

A Short (50-Year) History of ABB

On July 30, 1965, President Harry Truman was enrolled as Medicare's first beneficiary and received the first Medicare card when President Lyndon Johnson, at a ceremony at the Truman Library in Independence, Missouri, signed into law amendments to the 1935 Social Security Act creating the Medicare and Medicaid programs. Approximately 19 million people enrolled in Medicare when it went into effect in 1966.

A little over two years later, on December 5, 1967, President Johnson signed into law the "Partnership for Health Amendments of 1967," which included the "Clinical Laboratories Improvement Act of 1967 (CLIA '67)" establishing federal licensing requirements for clinical laboratories that solicit or accept, in interstate commerce, any specimen for (clinical) laboratory examination or procedures.

Just a few months later, in February 1968, regulations governing Medicare coverage for independent clinical laboratories were published. These regulations permitted laboratories to be paid by Medicare but were **not** the CLIA '67 regulations. The proposed CLIA '67 regulations were published on October 15, 1968, and became effective 30 days later, on November 14, 1968. The qualifications for clinical laboratory directors in the CLIA '67 regulations were the same as the February 1968 Medicare regulations (Section 405.1312), which required a physician or osteopath certified in pathology, or a physician or individual with an earned doctoral degree (in a chemical, physical, or biological science) and either

- Certification from the American Board of Medical Microbiology (ABMM), the American Board of Clinical Chemistry (ABCC) or "other national accrediting board acceptable to the Secretary..."

OR

- subsequent to graduation, 4 or more years of general clinical laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory – with a director at the doctoral level – of a hospital, a health department, university or medical research institution in a state that regulates clinical laboratory personnel, in a clinical laboratory acceptable to that state.

A short "grandfathering" clause was also included for individuals who directed a clinical laboratory for at least 12 months between July 1, 1961, and July 1, 1966, and who held a master's degree (plus 4 years of experience), or a bachelor's degree (plus six years of experience), or who passed an examination conducted by the U.S. Public Health Service between February 1, 1968, and July 1, 1970, and whose laboratory successfully participated in a state-operated or state-approved proficiency testing program.

Realizing the need for a nationally recognized certifying board for generalist laboratory directors, the AAB Board of Directors, on March 21, 1968, provided \$200 for expenses to create the American Board of Bioanalysis (ABB). On June 12, 1968, less than 3 months

later, the American Board of Bioanalysis was incorporated in the state of Missouri, and the first official ABB meeting was held on June 19, 1968.

Everett S. Beneke, Ph.D., professor of mycology at Michigan State University, was appointed chairman of ABB, a position he held for 36 years, until May 2004. Other members of ABB's first board included Victor Rodwell, Ph.D., professor of Biochemistry at Purdue University; Nick Serafy, Sr., owner/director of Serafy Laboratories in Brownsville, Texas; Stanley Marcus, Ph.D., professor of microbiology at the University of Utah Medical Center; Joseph Lazaroni, Ph.D., owner/director of Lazaroni Laboratories in Daly City, California; and Nell Hollinger, Ph.D., professor of Microbiology (retired) at the University of California, Berkeley.

By December 6, 1968, ABB had approved 150 applications for bioanalyst director certification, and had received several hundred other applications.

In 1968 ABB was not yet recognized under the Medicare regulations. From 1968 to 1970, most non-doctoral degreed AAB member directors qualified for Medicare reimbursement (for their laboratory) by passing an examination administered three times by the U.S. Public Health Service between 1968 and 1970 [this examination was different from the HHS (formerly HEW) Proficiency Examination for medical technologists administered eight times from 1975 to 1987.]

Within two years after the February 1968 Medicare regulations were finalized, efforts to revise them were underway.

The February 1968 Medicare regulations and the October 15, 1968, CLIA '67 regulations were similar, but not identical. Of particular concern for AAB members was a July 1, 1971, cut-off date to qualify for non-doctoral degreed clinical laboratory directors.

On February 16, 1972, proposed revisions to the 1968 Medicare regulations were published in the *Federal Register*. For the first time, ABB director certification was formally recognized in Section 405.1312 (b) as follows:

Standard: laboratory director – qualification.

The laboratory meets one of the following requirements:

... (5) He is a bioanalyst accredited in bioanalysis by the **American Board of Bioanalysis**, or possesses qualifications which are equivalent to those for such accreditation (board eligible).”

The 1972 proposed amendments to the Medicare regulations included two other important provisions:

1. The July 1, 1971, cut-off date for non-doctoral degreed directors was removed and replaced with a later cut-off date.
2. All laboratories were required to successfully participate in proficiency testing. [The 1968 Medicare regulations exempted doctoral-directed laboratories from proficiency testing requirements.]

In August 1972 ABB announced that it would begin certifying laboratory supervisors. By August 1973 ABB had certified over 300 laboratory supervisors, along with over 450 Bioanalyst Laboratory Directors (BLDs).

On September 19, 1974, the final revised Medicare regulations for coverage of independent laboratories were published in the *Federal Register*.

Included in the 1974 revised Medicare regulations were:

1. **Recognition of ABB** as a certifying board for clinical laboratory directors.
2. Recognition of AAB's Proficiency Testing Service.
3. An extension of the deadline date from January 1, 1971, to October 21, 1975, for qualifying non-doctoral degreed laboratory directors.

After the 1974 publication of the revised Medicare regulations, multiple efforts were made to revise and update the 1967 Clinical Laboratories Improvement Act (CLIA '67). Bills to amend and revise CLIA '67 were introduced in 1975, 1976, 1977, 1978, and 1979. None of these bills passed.

