local public health laboratories located in rural and smaller counties will find it particularly difficult to recruit directors with doctoral degrees and board certification. Closure of these laboratories will impair critical national Laboratory Response Network infrastructure for bioterrorism preparedness.

I have enclosed proposed language to amend the CLIA regulations to allow local public health laboratories to be directed by qualified individuals as specified under state law.

I am not aware of any scientific data that shows having a doctoral director correlates with improved quality of laboratory results. In fact, a study by Michael L. Kenney concluded that "a Doctorate is not a necessary or sufficient condition to assure laboratory quality as measured by proficiency testing" (Kenney, M.L., Laboratory performance and regulatory requirements. Clin Chem. 1987 Jun;33(6):1087-102; and Kenney, M.L., Laboratory performance and director qualifications. Clin Chem. 1987 May;33(5):725-38). California law maintains a higher standard than CLIA for bench level professionals, a standard for which the Kenny study indicates a correlation with laboratory quality as measured by proficiency testing.

Thank you for your consideration. I would be happy to discuss this issue in further detail with you or your staff.

Sincerely,

[ORIGINAL SIGNED BY]:

Richard Joseph Jackson, MD, MPH
State Public Health Officer

Enclosure

Proposed Amendment to CLIA Regulations

42 Code of Federal Regulations 493.1443. This would add a new section (7):

6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification, or

(7) For local Public Health Laboratories, be qualified under state law to direct a laboratory in the state in which the laboratory is located.

REQUEST FOR REMEDY FROM CCLHO AND CHEAC

**County Health Executives
Association of California**

**California Conference
of Local Health Officers**

**California Association of
Public Health Laboratory Directors**

February 7, 2002

The Honorable Tommy Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

We are writing to you on a matter of great urgency for which your help is needed to assure the continued availability of essential public health services to 34 million Californians. Unless action is taken quickly at the federal level, California's 61 local public health departments may soon be in a state of crisis due to the shortage of laboratory directors. The shortage will be due to federal regulations requiring a doctoral degree for all laboratory directors under the Clinical Laboratory Improvement Act of 1988 (CLIA).

The mission of local public health departments and laboratories is to protect the public against communicable diseases, assure the safety of our food and water, respond to bioterrorism and chemical threats and address the many other public health needs of our communities. California's thirty-nine local public health laboratories provide these critical services for our local health departments. Because of our state's large geographic size and population, California's existing state law mandates the availability of local public health laboratory services so that local health departments can respond quickly to public health threats.

California's laboratory director requirement (California Code of Regulations, Title 17, Section 1302) has served our citizens well for over 50 years. Specifically, California requirements under this Section are:

Director of the Public Health Laboratory. The director of a principal public health laboratory shall be a certified Public Health Microbiologist whose qualifications conform with the specifications for this position as established by the Department, pursuant to the provisions of the Health and Safety Code. The director shall have had four or more years of experience in public health laboratory work. The quality, variety and currency of this experience shall be satisfactory to the Department.

CLIA's requirement that all laboratory directors possess a doctoral degree and post doctoral board certification would already be devastating local public health laboratories in California, except for the "grandfather" clause that approves those qualified on or before February 28, 1992 "to direct a laboratory in the State in which the laboratory is located." Please consider the following:

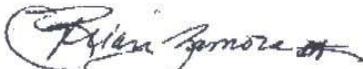
- Since 1992, **only one** new laboratory director with a doctoral degree has entered California's public health laboratory system.

- Within five years or less, at least one-half of current laboratory directors in California's local public health laboratories will retire, and almost all will do so within ten years. With current CLIA requirements in place, California's local public health laboratories will potentially be forced to close, effectively disabling the entire public health system in California.
- All local public health laboratories in California have served the public with high quality services for over fifty years, and 80% do not have doctoral directors, but all have met the quality performance standards of CLIA 1988 and continue to do so.
- A California study by Michael L. Kenney concluded that "a Doctorate is not a necessary or sufficient condition to assure laboratory quality as measured by proficiency testing."

California's local public health department directors, health officers and laboratory directors urge you to consider implementing a change in CLIA regulation that would retain the right of local public health laboratories to be directed by qualified individuals as specified under state law. This would assure that public health laboratory services continue to be available to local health departments, and would do so without compromising quality.

We thank you for your consideration of this request, and are available to discuss this issue in further detail with you or your staff. Please feel free to contact Dr. Thomas Maier, Legislative Chairman, California Association of Public Health Laboratory Directors at (805) 781-5507, Mr. Bruce Pomer, California Conference of Local Health Officers at (916) 441-7405, or Judith Reigel, Executive Officer, County Health Executives Association of California at (916) 327-7540 if you have any questions or comments.

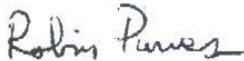
Respectfully,



Brian Zamora, President
County Health Executives
Association of California (CHEAC)



Poki Namkung, MD, MRH
President, California Conference
of Local Health Officers (CCLHO)



Robin Purves, President
California Association of Public Health
Laboratory Directors (CAPHLD)

cc: The Honorable Barbara Boxer
The Honorable Dianne Feinstein
Diana Bontà, DrPH, Director, CA Department of Health Services

CMS RESPONSE TO THE STATE OF CALIFORNIA

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group 062920050644

JUL 29 2005

Richard Joseph Jackson, M.D., M.P.H.
State Public Health Officer
1501 Capitol Avenue, Suite 6001
Sacramento, CA 95899-7413

Dear Dr. Jackson:

Your letter to Michael O. Leavitt, Secretary, Department of Health and Human Services, concerning the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations was referred for a response to the Centers for Medicare & Medicaid Services (CMS), which has responsibility for oversight of the CLIA program.

Specifically, you suggested the CLIA regulations be revised to eliminate the current education qualification requirement for laboratory director, which is a doctoral degree, to require no specific education other than meeting state qualifications, which have been in effect in California (CA) for over 50 years. You noted the important and vital services provided by local public health departments to meet the needs of the community and cited the absence of sufficient experienced doctoral-level persons to direct local public health laboratories in CA.

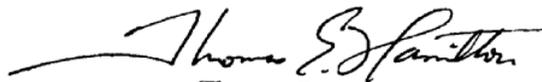
We believe a doctoral degree with board certification is an appropriate minimum requirement for directors of laboratories performing high complexity testing. Advancements in technology, complexity and diversity of laboratory testing continue to provide the critical information needed to meet the clinical as well as the public health needs you identified in your letter. To have quality services using this technology, testing must be performed in a laboratory under the direction of an individual who has demonstrated broad-based knowledge of laboratory science and has the skills required to perform the duties and responsibilities of a laboratory director.

Bolstering this belief are recommendations provided by the Clinical Laboratory Improvement Advisory Committee (CLIAC), the committee charged with providing recommendations concerning the CLIA regulations. CLIAC concurred with the current qualification requirements by noting the importance of assuring the minimum education requirement for directors of high complexity testing is commensurate with the responsibilities of the laboratory director and consistent with the educational requirements and responsibilities for the other personnel categories as described in the CLIA regulations. CMS published a proposed regulation that solicited comments on the specific question and the comments that were received were overwhelmingly in support of the current regulatory requirements.

Although shortages of directors as well as other laboratory personnel are being reported nationwide, CA is the first state health department to suggest lowering educational requirements as a means of addressing work force shortages. In our view, to create a separate requirement for the purpose of lowering educational qualifications for directors of public health laboratories is contrary to the important role and increasing responsibilities these individuals have in the local community and in public health. In recognition of the many critical services provided by public health laboratories, we strongly believe public health laboratories need to have the same personnel qualifications as clinical laboratories and making distinctions between these laboratories is not appropriate. However, we are concerned about your projected loss of laboratory directors and understand the future impact this loss will have on your public health departments. We would suggest you consider consolidation and partnering as options to address the projected director shortages in local public health laboratories in CA. CLIA regulations allow a qualified laboratory director to direct up to 5 laboratories (i.e. certificates) and also permit local government laboratories engaging in limited public health testing (not more than 15 moderately complex or waived tests per certificate) to obtain a single CLIA certificate.

Please know that CMS' CA regional and state offices will continue to work with you and the laboratories affected by current CLIA requirements. Therefore, you may wish to contact the CMS CA regional office regarding possible reconfigurations of existing CLIA certificates and for further information on administrative options available to public health laboratories. CMS has also committed to the American Association of Public Health Laboratories that it will collaborate with them to ensure that the directors of laboratories providing valuable public health services are well qualified and able to meet the broad responsibilities this position.

Sincerely,



Thomas E. Hamilton
Director

cc: CDC, Rhonda Whalen
FDA, Steve Gutman
CMS RO 9
DLS Reading File

APHL DOCUMENTS THE CLIA CREATED SHORTAGE FOR CALIFORNIA PHLs

Excerpts from the February 2002 APHL report “Who Will Run America's PublicHealth Labs? Educating Future Laboratory Directors” page 23.

“....Current laboratory directors are not optimistic about the adequacy of the candidate pool that will be available to fill future vacancies in directorships. More than two-thirds of the directors indicate that this candidate pool either is not adequate or only marginally adequate in size to meet the future demand for directors. Respondents identify two pressing barriers to recruiting adequate candidates: (1) the ability to offer sufficient salary to compete for qualified candidates; and (2) CLIA provisions that force organizations to exclude good candidates because they do not meet formal education requirements (e.g. doctoral degree and board certification) or experience requirements (e.g. management experience, technical experience). These recruitment barriers are encountered in both state and local laboratory settings, but are viewed as most severe at the local level. Formal degree programs and on-the-job training are generally viewed as the two most effective education and training modalities for the acquisition of knowledge and skills needed by future PHLDs...”

The full report is available on the APHL website at:

<http://www.aphl.org/Search/Results.aspx?k=who%20will%20run%20america's%20public%20health%20labs>

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Executive Summary

EXECUTIVE SUMMARY

LABORATORY QUALITY AND DIRECTOR QUALIFICATIONS: An Empirical Assessment of the Medicare Requirement That Directors of Independent Clinical Laboratories Possess Earned Doctorates

by Michael L. Kenney, Dr. P.H., M.C.P.

