

Priming the Pipeline of Future Public Health Laboratory Directors and Technical Supervisors: CLIA Certification in Public Health Microbiology

Current federal rules (42 CFR 493.1441) under the Clinical Laboratory Improvement Amendments (CLIA) set the following qualifications for a non-physician laboratory director of a medical or public health laboratory (PHL) that conducts high complexity testing on human specimens:

Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution, and

- a) **Be certified and continue to be certified by a board approved by the Center for Medicare and Medicaid Services (CMS);** or
- b) 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 two years of laboratory training or experience, or both; and two years of laboratory experience directing or supervising high complexity testing;

or

Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director on or before February 28, 1992 [under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538];

or

On or before February 28, 1992, be qualified under state law to direct a laboratory in the state which the laboratory is located.

These rules mean that while many older public health laboratory directors have been “grandfathered” under CLIA without taking and passing a CMS-approved certification examination, all future directors of high complexity testing laboratories must be certified by a board approved by CMS. As current PHL directors retire, their successors must actively seek and obtain certification under current CLIA requirements. However, most individuals interested in succeeding to the directorship of a state PHL currently lack the types of specialty training and/or experience required to sit for a majority of the existing CMS-approved board certifications.

Shortage of PHL Directors

During APHL’s 2007 Annual Meeting it was emphasized that over the next five years as many as 15 state public health laboratory directors may be retiring and that no specific programs are currently directed at recruiting, training and preparing future state PHL directors. From the 1960’s through the 1980’s the University of North Carolina and the CDC provided an active Dr.P.H. program that emphasized training in public health laboratory sciences and practice.

From that program, dozens of state PHL directors were employed across the country. Many of the graduates of this program were certified by the American Board of Bioanalysis (ABB) in microbiology. This UNC-CDC program was discontinued in the late 1980s due to cost. In addition, the CDC also served as an AAM-CPEP site providing a post-doctoral fellowship that emphasized public health laboratory training. Unfortunately, this program was also discontinued. APHL and CDC currently provide a post-doctoral fellowship program, but it is primarily directed at research and not in PHL practice and leadership needed to prepare scientist-managers for director-level positions.

Shortage Exacerbated by CLIA

Another significant area of concern at the 2007 Annual Meeting was voiced by Judy Yost, who oversees CLIA's regulatory program. Many states have had significant problems recruiting qualified directors for their state PHLs due to the CLIA requirement for board certification. Some states have addressed this problem by contracting with a pathologist or other CLIA-certified director to meet CLIA director requirements. Although this may be effective as a stop-gap measure, a state PHL would benefit more from the full-time services of a regularly employed CLIA director. In addition, the infectious disease training provided in the vast majority of pathology residency programs has little or no public health training or emphasis. One state reported that after a full year of unsuccessful recruiting, the state felt forced to split the directorship as defined above. Another state reported that its retiring state PHL director had to be retained on a part-time basis for nearly 15 months until a CMS-certified director could be recruited.

Limitations of Current CMS-Approved Examinations

Currently the following boards are approved by CMS under 42 CFR 493.1441:

- American Board of Bioanalysis (ABB)
- American Board of Clinical Chemistry (ABCC)
- American Board of Forensic Toxicology (ABFT)
- American Board of Histocompatibility and Immunogenetics (ABHI)
- American Board of Medical Genetics (ABMG)
- American Board of Medical Laboratory Immunology (ABMLI)
- American Board of Medical Microbiology (ABMM)
- National Registry of Clinical Chemists (NRCC)

Exacerbating the recruiting problem is that none of these board certifications really examine for the types of training and experience required to effectively direct a state PHL. Most of the certifications listed above are in narrow laboratory specialties that prepare specialists with clinical laboratory expertise needed in a hospital (e.g., ABCC, ABMM, ABMLI, NRCC, ABHI, ABMG) or forensic laboratory (ABFT). Although the American Board of Clinical Chemistry is sanctioned as a CLIA-approved board, it has little practical application to a state PHL. The American Board of Medical Microbiology (ABMM) is directly applicable, but individuals that receive post-doctoral training to qualify for this board are also limited to two weeks of exposure to public-health-specific laboratory operations and programs. The American Board of Medical Laboratory Immunology also is sanctioned by CLIA, but individuals trained in immunology may not have sufficient infectious disease experience or training to deal with the wide range of microbial and molecular testing found in most state PHLs.