I. Problem Statement

The State of California administers a comprehensive clinical laboratory regulatory program to protect public health and safety. One feature of this system is the licensing of laboratory directors who hold master's or higher degrees in an appropriate field, meet substantial experience requirements, and have passed a comprehensive state licensing examination. Since 1971 Medicare has required that independent laboratory directors have earned doctorates in order for their laboratories to qualify for Medicare reimbursement. This regulation has prohibited state licensed non-doctoral directors in California from directing Medicare laboratories and has had the effect of prohibiting them from directing all other independent laboratories because the financial success of independent laboratories is dependent upon Medicare certification and its linkage to Medicaid.

The Medicare requirement that licensed independent laboratory directors have an earned doctorate has effectively preempted California law with little empirical evidence to show that the Medicare requirement of doctoral direction of clinical laboratories provides a higher level of protection to the public than the California system which licenses non-doctoral personnel as clinical laboratory directors as part of a comprehensive quality assurance system.

II. Methodology

Proficiency test data for all four quarters of 1983 from laboratories participating in the American Association of Bioanalyst and American Society of Internal Medicine testing services were used to measure laboratory performance.

Five primary study groups composed of 275 licensed full service laboratories were evaluated: (1) 107 laboratories directed exclusively by persons with earned doctorates who were not board certified pathologists; (2) 68 laboratories directed exclusively by directors who were board certified pathologists; (3) 47 laboratories whose directors were exclusively non-doctoral bioanalysts licensed by the state; (4) 17 laboratories with both non-pathologist doctoral directors and pathologist co-directors; and (5) 36 laboratories with mixed doctoral and non-doctoral co-directors. All eligible laboratories in each category were included in the study; there is no sampling error.

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The Medicare requirement for an earned doctorate is based upon an implicit assumption that an earned doctorate is a guarantor of laboratory quality regardless of setting or scope of services offered. Unlicensed laboratories in physicians offices (POLs) are reimbursed by Medicare on the strength of the M.D. degree of the physician in charge. They are not subject to other regulatory requirements placed upon licensed laboratories. In order to test the validity of the logic exempting POLs from licensing requirements, a random sample of 69 limited service unlicensed laboratories in physicians' offices was selected for comparison with the 47 non-doctoral directed full service licensed laboratories included among the licensed laboratory study groups.

Statistical comparisons among licensed laboratories were made in nine chemistry analytes, five hematology analytes, parasitology, bacteriology, urinalysis, diagnostic immunology, syphilis serology, rubella, and immunochemistry. Statistical comparisons between POLs and non-doctoral laboratories were made on five common chemistry analytes and five common hematology analytes. The 95% level of confidence was the criterion of statistical discernibility.

The Kruskal-Wallis and Wilcoxon rank sum tests were the statistical methods used for continuous data comparisons. The test statistic employed for continuous data was the absolute z-score which both provides a combined measure of accuracy and precision, and which standardizes reported values without reference to methods/systems used by laboratories. Standardization was necessary because analytic techniques are critical variables in determining accuracy and precision and the comparison groups in this study were not large enough to allow multivariate statistical analyses to control for effects of method and system. For non-continuous data, the analysis was conducted by means of comparisons of confidence intervals constructed using Cochran's formula for computation of variance for clustered samples.

III. Summary of Findings

There was no pattern of statistically discernible differences among the 5 licensed study groups in any of the 14 quantitative analytes or in any of the 7 non-continuous analytes. Performance of all licensed laboratory groups was statistically equivalent for all analytes.

In nine of the ten analytes compared the licensed non-doctoral laboratories performed at statistically discernibly higher levels than the unlicensed physicians' office laboratories.

IV. Conclusions and Major Recommendations

CONCLUSION 1: An earned doctorate is not a necessary or sufficient condition to assure laboratory quality as measured by proficiency testing.

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CONCLUSION 2: There is no empirical justification for application of Medicare regulation 405.1312(b) requiring an earned doctorate for Medicare, Medicaid, and CLIA certification of clinical laboratories as a uniform national condition of participation. This study indicates that the use in California of a comprehensive regulatory system involving structural, process, and outcome components provides the necessary safeguards to protect public health and safety without reliance upon a requirement that laboratory directors possess earned doctorates.

RECOMMENDATION 1: Whenever possible, clinical laboratory structural and process quality assurance standards should have an empirical base and should rest upon measurable levels of public health protection afforded by those standards rather than upon assumed levels of protection thought to accompany formal requirements.

RECOMMENDATION 2: Medicare regulation 405.1312(b) should be amended to allow non-doctoral directors to direct Medicare-certified laboratories in those states that have comprehensive clinical laboratory regulatory programs which have demonstrated effectiveness, or can demonstrate effectiveness, in meeting acceptable outcome measures of laboratory quality.

RECOMMENDATION 3: For the purposes of CLIA certification, The Department of Health and Human Services should redefine criteria for determining whether or not local regulatory requirements are "equal to or more stringent than" federal standards. The redefinition should be based upon empirical outcome measures of laboratory quality rather than on formal structural requirements not empirically linked to laboratory quality.

RECOMMENDATION 4: The Department of Health and Human Services should commission a national study to determine if unlicensed laboratories in physicians' offices should be required to meet regulatory standards imposed on Medicare-certified independent laboratories.

V. Quality Control for this Study

This study has been guided by two advisory groups. The first is a panel of six professors from the University of California (five from the Berkeley campus and the co-director of the tropical disease laboratory from the San Francisco campus). The second advisory committee is a professional group composed of the Chief of the Laboratory Field Services Section of the State Department of Health, the director of the state's proficiency testing monitoring program, two pathologists, one non-doctoral bioanalyst, the immediate past president of the California State Public Health Laboratory Directors' Association, and a representative of the California Society of Medical Technologists.

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Executive Summary

LABORATORY PERFORMANCE AND REGULATORY REQUIREMENTS:

A Empirical Assessment of the Quality Assurance Effects of Selected
Regulatory Requirements on the Performance of Clinical Laboratories

by Michael L. Kenney, Dr.P.H.

This investigation, commissioned by the Centers for Disease Control, expands research described by the author in an earlier report.¹ The original research which used 1983 proficiency test results to compare the performance of groups of clinical laboratories in California produced two sets of findings:

(1) No pattern of statistically significant differences was found in the performance of full-service licensed doctoral directed and non-doctoral directed independent clinical laboratories when the two groups were compared in nine chemistry, five hematology, and six qualitative analytes; in two chemistry and hematology indices; and syphilis serology;

(2) full-service non-doctoral directed independent laboratories demonstrated higher performance levels than limited service unlicensed laboratories in physicians' offices (U-POLs) in nine of ten comparisons involving quantitative analytes.

The present investigation also employed 1983 proficiency test data as the basis for comparisons among the following types of laboratories in California: (a) physician directed licensed hospital laboratories; (b) licensed non-doctoral directed independent laboratories; (c) unlicensed laboratories in physicians' offices; and (d) licensed Medicare-exempt laboratories in physicians' (group practice) offices.

In an attempt to assure homogeneous comparison groups with respect to scope of services reported, only "full-service" laboratories (e.g., those subscribing to the AAB/ASIM Series 15 proficiency testing package or its equivalent in program modules) were included in the study.

Using most of the analytic laboratory procedures and the same non-parametric statistical methods employed in the earlier research, this investigation produced three sets of findings in two-way comparisons of laboratory performance:

Comparisons Between Hospital and Non-Doctoral Directed Laboratories

(1) There were no statistically significant differences in performance (at $p = 0.05$) in any of the nine chemistry analytes, an index of the nine chemistry analytes combined, any of the five hematology analytes, an index of the five hematology analytes combined, or in syphilis serology.

1. Kenney, Michael L. Laboratory Quality and Director Qualifications: An Empirical Assessment of the Medicare Requirement that Directors of Independent Clinical Laboratories Possess Earned Doctorates. Dr.PH dissertation. University of California, Berkeley. 1984.

CLIN. CHEM. 33/5 725-738 (1987)

Laboratory Performance and Director Qualifications

Michael L. Kenney

Since 1971, federal laboratory regulations have required that directors of approved laboratories possess earned doctorates. Private accrediting agencies and some states also require doctoral directorship of accredited laboratories. No empirical studies have demonstrated that a director's earned doctorate is necessary to assure laboratory quality. Laboratories in physicians' offices (POLs) are exempt from federal regulation but receive federal reimbursement on the basis of the physicians' medical degree. No empirical studies have demonstrated that unregulated laboratories perform comparably with regulated laboratories. This investigation found no statistically discernible differences in quality when 1983 proficiency test data were used to compare statistically the performance of doctoral- and non-doctoral-directed Medicare-certified independent laboratories in California. When regulated non-doctoral-directed full-service laboratories were statistically compared with unregulated limited service POLs, regulated non-doctoral-directed laboratories consistently demonstrated superior performance to POLs. Evidently a director's earned doctorate is neither a necessary nor a sufficient condition to assure laboratory performance. Government regulation appears to provide substantial quality assurance in the clinical laboratory field.

The federal government regulates clinical laboratories under the Medicare program (1) and the Clinical Laboratory Improvement Act (CLIA) (2). As a condition for participation in the Medicare program (e.g., for reimbursement for laboratory services), and as a requirement for receiving a CLIA license to provide laboratory services in interstate commerce (3), approved laboratories must be directed by persons with earned doctorates.^{1,2} Conditions for participa-

The first Report in this series appeared in Clin Chem 1987;33:328-38. This report does not necessarily reflect the views or position of the AACC.

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¹ Originally, federal and voluntary requirements for laboratory directors specified that the directors have medical or related degrees (MD, DO, DSS, DVM). Requirements have been changed in recent years to allow "doctoral scientists" (persons with Ph.D. degrees in appropriate fields such as clinical chemistry, microbiology, etc.) to direct participating laboratories.

² Under Medicare, the doctoral director requirement for "independent" laboratories (e.g., those not in hospitals or physicians' or group practice offices) is contained in Medicare regulation Subpart M 405.1312(b) in C.F.R., Title 20, Chapter III, Part 405. The doctoral director requirement under Medicare for hospital laboratories is somewhat ambiguous. It requires that laboratories not accredited by an accrediting agency with deemed status be "under the supervision of a physician with training and experience in clinical laboratory services or a laboratory specialist qualified by a doctoral degree." C.F.R., Title 20, Chapter III, Part 405, Section 405.1028(d)(1). HCFA interprets this section which discusses *super-*

tion in Medicare were "... intended to provide assurance of the quality and adequacy of the services and facilities participating in independent laboratories" (4).

The federal doctoral director requirements parallel standards used by professional societies that accredit clinical laboratories under voluntary accreditation programs. Laboratories in hospitals that are accredited by the Joint Commission on Accreditation of Hospitals (JCAH) and the American Osteopathic Association (AOA) are deemed under Medicare regulations to be in compliance with Medicare standards and are therefore exempt from direct Medicare regulation. Laboratories accredited by the College of American Pathologists are deemed by the Health Care Financing Administration (HCFA), which administers both the Medicare and CLIA regulatory programs for clinical laboratories, to be in compliance with CLIA regulations and are exempt from direct federal regulation.

The JCAH, AOA, and CAP accreditation programs require that accredited laboratories be directed by persons with earned doctorates. Several states regulate clinical laboratories. Most require that laboratory directors have earned doctorates. The JCAH and CAP programs emphasize that laboratory directors should be medical doctors, preferably pathologists.

The similarity of the mandatory federal requirements and voluntary professional standards with respect to clinical laboratory director requirements (and most other requirements) reflects decisions by the then Department of Health, Education and Welfare to incorporate existing private voluntary standards, with some modifications, into the new Medicare and CLIA regulations in the mid-1960s. JCAH standards formed the basis of Medicare regulations (5); the similar CAP standards formed the basis of CLIA regulations. Both sets of voluntary accreditation requirements were based on professional consensus (6) rather than on rigorous testing of the proposed standards by use of inferential statistical testing techniques.

The federal government based mandatory regulations on the voluntary standards also, without empirically testing their efficacy or appropriateness. The assumption that doctoral directorship of clinical laboratories is a *necessary* condition to assure acceptable laboratory performance was not empirically tested before adoption of the doctoral directorship requirement by Medicare and CLIA. Indeed, very few studies had been reported in the professional literature that attempted to link directors' or supervisors' formal education with laboratory performance. Those studies that had either focused on the question of director education levels and laboratory performance or had addressed the question tangentially found no evidence to support the

vision to mean that the *director* of the hospital laboratory must be a physician (telephone interview of May 13, 1985, with Dr. Stanley Edinger, HCFA).

doctoral directorship requirement (7-10). These were descriptive studies, which did not rigorously test the hypothesis that a director with an earned doctorate is a necessary condition to assure acceptable laboratory performance.

Since the federal government adopted the doctoral directorship requirement in the mid-1960s there have been a few studies reported that, although not designed specifically to test the validity of the doctoral directorship requirement, incorporate analyses of laboratory performance as a function of personnel training and (or) certification (11-14). These studies, which are more methodologically rigorous than the earlier reports, also found no evidence to support doctoral directorship requirements for clinical laboratories. Physician- and Group-Practice Laboratory Exemptions from Federal Regulation

A related feature of Medicare and CLIA regulations and voluntary accreditation standards for clinical laboratories under CAP, JCAH, and AOA is that they exempt physicians' office laboratories (POLs) from compliance with program requirements.^{3,4} However, laboratory services in Medicare-exempt laboratories are reimbursed by Medicare under the physicians' provider number as a physician's service. This reimbursement of unregulated laboratories in POLs implicitly treats the M.D. degrees of the physician directors as a *sufficient* condition to assure satisfactory levels of laboratory performance. This assumption was not empirically tested before the Medicare and CLIA regulations exempting POLs from regulation were adopted.

Although considerable editorial opinion on the topic is available, little empirical work has been done to assess the quality of work performed in unregulated physicians' office laboratories before or after the regulatory decisions were made. In general, work done on this topic has been limited to presentations of descriptive data or indirect findings with limited impact (15-17). One study, done in Oklahoma, reported that POL performance compares favorably with regulated or accredited laboratories (18). However, examination of the data from this study yields the opposite conclusion (19). A study done in 1981, in which inferential statistical testing procedures were used to compare the performance of state licensed (regulated) laboratories and unlicensed (unregulated) POLs in California, found that results from regulated laboratories were more accurate than those from unregulated POLs (20). However, the research design did not control for the effects of analytical methods on laboratory performance, so this conclusion cannot be supported from the data presented.

Non-Doctoral-Directorship Alternative—the Federal Exception

The Medicare regulations governing independent clinical

³ While the term "physician's office laboratory" is in common use, this label is somewhat misleading since it implies that the exempt laboratory is in the office of a solo-practice physician. Many exempt "physician's office laboratories" are in group practices, some of which may have hundreds of partners in the practice. The abbreviation "POL" is commonly used to refer to all exempt laboratories without regard to size of the practice.

⁴ Medicare exempts laboratories in physicians' offices and group practice offices if they accept no more than 99 specimens per year per specialty (defined as microbiology and serology, clinical chemistry, immunohematology, hematology, pathology, and radiobioassay) from patients outside the practice (Medicare regulation 405.1310(a)). Physician and group-practice laboratories exempt under CLIA must serve only the patients of the individual practice (42 U.S.C. 263(i)).

laboratories permitted individuals who did not hold an appropriate earned doctorate to direct Medicare-certified independent laboratories if they had qualified to participate in the Medicare program prior to July 1, 1971 (21). This "grandfather" provision cutoff date was later effectively extended to October 11, 1975, under very limited conditions applying only to California (22). The existence of this "grandfather" provision created a class of federally regulated (Medicare-certified) independent laboratories with non-doctoral directors.

Non-Doctoral Directorship—the California System

Since 1938, under the California Clinical Laboratory Act (23), licensed clinical laboratory technologists who met specified director standards have been licensed to direct clinical laboratories in California. Under current provisions of the Act, a person who does not have an M.D. degree may be licensed as a clinical laboratory bioanalyst (director) if she or he meets all of the following conditions: (a) holds either a master's degree or equivalent or higher degree with a major in biological science, obtained from approved educational institutions; (b) has a minimum of four years of experience as a licensed clinical laboratory technologist performing work in all phases of clinical laboratory activity in a licensed clinical laboratory; (c) must have obtained the required experience within the six years immediately preceding the application for a bioanalyst license; and (d) passes a written, oral, and practical examination administered by the State Department of Health Services.

California's regulatory system for clinical laboratories is extensive and comprehensive, and in some ways more stringent than Medicare regulations for clinical laboratories. In addition to director standards, all licensed independent or hospital laboratories must meet additional personnel standards, including the employment of licensed technologists, must conform to state quality-control requirements, and must successfully participate in a proficiency-testing program approved by the state, and must meet other detailed requirements. Periodic inspections are conducted by the State Department of Health Services to ensure compliance with the stringent state quality-assurance requirements.

Federal Pre-emption of California Law

The Medicare requirement that participating laboratories be directed by persons with earned doctorates was extended to cover reimbursement for Medicaid (24) services and to licensure for interstate laboratories under CLIA (3). While the obvious effect in California of Medicare Section 405.1312(b) and its incorporation into Medicaid and CLIA requirements was to prohibit—after the expiration of the grandfather clause—California-licensed non-doctoral bioanalysts from directing *only* those laboratories receiving Medicare and Medicaid reimbursement, the *primary* effect appears to have blocked California-licensed bioanalysts from assuming directorship of *any* state-licensed independent laboratory. This is true because Medicare and Medicaid reimbursement for laboratory service accounts for a substantial portion of laboratories' income; in general, laboratories without Medicare certification cannot survive financially.

This *de facto* blockage by federal regulation of state-licensed laboratory directors from directing clinical laboratories in California amounted to administrative pre-emption

of state law by the federal government.⁵ At the time the Medicare director standards were adopted there was no evidence that the public health and welfare had been or would be diminished by the unfettered operation of the California system of clinical laboratory director licensure.

The federal pre-emption of state law presented four important policy issues that were at the center of this research. First, there was a constitutional issue of the right of the federal government to pre-empt state law through administrative action (e.g., issuance of regulations).

Second, society has a strong interest in securing protection of public health and safety in the most cost-beneficial manner available (25). In the case of clinical laboratories, if empirical analysis were to demonstrate that work done in clinical laboratories directed by persons who do not have earned doctorates is at least equal in quality to the work done in doctoral-directed laboratories, one would have to conclude that unnecessary costs to the public were being generated through unnecessary education costs to supply the mandated number of doctoral-level directors, and through unnecessary compensation for director services, which are lower for non-doctoral than for doctoral directors.

Third, equity is an important concern of American society. The doctoral directorship requirement denies to a substantial number of people the ability to advance to the highest levels of their profession. Such a denial would be justified if it could be demonstrated empirically that the quality of work performed in non-doctoral-directed laboratories constitutes a threat to public health and safety while the quality of work performed in doctoral-directed laboratories does not constitute such a threat, or if it could merely be shown that the quality of work in non-doctoral-directed laboratories is significantly lower than the quality of work in doctoral-directed laboratories and may be presumed to be a threat to public health and safety. On the other hand, if empirical investigation were to show that laboratory performance is not dependent upon a director having an earned doctorate, this restriction would be inequitable and could be said to unfairly and perhaps unjustly deny individuals the right to excel in their profession and to deny them a substantial portion of their potential life-time earning power.

Fourth, society demands that there be a rational basis for public policy decisions. The "factual content of the problem the legislation seeks to solve" is a test of a state's regulatory power (26). The clinical laboratory field is particularly suited to the development of data-driven policy because the product of the laboratory is a report consisting of quantifiable entries giving concentrations of analytes in a specimen or identifying organisms in a specimen. These entries may be compared against external standards of accuracy and precision to determine their "quality."

Purposes of This Investigation

In order to illuminate these four aspects of clinical laboratory policy, this study was designed to test empirically the assumptions in the Medicare and CLIA regulatory systems (1) that doctoral directorship is a *necessary* but not sufficient

⁵ The administrative pre-emption of state law by the federal government was removed as of January 1, 1987, by an amendment to Title XVIII, Part II, Section 127(d) in the HR 5300, the 1986 Consolidated Omnibus Budget Reconciliation Act. The amendment prohibits the Secretary of Health and Human Services from requiring director standards that differ from state standards in any state that has its own director qualification standards.

condition to assure acceptable laboratory performance in federally regulated laboratories, and (2) that an M.D. degree is both a necessary and a *sufficient* condition to assure acceptable laboratory performance in unregulated laboratories.

Methods

Two distinct but linked analyses were conducted, one to test assumption 1 and a second analysis to test assumption 2. There was substantial overlap in the methodology applied in both analyses. Each analysis is described separately.