The American Board of Bioanalysis (ABB) also has a CMS-approved clinical microbiology examination leading to HCLD (High-complexity Clinical Laboratory Director) certification for

doctoral-level scientists that is a competing program to that of ABMM. However, the ABB and ABMM microbiology examinations are both directed to a broad spectrum of clinical microbiology seen in hospitals and commercial medical laboratories. ABB also provides a broader certification leading to a BCLD (Bioanalyst Clinical Laboratory Director) that requires the completion of three of four specialty examinations (i.e., microbiology, immunology, hematology, and chemistry).

Furthermore, individuals who have spent several years pursuing the specialty certifications provided by current CMS-approved boards generally expect to command high salaries and are rarely willing to take a director position in a PHL where salaries may be only marginally competitive and laboratory directors will be required to spend most of their time working outside their specialty area.

PHL practice and programs emphasize not only diagnostics and control of infectious disease microbiology (bacteriology, immunology, mycology, parasitology, and virology) and molecular biology but also environmental (food, dairy, water) microbiology, integrated data management, reference and specialized testing, biochemical genetics, environmental health and protection, food safety, laboratory improvement and regulation, policy development, emergency response, public health related research, training and education, partnerships and communication. Unfortunately, nearly all of the certifications listed above test for little or no laboratory education or experience outside of their specialty area.

Selecting the Right Certification

Review of requirements for the certification examinations and the infrastructures of the boards mentioned above led APHL's Workforce Development Committee (WDC) to propose that ABB be selected to partner with APHL in developing a needed examination in public health microbiology. The WDC proposed ABB as a partner for several reasons. First, only ABB is able to provide the flexibility, willingness, and turn-around-time wanted to complete this project. Second, there are currently 15-17 state public health laboratory directors who already hold a board certification from ABB and are available as volunteers to participate in item writers workshops. Only ABB can provide a sufficient number of already-certified APHL members who will not be compromised by writing and reviewing examination questions for the Public Health Microbiology examination.

In addition, only ABB has a sufficient number of CLIA-qualified individuals to form an examination development team possessing broad education and experience in public health microbiology and public health laboratory practice. CLIA-certified individuals who lack such education and experience could not develop a public health microbiology examination that accurately reflects the needs of this specialty area. Lastly, ABB expressed a desire to develop and support a separate examination that will emphasize public health microbiology rather than compete with the ABMM or ABB (HCLD in Clinical Microbiology) examinations that, as stated above, have a different focus.

The Certification Proposal

Therefore, to ensure that state PHLs have access to CMS-certified directors, and future PHL directors have access to a board examination that reflects the training and experience required of a PHL director, the APHL's WDC proposed that APHL, in partnership with ABB, develop, maintain, and market a CMS-approved examination in Public Health Microbiology for doctoral-level scientists who wish to be certified as a High-complexity Clinical Laboratory Director (HCLD).

A formal proposal was submitted to the APHL Board of Directors in October 2008. The proposal was approved that same month and the WDC chartered a Certification Task Force, chaired by David Smalley (TN), to work with ABB and APHL members to implement the proposal. Also in October the Board of Directors of the ABB gave its approval to develop a Public Health Microbiology examination.

Under the proposal the APHL will provide member expertise to support examination development (e.g., finalizing the examination's content outline, writing examination items, validating examination items, and providing some joint marketing of the examination with ABB). ABB will provide technical expertise to support examination development and maintenance (e.g., presenting item writers workshops; maintaining the item pool; printing and distributing examinations; marketing the examination; scoring and post-test validating examinations; reporting results to examinees).