1. Primary Analysis—Comparison of Doctoral and Non-Doctoral-Directed Full-Service, Licensed, Independent Laboratories

The dependent variable. The theoretical dependent variable is "laboratory performance." Laboratory performance was further defined to refer to the accuracy and precision of reporting of laboratory findings rather than to common surrogate measures of laboratory performance such as compliance with personnel requirements or tallies of deficiencies noted during inspections conducted by federal or state regulators.⁶ Note that this operational definition of laboratory performance assumes that the product of the clinical laboratory is *information* which is useful to physicians in medical decision-making, but that the laboratory testing process is not itself the practice of medicine. The ordering of tests, the interpretation of test results, and decisions regarding patient management which incorporate laboratory test findings are assumed to be medical functions separate from the production of laboratory information (reports).

Proficiency test results for 1983 from the American Association of Bioanalysts and American Society of Internal Medicine proficiency-testing services were used to operationally define laboratory performance. (It was not possible to include proficiency-testing results from the interlaboratory survey program of the College of American Pathologists, because too few non-doctoral directed laboratories subscribed to this proficiency-testing service to produce an adequate sized study group.)

Mailed proficiency testing used for regulatory purposes provides an incomplete and imperfect measure of laboratory performance. The most common criticism of mailed proficiency testing is that results are biased, because laboratories are often presumed to routinely provide special handling to proficiency-test samples, thus providing at best a measure of the laboratory's capability rather than of its routine performance (11, 27). This view is challenged by some commentators (28):

Proficiency testing programs which are carefully performed and comprehensive can define the state of the art, that is, current practice. . . . In the great majority of instances, proficiency testing data relate to routine conditions. . . .

A second limitation of mailed proficiency testing is that it grades only the accuracy of participating laboratories but does not grade important performance variables such as precision, sensitivity, specificity, or turnaround time. A third limitation is that grading systems for proficiency tests make use of arbitrary decision levels for determining the

⁶ Peddecord and Taylor (*op. cit.*) found no statistical correlation between proficiency test results and inspection deficiencies, indicating that these two sets of data measure separate dimensions of clinical laboratory operations.

accuracy of results reported as continuous data, generally labeling as "acceptable" all reports of results within two standard deviations on either side of the peer-group mean and labeling as "unacceptable" all outside of this central range, which encompasses 95% of all results. This elastic grading system is not closely associated with clinical decision making by physicians who are using test results. A fourth limitation is that proficiency test results reported in or converted to dichotomous findings lose the ability to indicate severity of the impact of laboratory errors on patient health. Finally, proficiency test specimens are prepared to mimic fresh human materials, but they may vary widely from actual materials of human origin.

In spite of the perceived weaknesses outlined above, mailed proficiency testing has gained widespread acceptance by laboratories, voluntary accrediting organizations, and government regulatory agencies since it was developed in the mid-1940s. Mailed proficiency testing is mandated by Medicare and CLIA in the federal regulatory programs; by CAP, JCAH, and AOA in the voluntary sector; and also by many state regulatory programs. There are a number of reasons for this acceptance, and a pragmatic underpinning to the widespread use of proficiency testing by regulatory and voluntary accrediting agencies to measure laboratory performance. Even if it is granted that proficiency testing measures the best a laboratory can do and not its routine day-to-day performance, proficiency testing is effective in identifying laboratories that are out of control (29). Mailed proficiency testing is widely recognized as having a vital role, both in improving the quality of laboratory testing (30) and in documenting the improvements in laboratory quality since Medicare and CLIA standards were adopted (31).

Results of mailed proficiency testing were adopted as the empirical outcome measure of clinical laboratory quality for this study because proficiency testing is in widespread use by the profession; because it is widely understood within the profession; because it is effective in providing feedback to laboratories, regulators, and the profession in general; and because it is the *only* available empirical outcome measure of clinical laboratory quality. Even if proficiency testing tends to measure the best laboratories are capable of, results are not identical; there *are* distributions of scores among laboratory groups. Those distributions can be compared by use of inferential statistical analysis procedures. Hypotheses regarding differences in performance of doctoral-directed and non-doctoral-directed laboratories may be evaluated by using distributions of proficiency test scores.

Procedures Included in the Primary Comparison

All laboratories in California, including unlicensed laboratories in physicians' offices, are required by state law to participate successfully in a recognized proficiency-testing program. The California State Department of Health Services monitors proficiency test results from 24 "index procedures" in six laboratory specialties for all laboratories in the state. These 24 procedures, which are considered basic tests that all clinical laboratories should be able to perform well routinely, are given in Exhibit 1. Because this study was designed in part to assess the effectiveness of the state system, the state's index procedures were selected as the core analytes to be included in this analysis.

Four analytes, two each in chemistry and hematology, were added for the study for the primary analysis comparing doctoral- and non-doctoral-directed full-service independent clinical laboratories. Two chemistry analytes not monitored

Exhibit 1. State of California Index Procedures Monitored under the State's Proficiency-Test Regulatory Program

<i>Chemistry</i>	<i>Immunohematology</i>
Calcium	Blood grouping
Cholesterol	Rh typing
Glucose	Irregular antibody detection
Potassium	
Sodium	<i>Microbiology</i>
Uric acid	
Urea nitrogen	Bacteriological
Urinalysis	identn.
	Parasitological
<i>Diagnostic immunology</i>	identn.
Antistreptolysin-O	<i>Syphilis serology</i>
Rheumatoid factor	
Rubella	VDRL
	ART
<i>Hematology</i>	RPR
	RST
Hematocrit	FTA-ABS
Hemoglobin	
Prothrombin time	

Source: "Guidelines to Laboratory Management," California Dept. of Health Services, no. C-7, May 1979.

by the state, bilirubin and creatinine, are measured with approximately the same frequency nationally as the seven that are monitored by the state (calcium, cholesterol, glucose, potassium, sodium, urea nitrogen, and uric acid). All nine analytes were reported by between 1118 and 1783 laboratories in the national AAB/ASIM proficiency test program in 1983 (32). No other chemistry analyte was measured by as many as 1000 laboratories. At the lower end of the scale were lithium (372 laboratories), iron binding (352 laboratories), and lipoprotein (302 laboratories). The nine chemistry analytes reported by 1118 or more laboratories appeared to form a natural unit helping define full-service laboratories.

A similar phenomenon was noted for hematology. California monitors only hemoglobin, hematocrit, and prothrombin time; however, when erythrocytes and leukocytes are considered, all five hematology analytes had between 1574 and 1980 licensed laboratories reporting. Visual inspection of the data showed that erythrocytes and leukocytes are often sources of variation (e.g., errors tend to show up in these analytes when they do not show up in other hematology analytes).

Because bilirubin, creatinine, erythrocytes, and leukocytes are extensively reported, because they are important procedures in full-service laboratories, and because addition of these analytes would both increase the data base available to this study and add a source of variation which would enhance the ability to detect differences, if any, between study group categories, these four analytes were added to the index procedures monitored by the state for inclusion in the licensed laboratory analyses.⁷

⁷ All inclusion/exclusion decisions regarding study groups and analytes investigated were taken before data analysis began.

Sample Selection

On the basis of the California director-qualification coding system, all laboratories were classified into five categories:

Non-doctoral-directed: Laboratories directed by one or more state-licensed non-doctoral bioanalysts. Not all had master's degrees because some qualified for both Medicare certification and state licensure before the master's degree requirement was put into place by the state.

Non-pathologist doctoral directed: Laboratories directed by persons with M.D. degrees, except for one Ph.D. None of the M.D. directors was identified on laboratory license applications as a pathologist. These laboratories had either a single director or two or more co-directors.

Pathologist directed: Laboratories directed by a single pathologist or co-directed by two or more pathologists according to data provided by the laboratories on their license applications.

M.D./pathologist directed: Laboratories directed by two or more co-directors, at least one of whom was a physician who was not a pathologist and at least one of whom was a pathologist.

Mixed directorship: Laboratories directed by two or more co-directors, at least one of whom possessed an earned doctorate and at least one of whom was a licensed non-doctoral bioanalyst. The doctoral co-directors consisted of physicians who were not board-certified pathologists, board-certified pathologists, and Ph.D. level bioanalysts. Most non-doctoral co-directors were Medicare-certified; a few were not. It should be noted that while the "mixed-director" group is legally doctoral-directed—i.e., Medicare-certified on the strength of the doctoral co-director(s) in laboratories with no Medicare-certified non-doctoral co-director—evidence was found to suggest that in practice many of the mixed-director laboratories are predominantly or exclusively directed by the non-doctoral co-director(s). In spite of this ambiguity, the mixed-group was maintained in the study because it represents a feature of the existing laboratory regulatory arena.

This *de jure* classification system produced one non-doctoral-directed study group (no. 1) and a set of four doctoral-directed laboratory groups (nos. 2–5) for comparison.

Scope-of-Service Levels

Only "full-service" independent clinical laboratories were included in the primary comparison, because the "control group" (non-doctoral-directed laboratories) generally consists of full-service laboratories. Only 13 of 60 non-doctoral-directed laboratories were not classified as full-service laboratories under the classification scheme described below. Also, only full-service laboratories can report proficiency test results for all the 24 index procedures monitored by the state's regulatory program for clinical laboratories.

A decision protocol was devised to define full-service laboratories operationally. The AAB/ASIM proficiency test service used a computer coding system corresponding to its three main product lines involving proficiency test kits with limited, intermediate, and full-service specimen arrays. The full-service test package is designated by the proficiency testing service by the computer code 15000. It consists of blood chemistry (26 analytes), hematology (six analytes), urinalysis (nine items), immunohematology (blood grouping and typing, irregular antibodies, and crossmatch), and mi-

crobiology (bacteriology, parasitology, and diagnostic immunology including antistreptolysin-O, infectious mononucleosis, and rheumatoid factor). Laboratories subscribing to the 15000 package could also add syphilis serology and (or) rubella to their total test package. Laboratories were selected for the study if their proficiency testing code was 15000, 15R00 (indicating the addition of syphilis serology and rubella), or 15S00 (indicating the addition of syphilis serology). Laboratories could also subscribe individually to chemistry, hematology, and other program modules rather than taking the 15000 package. Laboratories could thus be classified as "full-service" laboratories by appropriate combinations of individual modules identified by letter combinations.⁸

Under this decision criterion 275 laboratories qualified for inclusion in the study. The distribution of laboratories by study-group category was as follows: non-pathologist doctoral directed, 107; pathologist directed, 68; non-doctoral directed, 47; mixed doctoral and non-doctoral directorship, 36; mixed non-pathologist doctoral directors and pathologist directors, 17. All qualifying laboratories were included in the study; there was no sampling error for the 1983 data set used in the study.⁹

Test Statistic—Continuous Data: the Absolute Z-Score

One of the important co-variables determining laboratory quality is the effect of the methods and (or) systems used by the laboratory in its analyses. Finkel and Miller (11) demonstrated that "The techniques used had a considerable effect on the accuracy and precision of reported analyses." They reported that "... poor selection of techniques is an important factor in the low rate of acceptability of laboratory determinations."

Because of the small data base available in California, it was not deemed possible to design a multivariate study that would remove the confounding effects of analytical methods used by participating laboratories. Therefore, it was necessary to use another method to control for the effects of method and system on the outcome measure. The method we selected was transformation of the raw proficiency test data (means and standard deviations) within each method/system category to the absolute-z score ($|z|$), which standardizes results and removes method/system bias.¹⁰

The z-score for any distribution is computed as follows. The difference between an individual score and the mean value of all scores within the group that includes the

⁸ Laboratories included in the study had subscriptions with the following computer codes: (1) 15000 or any code with the first two places occupied by 15, followed by any combination of program modules; or (2) the following module groupings equivalent to or more extensive than the 15000 code: CHXUM; CHRYO, CHRUM, CHSZM, CHRUM, CHRUS, CHSUP, CHSUD, CHSUO, or CHSUM.

⁹ Inferential statistical testing theory that underlies the use of probability values to assess observed differences between study groups assumes that data analyzed are sampled from a population. For statistical testing purposes, the data set may be thought of as a one-time sample (for the year 1983) of laboratory performance that is continuous from year to year. Probabilities ascribed to statistical test results refer to the probabilities that similar results would be found if the study were repeated for differing time periods.

¹⁰ I am indebted to Dr. Franklin Elevitch for the suggestion to use the $|z|$ score as the test statistic in this study (personal interview, August 12, 1983). The $|z|$ is the z-score with positive and negative signs removed. The z-score is used by the College of American Pathologists proficiency test service in its reporting of results to its subscribers. CAP defines the z-score as the "Standard Deviation Index" or SDI.

individual score is divided by the standard deviation of the group from which the individual score was taken. The formula for computing an individual z-score is:

$$z = \frac{x_i - \bar{x}}{SD}$$

where x_i is an individual score, \bar{x} is the peer-group mean, and SD is the peer-group standard deviation.

In formal terms, transformation of data to z-scores creates distributions with means of zero and standard deviations of 1. Sets of data from within these distributions can be compared without reference to the original scales used to create the data. Z-scores with valences are not appropriate test statistics for two reasons. First, even though the range of possible scores is bounded at one end, the direction of the error is irrelevant. A score two standard deviations from the mean in one direction represents the same level of accuracy (or inaccuracy) as a score two standard deviations from the mean in the other direction; only the magnitude of the error is significant. Second, and perhaps more importantly, z-scores with signs would cancel each other, distorting the findings. For example, two laboratories producing z-scores of -2.5 and $+2.5$ would have a combined score of 0.0, indication error-free work for this small group when, in fact, both laboratories in the group had produced scores beyond the customary range of acceptable accuracy.

Relationship of the |z| score to accuracy and precision: The |z| score combines the two dimensions of laboratory quality measured by proficiency testing. The numerator of the |z| formula contains a measure of accuracy—the distance from the peer-group method- or system-specific mean of the individual laboratory's finding. The denominator consists of the basic measure of precision in laboratory work, the standard deviation.

Statistical Testing Method: Kruskal-Wallis

Use of the |z| score as the test statistic for this analysis requires that nonparametric statistical test procedures be used, because |z| scores are not normally distributed. The Kruskal-Wallis and Wilcoxon rank sum tests were selected.¹¹ The Kruskal-Wallis procedure is used to assess the differences in results among three or more comparison groups. It is a generalization of the Wilcoxon rank sum test used to assess difference between two comparison groups. In both procedures, the test statistics used (in this case the |z|) are transformed to ranks, and calculations are done on the sums of ranks within each comparison group. If there is no difference in performance among comparison groups, the sums of the ranks of each group will be equal, or nearly so. Differences in sums of ranks are assessed using a known probability distribution and are expressed as probability or "P-values."

Each reader must judge how significant a probability value is. In this report the convention of using a probability value (confidence level) of 0.05 or less as the decision criterion for statistical discernibility is followed. Any P-

¹¹ This is the nonparametric equivalent of one-way analysis of variance. It employs the chi-squared distribution to assess the probabilities that differences found are due to chance or to systematic influences of the independent variable(s). Kruskal-Wallis computations were done with the Statistical Analysis System (SAS) program.

value <0.05 is considered statistically discernible. The 0.05 level is not related to any natural phenomenon; it is purely artificial and arbitrary. The 0.01 level of confidence is sometimes used when more rigorous testing of statistical discernibility is desired. However, the reader may feel, as I do, that a probability value of 0.06, or even greater, may be worthy of consideration, depending on the circumstances of the investigation. For this reason, actual probability values associated with each statistical test are reported so the reader may make his or her own assessment of statistical discernibility.¹²

Aggregation of data. Three levels of data aggregation are used in this study for analytes reported in the continuous data format; statistical testing was conducted at each of the three.

Level one: individual analyte. The study groups were compared by the Kruskal-Wallis procedure for each of the nine chemistry and five hematology analytes in the study (e.g., for continuous data).

Level two: specialty performance indices. Each laboratory was also assigned an overall value for its performance on the nine chemistry analytes combined, and a separate value for its performance on the five hematology analytes combined. These two values are called the "chemistry index" and the "hematology index." They were computed by calculating a mean |z| score based upon values for each laboratory for all analytes reported on within the specialty area.

Level three: proportion of total errors by specialty. The full-service series of the AAB/ASIM proficiency-testing program includes 25 chemistry analytes. Two specimens are provided per quarter for 21 analytes, one specimen per quarter for the other four. This means that a laboratory evaluating all specimens can produce a maximum of 46 chemistry reports per quarter. The testing service summarizes chemistry and hematology results for all reports for each laboratory by showing the total number of scores outside the range of two standard deviations on either side of the mean ("unacceptable scores"), and gives the percentage of all scores within the four standard deviation central range ("acceptable scores"). This percentage of acceptable scores constitutes a third level of data aggregation, which may be thought of as a second type of index for both the chemistry and hematology specialties.

For chemistry, inclusion of this index allows for a comparison among study groups involving their *total performance* in the specialty area, rather than a comparison limited to nine analytes. For this reason it was adopted as a third level

¹² Traditionally, investigations in which tests of statistical inference are involved use the terms "statistical significance" or "statistically significant" to assess the probability that the magnitudes of differences found in empirical measurements on the dependent variable result from random variation in the data or result from the effects of the independent variable(s) on the dependent variable. The use of the word "significant" creates ambiguity, because statistically "significant" differences may have no significance *operationally* in the arena under study. Thus, statistically "significant" differences in the quality of laboratory performance by two laboratories may have no clinical significance for physicians using the laboratory reports from both laboratories. Replacing the term "statistical significance" with "statistical discernibility" in this study avoids potential confusion between statistical and clinical significance and focuses attention precisely on what is at issue: the comparability of laboratory reporting among differently defined laboratory groups. Use of the terms "statistically discernible" and "statistical discernibility" follows Thomas H. Wonnacott and Ronald J. Wonnacott, *Introductory Statistics for Business and Economics* (New York: John Wiley & Sons, 1977), 2nd ed.

of analysis in this study.¹³ Even though all hematology analytes are included in the hematology index described above, the proportion of correct hematology reports was also adopted for use in this study because it measures a dimension of laboratory quality in common use by regulators: acceptability as defined by the central four standard deviation range. The proportion of all errors in chemistry and hematology was computed for each laboratory for the year.

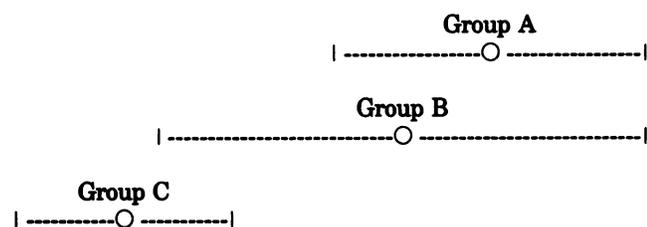
Test Statistic—Dichotomous Data Format

The Kruskal–Wallis and Wilcoxon procedures are not appropriate statistical testing methods for comparison of proportions of dichotomously scored errors, by study group. The statistical procedure used for assessing differences of proportions is described below.

Data for all analytes in all specialties other than chemistry, hematology, and syphilis serology are either reported in dichotomous forms (e.g., microbiology) or in forms converted to dichotomous results (e.g., rubella, diagnostic immunology, etc.) for purposes of determining the acceptability or non-acceptability of responses. The dichotomous format leads to assessment of statistical discernibility based on comparisons of proportions of correct (or incorrect) responses produced by the study groups for each analyte.

A critical feature of the proportions calculated for use in this study is that they result from clustered data. Each laboratory in a study group produces a unique cluster of responses, which will provide different weights to the group result. The standard binomial test of the differences between proportions cannot be used because the variance of proportions of clustered data differs from the variance of proportions calculated from non-clustered data. Cochran (33) developed a formula for calculation of the variance of clustered data, which is used in this study. Using Cochran's method to calculate the variance of clustered data, it is possible to construct confidence intervals around the proportion of errors of each group.¹⁴

The confidence intervals are used as the basis for statistical comparisons among groups. The following example illustrates the comparison of three confidence intervals calculated for three study groups:



In this example, the confidence intervals of Groups A and B overlap and the confidence intervals of Groups B and C overlap, but there is no overlap in confidence intervals of Groups A and C. A convention among statisticians is that there is no statistically discernible difference between Groups A and B where there is overlap, or between Groups B and C where there is also overlap, but in the case of

¹³ Because determinations of acceptable or unacceptable results are made by using means and standard deviations specific to the method/system reported by the laboratory, proportions of acceptable responses are free of method/system bias.

¹⁴ I am indebted to Professor Richard Brand (Dept. of Biostatistics, School of Public Health, University of California, Berkeley) for the suggestion to use Cochran's formula for the calculation of variance for clustered samples.