The examination developmental costs to APHL will be \$7,000-\$14,000, depending on whether one or two item writers' workshops are required. Cost to ABB will be \$5,000-\$7,000 in staff time. With the timely approvals of the proposal and expenses by the APHL and ABB, the new examination could be ready in the fall of 2009. How often and for how long this examination will be provided will depend on product demand to offset the ABB's ongoing expenses. Initially ABB envisions offering the exam twice a year, once at the APHL Annual Meeting and at another national meeting of ABB's choice.

The Certification Program

The WDC recommended a certification examination in public health microbiology for several reasons. First, historically, a majority of PHL directors come from the ranks of microbiologists and an examination in public health microbiology will meet the need of this majority. Second, an examination in public health microbiology is one that will fill a real and vacant niche in microbiology certification. This same examination also can be marketed to public health microbiologists who hold an acceptable doctoral degree but are still earning the required high-complexity testing and/or supervisory experience, and to public health microbiologists who lack a doctoral degree but otherwise meet ABB requirements to be certified in the specialty area. And, third, an examination in public health microbiology is one that APHL readily can help develop by drawing on the existing knowledge and expertise of APHL members.

If the certification examination in public health microbiology proves successful, there are several other possible examinations that could be considered:

- (1) Environmental Chemistry: Director-level certification (HCLD in this area)
- (2) Newborn Screening: Director-level certification (HCLD in this area)
- (3) Environmental Chemistry: Non-doctoral level certification
- (4) Newborn Screening: Non-doctoral level certification

Examination Eligibility Criteria

The eligibility criteria for the examination will be taken from both the requirements under current CLIA rules and the general eligibility requirements already approved by CMS for the ABB's examinations.

To be eligible for ABB certification as a High-complexity Clinical Laboratory Director (HCLD), an applicant must:

1. Meet the qualifications as a laboratory director of a laboratory performing high complexity testing under the CLIA '88 regulations, Subpart M, Section 493.1443.

OR

2. Hold an earned doctoral degree* from an accredited institution with a chemical, physical, biological, or clinical laboratory science as the major subject and have successfully completed 32 semester hours (minimum) in chemistry or the biological sciences acceptable to the Board.

AND

1. Have a minimum of four years of clinical laboratory training or experience on human specimens, or both, including at least two years of experience directing or supervising high complexity testing;

AND

2. Pass an ABB examination in General Knowledge and in at least one of the following clinical laboratory disciplines or specialties: Andrology; Chemistry (including urinalysis, endocrinology and toxicology); Diagnostic Immunology; Embryology; Hematology (including flow cytometry); Microbiology (including bacteriology, parasitology, virology, and mycology); Molecular Diagnostics and **Public Health Microbiology**.

To be eligible for certification as a Technical Supervisor (TS) in **Public Health Microbiology**, an applicant must:

1. Hold an earned doctoral degree from an accredited institution* in a chemical, physical, biological or clinical laboratory science or medical technology and have at least one year of clinical laboratory training or experience on human specimens, or both, in high complexity testing within the specialty.

OR

2. Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy and have at least one year of clinical laboratory training or experience on human specimens, or both, in high complexity testing within the specialty.

OR

3. Hold an earned master's degree from an accredited institution* in a chemical, physical, biological or clinical laboratory science or medical technology and have at least two years of clinical laboratory training or experience on human specimens, or both, in high complexity testing within the specialty.

OR

4. Hold an earned a bachelor's degree from an accredited institution* in a chemical, physical or biological science or medical technology and have at least four years of laboratory training or experience on human specimens, or both, in high complexity testing within the specialty.

AND

5. Pass the ABB examination in Public Health Microbiology.

It should also be noted that a doctoral-level scientist who passes the Technical Supervisor (TS) certification in Public Health Microbiology would be eligible to sit for the General Knowledge Examination to acquire the HCLD after completing four years of training or experience and is not required to retake ABB's Public Health Microbiology examination.