Groups A and C, where the confidence intervals do not overlap, there is a statistically discernible difference in their proportions.¹⁵

Simultaneous estimates of confidence intervals. When two or more confidence intervals are compared, each calculated at the 0.95 level, the confidence level that both true population values simultaneously lie within the confidence intervals is not 0.95 but rather 0.95^2 , or 0.90. When five confidence intervals, each constructed at the 0.95 level of confidence, are simultaneously compared, the overall level of confidence that all five true but unknown population parameters simultaneously lie within the five confidence intervals is 0.95^5 , or 0.77. If one is to construct a "global" confidence level that provides a confidence level at .95 for a *simultaneous comparison* of five confidence intervals, each individual confidence interval must be constructed by using the fifth root of 0.95, or 0.99. Thus, all judgments of statistical discernibility involving comparisons of five confidence intervals are based upon a global confidence interval of 0.95, which was achieved by setting each individual confidence level at 0.99. The formula used was:

$$C.I. = P \pm Z_{.995} (V)$$

Where C.I. is the global confidence interval, P is the proportion of errors, $Z_{.995}$ is the confidence coefficient of the standard normal distribution, and V is the variance of the proportion.

II. Secondary Analysis—Comparison of Licensed Non-Doctoral-Directed Full-Service Independent Laboratories with Unlicensed Laboratories in Physicians' Offices

The independent variable. The theoretical independent variable to test the assumption that an M.D. degree is a necessary and sufficient condition to assure laboratory quality is also laboratory directorship. In this second analysis the same "control group" (47 non-doctoral-directed licensed independent laboratories) was used, but the "treatment group" was changed to consist of unlicensed (unregulated) limited-service laboratories in physicians' offices.

The dependent variable. Proficiency test scores for 1983 for both study groups were used as the operational definition of the theoretical dependent variable, laboratory performance.

Study-Group Selection Procedures

Procedures used to select unlicensed laboratories in physicians' offices (POLs) were designed to set up an extreme test of the underlying Medicare logic that an M.D. degree in any setting and at any level of scope of services is a guarantor of laboratory quality. If a physician's medical degree is a guarantor of POL quality, the quality assurance effects of that degree should be apparent in the POL setting *without reference to the scope of services offered*. Unregulated doctoral-directed POLs providing a limited scope of services should perform at a *higher* level of quality than licensed full-service non-doctoral-directed laboratories if a director's doctoral degree is a necessary and sufficient condition to assure laboratory quality.

POLs selected for inclusion into this study were restricted to "limited service" laboratories, in contrast to the full-

¹⁵ I am once again indebted to Professor Richard Brand for the suggestion to use this method of assessment of the statistical discernibility of differences in proportions calculated for this research.

service laboratories included in the licensed group. Under this design criterion the null hypothesis is: there is no pattern of statistically discernible differences in quality between non-doctoral-directed licensed full-service independent laboratories and unlicensed limited-service laboratories in physicians' offices. This is an extreme test, because there is evidence indicating that the opposite outcome can be expected (see Appendix A).

The operational definition of limited-service laboratories that we used to select POLs for inclusion in the study was subscription to the AAB/ASIM Series 2 proficiency test package. The computer code for this series is 02000. Part of the reasoning behind the decision to select limited-service POLs for comparison with full-service licensed non-doctoral-directed laboratories was that the full effect of doctoral supervision would probably be found in the POLs with the 02000 test package. POLs subscribing to the 15000 or 15S00 or 15R00 packages or equivalent groups of test modules would be more likely to employ trained technicians or licensed technologists as laboratory supervisors. If an M.D. degree is a necessary and sufficient condition to assure laboratory quality in unlicensed laboratories, theoretically that quality-assurance effect should be discernible in small laboratories that do not employ highly trained technicians or technologists.

Sixty-nine POLs subscribing to Series 2 were randomly selected from all AAB and ASIM Series 2 subscribers for 1983. This number of laboratories represented a ratio of approximately 1.5 POLs to each non-doctoral laboratory in the comparison, following a rule of thumb that the rate of increase in the power to discriminate between study-group responses levels off at a ratio of about 1.5:1. Thus adding more POLs to the study group beyond the 1.5:1 ratio would not have been a cost-effective use of the limited financial resources available to the study, because most of the POLs in the study are ASIM subscribers and their data had to be hand coded.

Analytes Compared

Selection of laboratories subscribing to Series 2 yields comparison on five chemistry analytes (bilirubin, cholesterol, glucose, urea nitrogen, and uric acid) and five hematology analytes (erythrocyte count, hematocrit, hemoglobin, leukocyte count, and prothrombin time). One drawback to using the Series 2 package is that it was not possible to include immunohematology, syphilis serology, rubella, or microbiology in the analysis. This fact limits the applicability of the findings of this study to common chemistry and hematology analytes only. However, if it is shown by statistical testing methods that, for these chemistry and hematology analytes, POLs consistently produce results statistically discernibly lower in quality than the results of non-doctoral-directed laboratories, the assumption that an M.D. degree is a necessary and significant condition to assure laboratory quality will have been called into question for common procedures for which consistently high levels of quality are to be expected.

Test Statistic

The $|z|$ score was the test statistic used for comparisons of performance between licensed non-doctoral-directed laboratories and unlicensed POLs. However, because the data for licensed laboratories and unlicensed laboratories were aggregated and reported separately by the AAB/ASIM testing

service, two distinct distributions of results with differing means and standard deviations result. Absolute z -scores computed for licensed laboratories from the licensed laboratory distribution are not directly comparable with $|z|$ scores computed for unlicensed laboratories, because the AAB/ASIM proficiency-testing service reported the means and standard deviations used in licensed laboratory computations separately from those used in unlicensed laboratory computations. In essence this resulted in a more lenient grading system for unregulated laboratories, because they consistently had larger coefficients of variation than did regulated laboratories using the same laboratory testing methods for the same analytes (Appendix A).

Ideally, both populations could be merged into a single, overall data base combining results from licensed and unlicensed laboratories. Such a combined data base would produce a single set of means and standard deviations for each analyte by method/system. These means and standard deviations would be common to the licensed and unlicensed laboratories and could be used for direct comparisons. Unfortunately, the AAB/ASIM data base was not organized in this manner. An alternative method of designing comparable $|z|$ scores was required.

The alternative method we chose was to use the means and standard deviations of the *licensed laboratories* for each method/system in the calculations of the $|z|$ scores for the unlicensed laboratories.¹⁶ The formula for the computation of the $|z|$ scores for the unlicensed laboratories is:

$$|z| = \frac{|x_{\text{pol}} - \bar{x}_1|}{SD_1}$$

where x_{pol} is the POL individual score; \bar{x}_1 is the method/system-specific peer-group mean of licensed laboratories, and SD_1 is the method/system-specific peer-group standard deviation of licensed laboratories.

The logic underlying the decision to use this formula is that if the licensed and unlicensed laboratories are in fact performing at the same levels of quality, the $|z|$ scores calculated for each group will, on the average, be at about the same distance from the licensed group mean. However, if the unlicensed laboratories are less precise than the licensed laboratories, the lower precision of the unlicensed laboratories will produce $|z|$ scores that consistently are farther from the "presumed true value" of the specimen—the licensed-laboratory group mean. In essence, this method of calculating $|z|$ scores holds the unlicensed laboratories to the same standard as the licensed laboratories; it treats them as if they were licensed laboratories for the purpose of this comparison.

Results

Findings of the analysis are presented by specialty, type of data (continuous or dichotomous), and by level of aggregation of data (individual analytes or indices).

A. Primary Analysis: Doctoral- and Non-Doctoral-Directed Licensed Full-Service Independent Laboratories

(1) Chemistry—Continuous Data Format

No statistically discernible differences were found among the five licensed laboratory comparison groups (*a*) for any of the nine chemistry analytes studied individually, (*b*) when the nine chemistry analytes were aggregated into a "chem-

¹⁶ Professor Brand suggested this strategy.

istry index," or (c) in the proportion of errors in total chemistry reports. No statistically discernible gradient of responses was found. The five sub-groups may be thought of as one homogeneous group of regulated, full-service, independent laboratories. The *P*-values associated with each test of discernibility are presented in Table 1.

(2) Chemistry—Dichotomous Data Format: Proportion of Errors

No statistically discernible differences were found in the levels of performance of the five licensed comparison groups in proportions of errors in chemistry. All confidence intervals overlap as shown in Table 2.

(3) Hematology—Continuous Data Format

No statistically discernible differences in performance were found among the five licensed-laboratory comparison groups for any of the five hematology analytes studied individually. Table 3 presents the *P*-values for this comparison.

The Kruskal-Wallis test showed a statistically discernible variation in performance ($P \leq 0.01$) among the five licensed laboratory groups when the five hematology analytes are aggregated into a hematology index. The Wilcoxon rank sum test was used to compare the non-doctoral-directed laboratories with each doctoral-directed laboratory sub-group in a set of pairwise comparisons.¹⁷ Non-doctoral-

¹⁷ Technically a probability value is associated with a single statistical significance. If 20 statistical tests are performed in a series, at the 0.05 level of confidence one would expect to find one statistically discernible (significant) relationship by chance alone (a Type I error). The probability assigned to any one test in the set changes as each additional test is added. For some statistical testing procedures it is possible to compute overall probability values which take into account repetitive testing. There are no such procedures available for the Kruskal-Wallis and Wilcoxon tests.

Table 1. Probability Values for Kruskal-Wallis Comparisons of Nine Individual Chemistry Analytes, with Index of Nine Analytes Combined, for All Licensed Study Groups

Analyte	Probability
Bilirubin	.67
Calcium	.22
Cholesterol	.41
Creatinine	.28
Glucose	.80
Potassium	.13
Sodium	.65
Urea nitrogen	.85
Uric acid	.47
Nine analytes combined	.12

Table 2. Chemistry—Proportion of Scores 2 SD on Either Side of the Mean, with SD of the Proportion and Confidence Intervals

Study group	No. labs	No. errors	No. chances	Proportion of errors	SD	Confidence interval	
						High	Low
Mixed	36	156	4878	.032	.006	.026	.038
Doctoral*	107	402	12113	.033	.003	.030	.036
Non-Doctoral	47	235	6527	.036	.004	.032	.040
Pathologist	68	436	9913	.048	.005	.043	.053
M.D./Pathol.	17	161	2387	.067	.011	.056	.078

*"Doctoral" in this table and those that follow refers to the group of laboratories directed by non-pathologist directors who have earned doctorates.