* Individuals with an M.D. or D.O. degree, or the equivalent, must also be licensed to practice medicine in at least one state in the U.S. In addition, degrees earned in the United States must be from a college, university or other institution accredited by an accreditation organization recognized by the U.S. Department of Education. All degrees received from educational institutions outside the United States must be evaluated by an agency approved by ABB. Fees for such an evaluation shall be borne by the applicant. A list of approved agencies is available from ABB and is also available on the ABB web site at www.abbcert.org.

Examination Responsibilities and Maintenance

Under this joint program ABB will, with APHL's help, establish a Public Health Microbiology board certification for doctoral-level scientists with experience and training as required to meet CLIA requirements. ABB also will establish a Public Health Microbiology board certification for Technical Supervisors (for doctoral, masters, or baccalaureate degreed individuals) with experience and training as required to meet CLIA requirements.

The ABB also will advertise the certification program and to provide information on its website that includes examination eligibility requirements (see below), applications, dates of testing and testing locations, fees for examinations, and other pertinent guidance. In addition ABB will advertise the certification to interested parties, manage the examination question pool, provide standardized guidance on test question selection based on the approved content outline, print the test materials and administer the examinations, grade and validate the examination and provide notification of passing/failing to examinees.

The APHL will support ABB in establishing a Public Health Microbiology board certification for doctoral-level scientists with experience and training as required to meet CLIA requirements and in establishing a Public Health Microbiology board certification for Technical Supervisors (for doctoral, masters, or baccalaureate degreed individuals) with experience and training as required to meet CLIA requirements by:

- (i) Sponsoring one or two Item Writers' Workshops;
- (ii) Providing APHL member-experts to participate in:
 - [1] Developing the content outline;
 - [2] Item writers workshop(s); and
 - [3] Generating and validating examination questions.

APHL also will provide a room suitable for examination administration at the APHL Annual Meeting and at least one (1) night's hotel accommodations for ABB staff who administer the examination at the APHL meeting [if the number of examinees is fewer than 20]. In addition APHL will co-market the certification examinations to interested parties by brochure and website announcements, and encourage members to use the ABB certification designation on personal documentation and correspondence, as well as in advertisements for employment positions.

Developing and Conducting the Examination

APHL will provide member volunteers and ABB will provide staff who will be involved in carrying out or supporting the following steps in examination development:

(1) Content outline. A Content Outline must be established for the Public Health Microbiology specialty examination that defines the specific content areas and the amount of emphasis on individual areas. APHL member experts will provide input into developing a final content outline.

(2) Item writing.

(a) Item writing training. ABB will provide guidance on item writing standards for test items, answers and uniformity of format.

(b) Item pool development. APHL and ABB will solicit questions (items) from current SPHL directors and appropriate interested parties who have expertise in the area(s) that directly relates to the content outline so that a pool of questions (items) can be established for testing purposes.

(c) Item/pool pre-test review/validation. Once the test item pool is established, APHL will sponsor a group of 4-6 SPHL directors to meet with ABB staff to review each item for content application, clarity, and accuracy of answers, and to format items in the most effective process acceptable to psychometricians. ABB will provide the item-writer training prior to the review in order for the review group to be aware of the required processes.

(3) Item pool maintenance and updating.

(a) Item Writers Workshops. ABB will assume responsibility for providing Item Writers Workshops at least every two years to update and revise the test item pool.

(b) Additional pool items. Additional items may be solicited from experts in the field to provide additional pool items based on amendments to the content outline, changes in the field/science, and on the need for revising/updating.

(4) Printing and distributing exam materials. ABB will print the test materials and administer the examinations.

(5) Test scoring and post-test item validation. ABB will provide a statistician with experience in psychometrics to provide training for Item Writers Workshops, assist with examination development, and to provide post-examination review and statistical evaluation of the examination.

(6) Results notification to examinees. ABB will provide examinees with notification of their results, either passing or failing. In addition to this pass/fail notification, each examinee will be notified of the percent of the questions they successfully answered in each Content Outline category. This enables examinees to determine the areas in which they did well and in areas where they need improvement.

(7) Re-sitting for examinations. After one failed attempt, an examinee may retake the examination at the next opportunity. After two failed attempts, ABB requires a one-year waiting period before the examinee may retake the examination a third time. If the examinee fails on the third attempt, ABB requires the examinee to wait an additional two years and submit a new application (with appropriate fees) to the Board for consideration.