Table 3. Probability Values of Comparisons of Five Individual Hematology Analytes, with Index of Five Analytes Combined, for All Licensed Study Groups

Analyte	Probability
Erythrocytes	.19
Leukocytes	.42
Hemoglobin	.88
Hematocrit	.13
Prothrombin	.14
Five analytes combined	.01

directed laboratories performed at a statistically discernibly higher level of quality than the pathologist-directed laboratories in this set of paired comparisons. Results of this comparison are shown in Table 4.

The probability that the mean rank scores would differ from the expected sum of ranks as set out by the null hypothesis that there would be no statistically discernible difference between the groups was 0.0291. Because lower ranks indicate that the $|z|$ scores are closer to the target value (the comparison group mean) than higher scores, the lower mean rank score above indicates statistically discernibly superior performance. However, the greater mean $|z|$ scores of the pathologist-directed laboratories are generally only at a level of plus or minus one standard deviation away from the peer group mean. By conventional standards, these mean $|z|$ scores do not represent unacceptable levels of quality.

(4) Hematology—Dichotomous Data Format: Proportion of Errors

No statistically discernible differences were found among the five licensed laboratory groups in the proportion of errors made for all hematology analytes combined. All confidence intervals overlap, as shown in Table 5.

There is an apparent contradiction between the results of the hematology index constructed by combining mean $|z|$ scores for all five hematology analytes by comparison group and the proportions of errors found in all hematology analytes by comparison group. The *index* of five hematology analytes was sensitive enough to show a statistically dis-

Table 4. Ranks of $|z|$ Scores for Non-Doctoral- and Pathologist-Directed Laboratories in the Hematology Index

Group	No.	Sum of ranks	Expected sum of ranks	Mean rank score
Pathologist	68	4328	3944	63.65
Non-Doctoral	47	2342	2726	49.83

Table 5. Hematology—Proportion of Scores 2 SD on Either Side of the Mean, with SD of the Proportion and Confidence Intervals

Study group	No. labs	No. errors	No. chances	Proportion of errors	SD	Confidence interval	
						High	Low
Mixed	36	65	335	.046	.010	.036	.056
Doctoral	107	241	4026	.060	.006	.054	.066
Non-Doctoral	47	120	1782	.067	.009	.058	.076
Pathologist	68	207	2489	.083	.009	.074	.092
M.D./Pathol.	17	43	654	.066	.012	.054	.078

cernible but not operationally significant difference in mean $|z|$ scores between non-doctoral-directed laboratories and pathologist-directed laboratories. This pattern is also visible in the proportion of hematology errors for both groups (0.076 for the non-doctoral-directed laboratories, 0.092 for the pathologist-directed laboratories). The proportions of errors are so small that the statistically discernible difference in mean $|z|$ scores between these two groups does not appear to represent a significant difference in quality of laboratory performance.

(3) Syphilis Serology

No statistically discernible differences were found among the five licensed laboratory comparison groups in syphilis serology. The mean percent of correct scores was the test statistic used to test for statistically discernible differences in performance among the five licensed laboratory groups. The Kruskal-Wallis test was used to compare the ranks of the mean percent of correct scores. The probability value found by the Kruskal-Wallis test was 0.32.

(4) Specialties Reported in Dichotomous Scores

When the proportion of errors among the five licensed full-service laboratory study groups were compared for bacteriology, parasitology, blood grouping and typing, diagnostic immunology, irregular antibody detection, rubella, and urinalysis, no statistically discernible differences in performance were found. Table 6 presents the proportion of errors in qualitative procedures for each of the licensed study groups by analyte. In irregular antibodies the pathologist- and non-doctoral directed groups made no errors, producing a percent of errors of 0.00. All confidence intervals overlap in all analytes, except for irregular antibodies, where there are no confidence intervals for two comparison groups that made no errors in 1983.¹⁸

¹⁸ The original report upon which this article is based presents tables containing the number of laboratories in each group, the number of errors reported, the number of chances for error, the standard deviations, and the confidence intervals as well as the proportion of errors. Kenney ML, Laboratory Quality and Director Qualifications: An Empirical Assessment of the Medicare Requirement That Directors of Independent Clinical Laboratories Possess Earned Doctorates, Dr. P.H. dissertation, School of Public Health, University of California, Berkeley. 1984. Available through the University Microfilms service.

B. Licensed Non-Doctoral-Directed Laboratories Compared with Unlicensed Physicians'-Office Laboratories

(1) Chemistry

Licensed non-doctoral-directed laboratories performed at a statistically discernibly higher level of performance than POLs in four of the five chemistry analytes studied. Table 7 presents the mean rank values associated with mean $|z|$ scores for the two comparison groups, and the probabilities associated with these mean rank values by analyte and for the index of the five hematology analytes combined.

(2) Hematology

Licensed non-doctoral-directed laboratories performed at a statistically discernibly higher level of performance than did POLs in all five hematology analytes studied. Table 8 presents the mean rank values associated with mean $|z|$ scores for the two comparison groups and the probabilities associated with these mean rank values by analyte and for the index of the five hematology analytes combined.

Discussion

There are some design limitations to this study. One is that it was conducted only in one state, California, rather than in the nation as a whole or as a comparison of a number of states. The scope of the study is also limited to data available for the year 1983 from the AAB/ASIM proficiency test services. The study involved only two dimensions of laboratory performance: accuracy and precision. Other outcome dimensions of laboratory quality such as specificity, sensitivity, and turnaround time were not considered. No attempt was made to analyze surrogate measures of laboratory performance such as inspection deficiencies. Finally, no attempt was made to link proficiency test results with clinical significance.

Although the study is limited by these factors, the richness of the proficiency test data for 1983 for the 275 licensed laboratories and 69 unlicensed laboratories in the study, combined with use of appropriate inferential statistical testing procedures and comparison group selection protocols has produced a pilot study that provides an ample foundation from which to derive carefully drawn conclusions, and it identifies areas for further research.

Table 6. Proportion of Errors in Qualitative Procedures by Licensed Laboratory Study Group—Summary

Study group	Analyte						
	Bacteriology	Parasitology	Blood group	Diag. imm.	Irreg. antib.	Rubella	Urinalysis
Mixed	.1404	.1164	.0125	.0593	.0588	.0372	.0164
Doctoral	.1499	.1773	.0179	.0577	.0189	.0110	.0276
Non-Doctoral	.1190	.1463	.0117	.0461	.0000	.0144	.0191
Pathologist	.1929	.2100	.0097	.0529	.0000	.0253	.0198
M.D./Pathol.	.2074	.1854	.0357	.0703	.2353	.0714	.0206

Table 7. Probability Values of Comparisons of Chemistry Analyte Reports for Non-Doctoral and Unlicensed Physicians' Office Laboratories, Four Quarters, 1983, with Mean Rank Values

Analyte	Mean rank values		Probability ^a
	Non-Doctoral	Physicians' off.	
Bilirubin	33.33	37.59	.40
Cholesterol	39.66 ^b	53.59	.02
Glucose	50.87 ^b	63.70	.05
Urea nitrogen	36.39 ^b	52.99	.003
Uric acid	35.89 ^b	53.11	.002
Five analytes combined	42.28 ^b	69.55	.0001

^a Read as "probability equal to or less than . . ."

^b Statistically discernibly superior performance.

The data presented here indicate parity between non-doctoral-directed laboratories and all formally identified categories of doctoral-directed laboratories in the dimension of quality measured by proficiency testing for 27 commonly measured analytes and for indices of chemistry and hematology.

Tests of statistical discernibility, done on 1983 proficiency test data in California comparing the performance of licensed non-doctoral-directed laboratories and unlicensed laboratories in physicians' offices, showed patterns of statistically discernible differences in four of five chemistry analytes, in all five hematology analytes, and in chemistry and hematology indices combining the five analytes in each category. The licensed doctoral-directed laboratory comparison group performed at a statistically discernibly higher level of quality than did the unlicensed POL comparison group. The relationship between these statistically discernible differences and clinical significance has not been investigated.

The first conclusion to be drawn from the analysis is that an earned doctorate is neither a necessary or a sufficient condition to assure laboratory quality as measured by proficiency testing. Two sets of evidence lead to this conclusion. First, all licensed laboratories in California experience the full effects of California's comprehensive clinical laboratory quality assurance system. Among these laboratories, there appears to be no discernible difference in the level of proficiency test performance between full-service non-doctoral- and full-service doctoral-directed laboratories. If the doctoral degree were necessary to assure laboratory quality, the full-service non-doctoral-directed laboratories should consistently perform at statistically discernibly lower levels of performance than full-service doctoral-directed laboratories. In 1983 they did not do so; rather, the levels of quality were comparable.

Table 8. Probability Values of Comparisons of Hematology Analyte Reports for Non-Doctoral Laboratories and Unlicensed POLs, Four Quarters, 1983, with Mean Rank Values

Analyte	Mean rank values		Probability ^a
	Non-Doctoral	Physicians' off.	
Erythrocytes	36.48 ^b	47.92	.04
Hematocrit	50.04 ^b	62.73	.05
Hemoglobin	38.57 ^b	69.46	.0001
Leukocytes	42.55 ^b	65.16	.0002
Prothrombin	31.55 ^b	45.28	.01
Five analytes combined	38.15 ^b	45.28	.0001

^a Read as "probability equal to or less than . . ."

^b Indicates statistically superior performance.

Second, if a doctoral degree were a sufficient condition to assure laboratory quality, unlicensed limited-service laboratories in physicians' offices should consistently perform at a statistically *higher* level of quality (as measured by proficiency testing) than full-service non-doctoral-directed laboratories without need for the structural and process requirements from which they are currently exempt. However, rather than performing better than non-doctoral-directed laboratories, physician-directed office laboratories in the study in general performed less well than the non-doctoral-directed laboratories in the study.

While these findings are taken from California data, the conclusion that a doctoral degree is not in and of itself a guarantor of laboratory quality is valid without qualification: if a director's doctoral degree were either a necessary or sufficient condition to assure laboratory quality, it would manifest its global quality assurance effects in *any political jurisdiction and at any level of service scope*.¹⁹

A corollary conclusion may be drawn from the evidence presented: laboratories falling under comprehensive regulatory requirements perform significantly better than unregulated laboratories. This finding must be considered tentative since it follows from the comparison of *full-service* regulated laboratories and *limited-service* unregulated laboratories. The scope of service provided is a potential confounding variable that must be controlled for in additional empirical investigations to provide a direct comparison of regulated and unregulated laboratories.²⁰

Recommendations

A set of recommendations was presented in the original report¹⁸ of this investigation. A revised presentation of those recommendations follows.

First, the following principle should be adopted by federal and state governments in developing quality assurance standards for clinical laboratories. Whenever possible, clinical laboratory quality-assurance standards should have an empirical base and should *rest upon measurable levels of public health protection* rather than upon assumed levels of protection thought to flow from compliance with requirements for surrogate measures of laboratory performance. This principle is a restatement of the general principle in American society that calls for public policy to have a rational basis.

The second recommendation was that Medicare regulation 405.1312(b) should be amended to allow non-doctoral directors to direct Medicare-certified laboratories in those

¹⁹ A follow-up investigation commissioned by the Centers for Disease Control (CDC) compared the same group of 47 non-doctoral-directed laboratories in California with all full-service, JCAH-accredited hospital laboratories, using 1983 proficiency test data and the same set of analytes and indices. No pattern of statistically discernible differences in performance were found between the two comparison groups. Kenney ML, Laboratory Performance and Regulatory Requirements: An Empirical Assessment of the Quality Assurance Effects of Selected Regulatory Requirements on the Performance of Clinical Laboratories. Report to the Laboratory Program Office, CDC, 1985. This analysis will be described in a future Special Report in Clin Chem.

²⁰ The follow-up investigation commissioned by the CDC compared regulated non-doctoral-directed laboratories and unregulated POLs with the scope-of-services variable held constant. That investigation found a pattern of superior performance by regulated laboratories when compared with unregulated laboratories, but the differences were not as pronounced as in the present analysis. The follow-up study also demonstrated a statistical relationship between scope of services and laboratory performance in general. *Ibid.*

states having comprehensive clinical laboratory regulatory programs that *have demonstrated effectiveness, or can demonstrate effectiveness*, in meeting the minimum national-outcome measure of laboratory quality. This recommendation incorporates the principle that quality-assurance standards rest upon empirical measures of protection of the public health that are afforded by those standards. It also was based upon the principles of equity and balance between federal and state powers.

Adoption of this recommendation was not expected to involve a reduction of quality-control standards. It was designed to rest upon minimum national *measurable* public health protection standards that could be met by states or territories. States would have the option of requiring an earned doctorate as one feature of a comprehensive laboratory quality-assurance program. However, those jurisdictions would also have the option of licensing laboratory directors with differing educational requirements if the overall effects of the quality-assurance system met minimum measurable levels of public health and safety protection. Development of minimum national outcome measures of laboratory quality for regulatory purposes was seen as a necessary feature of activities undertaken to implement this recommendation.

One feature of this recommendation was implemented through an amendment to Medicare adopted by Congress in 1986.⁵ It prohibits the Department of Health and Human Services from enforcing laboratory director standards in any state that has its own director standard(s). The amendment removes the federal pre-emption of California's director standards, which are embedded in a comprehensive regulatory system that this study has demonstrated to be effective in assuring laboratory performance. However, it also effectively accepts *any* state director qualification standard, *without reference to empirical evidence* demonstrating that the individual state director standard or the state director standard in conjunction with other state laboratory regulations effectively assures acceptable levels of public health protection. The amendment as adopted may not provide sufficient public health protection if states adopt inappropriate director standards or do not link director standards with other appropriate requirements.

A *third recommendation* was that the Department of Health and Human Services should commission a national study to determine if laboratories in physicians' offices should be required to meet regulatory standards imposed on licensed laboratories to qualify for Medicare and Medicaid reimbursement.

The follow-up studies required to implement this recommendation would have at least two separate goals.

One would be to conduct a valid empirical analysis using a national data base to verify (or disprove) that in general unlicensed laboratories in physicians' offices are consistently less accurate and (or) precise than licensed laboratories are at all levels of service.

The second goal would be to determine the clinical significance of any differences in accuracy or precision between licensed and unlicensed laboratories—to assess the risk to patients that accompanies less accurate and precise test results which might be reported by laboratories in physicians' offices.²¹

²¹ In 1985 the U.S. Congress passed legislation directing the Secretary of Health and Human Services to report to Congress within one year on standards that might be appropriate for physicians' offices receiving Medicare reimbursement for laboratory tests

The findings from the present investigation were incorporated into a more comprehensive set of recommended changes to the federal system of regulation of clinical laboratories reported previously (34).

The concept for this research was suggested by Mr. Rod Hamblin, M.P.H., Chief, Laboratory Field Services Section (LFS), California Department of Health Services to the California Association of Bioanalysts (CAB). The CAB asked Professor Richard M. Bailey of the School of Public Health at the University of California, Berkeley, to conduct the research. Professor Bailey recommended the author for the task. The CAB provided the bulk of funding for the research. The author attempted to broaden the funding base by inviting other professional associations to co-sponsor the research. The California Society for Medical Technology and the California Association of Public Health Laboratory Directors also provided financial support. The American Association of Bioanalysts, The American Society of Internal Medicine, and the College of American Pathologists declined to co-sponsor the investigation. LFS provided office space, unlimited access to necessary information, and other valuable support services. The American Association of Bioanalysts (AAB) provided AAB proficiency test results on computer tape. This investigation was also supported in part by biomedical research support grant 5-SO7R-RR-05441 from the National Institutes of Health, DHHS, through the School of Public Health, U.C., Berkeley. The research was also supported by a grant from the Grossman Fund administered by the School of Public Health at U.C. Berkeley, and through a U.S.P.H.S. Traineeship awarded through the Bureau of Health Professions of the DHHS.

Two advisory committees guided the research. The first was a dissertation committee at the School of Public Health, U.C., Berkeley, under the chairmanship of Professor Bailey. Other U.C. School of Public Health members were Stewart Madin, D.V.M., Ph.D., professor of pathology; Sheldon Margen, M.D., professor of nutrition and former director of an independent lab.; and Richard Brand, Ph.D., professor of biostatistics. Richard Meier, Ph.D., professor of environmental design at U.C. Berkeley, and Donald Heyneman, Ph.D., professor of parasitology and co-director of the tropical diseases laboratory at the University of California at San Francisco, were members of the committee from outside the School of Public Health.

The second advisory group was composed of members of the clinical laboratory profession. Members of this panel were Roderick Hamblin, M.P.H.; James Cleaves, M.P.H., supervisory examiner for proficiency testing, LFS; Robert Mann, Bioanalyst, Director of Mann Medical Laboratories; Annamarie Barros, M.A., C.L.S., management consultant and faculty member in the Graduate Program in Clinical Sciences at San Francisco State University; and Mr. Ken Takata, M.S., Director, Sacramento County Public Health Laboratory. Two prominent pathologists in the San Francisco Bay area were also members of this advisory panel but asked to remain anonymous. All members of both advisory groups provided essential assistance in developing and conducting this research.

A large number of other academic advisors and professionals in the clinical laboratory were consulted from time to time on an "as needed" basis when specific questions led me to seek their assistance. Space will not permit identification of all who helped. However, special thanks must go to Nicholas T. Serafy, M.A., Director of the American Association of Bioanalysts Proficiency Testing Service; William Argonza, B.A., supervisory examiner for Medicare compliance, LFS; Professor K. Michael Peddecord of San Diego State University; and June Thomas and John Keith of the Bureau of Health Statistics, California State Department of Health Services.

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1. Title XVIII of the Social Security Act (Health Insurance for the Aged and Disabled), PL. 89-97, 1975, as amended.
2. Clinical Laboratory Improvement Act of 1967, PL. 90-174, as amended.

performed in unregulated physician and group practice laboratories (House Resolution 3101). Discussions with HCFA staff members indicate that the Congressionally mandated report will not involve an empirical assessment of physician office laboratory accuracy and precision as recommended here.

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21. C.F.R., Title 20, Chapter III, Section 405.1312(b)(5).
22. *Ibid.*, note following Section 405.1312(b)(5)(iv).
23. California Business and Professions Code. Division 2, Chap 3, Sections 1200-1322 inclusive. 1978.
24. Title XIX of the Social Security Act, "Grants to States for Medical Assistance," P.L. 89-97, July 30, 1965. 42 USC 1396(a)(9).
25. President Reagan made this value explicit and a federal government priority in Executive Order 12291 of February 17, 1986: "Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society. . ." Fed Reg 1986;46:13193.
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Appendix A: Evidence of Lower Levels of Precision in Unregulated Laboratories When Compared with Regulated Laboratories in a National Data Set

A comparison of coefficients of variation (CVs) was made for all laboratories in the United States subscribing to the AAB/ASIM proficiency test service, using AAB/ASIM data for licensed and unlicensed laboratories. The comparison provides descriptive evidence that the mean scores of licensed and unlicensed laboratories are similar, but that unlicensed laboratories consistently have a wider range of results for most analytes for all analytical methods/systems used than do the licensed laboratories. This finding may be restated: As measured by proficiency test scores, the accuracy of unlicensed laboratories is in the aggregate equivalent to the accuracy of licensed laboratories, but the interlaboratory *precision* of unlicensed laboratories is consistently lower than the interlaboratory precision of licensed laboratories. However, since the mean scores of the unregulated laboratories are computed from distributions with wider dispersions than those of regulated laboratories, there will be a greater number of inaccurate reports at either end of the distribution for the unregulated laboratories than for the regulated laboratories.

Table 1-A compares CVs of licensed and unlicensed laboratories for the first specimen of 10 analytes for 1983 for all laboratories in the United States subscribing to the AAB/ASIM test service. Differences in CVs are computed as the "proportional difference in CVs" by dividing the larger CV by the smaller CV. For example, the first entry is bilirubin. The CV for all licensed laboratories reporting bilirubin (all methods combined) was 16.9%. The CV for all unlicensed laboratories reporting bilirubin was 19.6%. When 19.6 is divided by 16.9 the proportional difference between the two groups is 1.16. In this example, the proportional difference in CVs may be understood to mean that the CV of the unlicensed laboratories for bilirubin was 1.16 times larger than the CV for bilirubin computed for licensed laboratories.

Table 1-A is presented in two parts. The first part includes mean scores and CVs for the first quarter of 1983 for licensed and unlicensed laboratories, as well as the proportional difference in CVs. This was done to show that the mean scores (accuracy) of the licensed and unlicensed