Projected Program Costs

APHL members will volunteer their time to develop the Content Outline, write items for the examination, and take part in Item Writers Workshops for development of the examination and for the ongoing review of the examination.

Cost to APHL: \$0. Typically members have an interest in the establishment and maintenance of the certification examination and will volunteer their time for this process.

APHL will fund the cost of providing one or two Item Writers' Workshops for member-experts to learn how to review potential examination items and develop item pools. ABB will provide expertise for examination development, a location for Item Writers Workshops, and staffing and preparation for Item Writers Workshops, examination formatting, and printing.

Cost to APHL: \$7,000 – \$14,000. One or two Item Writers Workshops will be required for initial examination development. Item Writers Workshops typically cost between \$6,000 and \$7,000 each, mostly for travel and related expenses.

Cost to ABB: \$5,000 – \$7,000 annually for staff time in preparing and developing examinations. The projected cost is assuming the examination will be reviewed at least biannually. In order to maintain the examination, the number of applicants needs to be sufficient to warrant this ongoing expense.

APHL will provide a room suitable for examination administration at the APHL Annual Meeting. If the number of examinees falls below twenty (20) APHL will provide at least one (1) night hotel accommodations for ABB staff who administer the examination. ABB will provide staffing for examination administration at the APHL annual meeting, and will pay expenses for proctors to travel to the examination location.

Cost to APHL: \$0 – \$300. Typically, conference facilities will provide a meeting room and a number of sleeping rooms complimentary.

Cost to ABB: \$800 – \$1,200.

APHL is expected to incur minimal program/examination marketing costs. ABB's marketing costs will be covered as a part of its general business/marketing expenses. Lastly, the cost of each post-exam item validation by a psychometrician/statistician will be paid by ABB.

Projected Timeline

The APHL and ABB Boards of Directors' timely approvals of the certification examination proposal in October have set the stage for fast-tracking this project. Also in October the WDC established a "Certification Task Force" chaired by David Smalley. Task Force members are Philip T. Amuso, PhD, Florida Bureau of Laboratories; Robyn Atkinson, PhD, Deputy Director, Tennessee Laboratory Services, Knoxville Regional Laboratory; Joanne M. Bartkus, PhD, Laboratory Director, Minnesota Public Health Laboratory Division; John M. (Jack) DeBoy, II, DrPH, MPH, Director, Maryland Laboratories Administration; Frances P. Downes, DrPH, Director, Michigan Public Health Laboratory; Bernard Jilly, PhD, Director, Alaska Department of Health & Social Services, Division of Public Health Laboratory; and Lou F. Turner, DrPH, MPH, HCLD, Deputy Section Chief, Epidemiology, North Carolina State Laboratory of Public Health, Division of Public Health. Additional support has been provided by Roberta Lopez, DrPH, BCLD(ABB), Biological Administrator II, Florida Bureau of Laboratories; Susan U. Neil, PhD, MBA, Director, Laboratory Services Section, Texas Department of State Health Services; Shahiedy I. Shahied, PhD, Bureau Director, Pennsylvania Bureau of Laboratories; and Leslie Wolfe, PhD, Laboratory Director, North Carolina State Laboratory of Public Health.

Already the Task Force is in the process of approving a final Content Outline and looking forward to beginning the process of examination development. If APHL members provide sufficient numbers of examination items and Task Force members take part in Item Writer Workshops in a timely manner, ABB believes the examination could be ready by fall 2009.

A tentative calendar for examination development is listed below.

- October 2008 - APHL BOD and ABB approve proposal and authorize expenses
- October-November - Review and update Content Outline
- Nov. 2008-Feb. 2009 - Solicit test items from content experts and APHL members
- April 2009 - 1st Item Writers Workshop
- Spring 2009 - Begin marketing examination
- June 2009 - 2nd Item Writers Workshop (if needed)
- Fall 2009 - 1st examination ready