On January 1, 1978, ABB implemented a mandatory continuing education requirement to maintain ABB certification. Originally, 4.0 CEUs (40 contact hours) were required every two years. On September 19, 1992, the number of required CEUs was reduced to 2.4 (24 contact hours) every two years, to be consistent with Florida's CEU requirements.

On December 11, 1981, ABB established a certification for Bioanalytical Laboratory Managers (BLM). And on May 26, 1982, ABB created the Bioanalytical Laboratory Supervisor (BLS) designation for ABB-certified supervisors.

It wasn't until 1988, following a Wall Street Journal expose regarding "Pap mills," that the CLIA '67 statute was amended as CLIA '88. The CLIA '88 statute greatly expanded the definition of "interstate" laboratories to include virtually all clinical laboratories, a major change from CLIA '67. But the regulations implementing the CLIA '88 statute were not finalized until four years later, on February 28, 1992.

The February 28, 1992, CLIA qualifications for directors were segmented into 4 categories: high complexity, moderate complexity, physician-performed microscopy, and waived.

For high-complexity directors, the requirements were similar to the 1974 Medicare regulations, with the following modifications:

1. Physicians and osteopaths had to be licensed to practice medicine or osteopathy in the state in which the laboratory was located.
2. Physicians and osteopaths that were not board certified were required to have at least one year of laboratory training during medical residency or two years directing/supervising high complexity testing (instead of 4 years of general laboratory training/experience, of which 2 years were spent in a laboratory specialty);

3. For those with an earned doctoral degree, board certification by the “American Board of Medical Laboratory Immunology (ABMLI) or other board deemed comparable by HHS” was added (ABB, ABMM and ABCC were already included in the 1974 regulations and continued to be specifically recognized in the 1992 CLIA regulations).
4. The maximum number of laboratories an individual could direct was changed to five.
5. As of September 1, 1994, individuals qualifying as high complexity clinical laboratory directors had to have an earned doctoral degree (in an appropriate science) and be certified by a CLIA-approved board, such as ABB. [The implementation date of this requirement was delayed 4 times, and eventually took effect on February 24, 2003, with an added provision: “...and continue to be certified (by a CLIA-approved Board).”]

Another important development occurred during that time. In the summer of 1991, the American Society of Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) announced that HHS officials had informed them that IVF/GIFT laboratories were to be covered under CLIA '88.

IVF/GIFT laboratory directors would therefore need a CLIA-approved certification board to qualify under the CLIA '88 regulations, but none of the CLIA-approved boards certified andrologists and embryologists.

In June 1991 Brooks Keel, Ph.D., HCLD(ABB), asked ABB to consider developing a certification program for andrologists and embryologists.

The ABB Board approved Dr. Keel's request with one condition: that Dr. Keel would join the ABB Board to provide expertise and leadership in the development of the certification program for andrologists and embryologists. Dr. Keel agreed and was appointed to the ABB Board that year.

With the help of Jeffrey May, Ph.D.; Kevin Osteen, Ph.D., HCLD(ABB); Jeffrey Boldt, Ph.D., HCLD(ABB); and Dr. Keel, the first director-level andrology and embryology examinations were created and administered on November 4, 1994, in San Antonio, Texas, prior to the 1994 ASRM meeting.

Then, surprisingly, IVF/GIFT laboratories were not specifically mentioned in the CLIA '88 regulations (published on February 28, 1992) as expected by ASRM and SART. This created a period of confusion and uncertainty regarding the regulatory oversight of andrology/embryology laboratories. In 1992, Senator Ron Wyden (D-OR) introduced the “Fertility Clinic Success Rate and Certification Act (HR 3940),” commonly referred to as the “Wyden Bill,” which directed the Centers for Disease Control and Prevention (CDC) to develop a model licensing bill for states to use to license IVF/GIFT laboratories. A debate ensued about whether embryology laboratories met CLIA's definition of a clinical laboratory. In 1994, Dr. Keel obtained an advisory letter from the Health Care Financing Administration (now CMS) that said that in vitro fertilization is **not** covered by CLIA because it is a therapeutic procedure, not a diagnostic procedure.

AAB/ABB took the position that IVF laboratories do perform CLIA-covered laboratory tests; ASRM and SART took an opposite position.

On May 29, 1998, Brooks Keel, Ph.D., HCLD(ABB); Thomas B. “Rusty” Pool, Ph.D., HCLD(ABB); and Mark Birenbaum, Ph.D., attended the May 29, 1998, meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC) in Atlanta, Georgia, where Dr. Pool gave a detailed presentation about the laboratory tests that are performed in IVF laboratories. CLIAC deferred making a recommendation until its September 16, 1998, meeting at which Marybeth Gerrity, Ph.D., HCLD/CC(ABB); Tammie Schalue, Ph.D., HCLD/ELD/CC(ABB); and Brooks Keel, Ph.D., HCLD(ABB), testified in favor of CLIA coverage. Jacob Mayer Jr., Ph.D., HCLD/ELD/CC(ABB), testified against CLIA coverage.

On September 16, 1998, CLIAC voted: 12 in favor, 2 opposed, to recommend CLIA coverage of embryology laboratories and that the College of American Pathologists’ (CAP’s) and ASRM’s accreditation checklist be used as a starting point for the CLIA regulations covering embryology laboratories.

Although this was a significant development, the CLIAC recommendation was not binding. HHS Secretary Donna Shalala still had to accept the recommendation of CLIAC, which she never did. In fact, Secretary Shalala declined to make a decision about CLIA coverage of embryology laboratories, prompting the AAB Board of Directors to file a lawsuit on March 16, 1999, seeking to force HHS to make a decision. ASRM filed an “amicus” brief opposing AAB’s lawsuit. AAB’s lawsuit was dismissed on March 8, 2000, because Judge Thomas F. Hogan

decided that AAB did not have “standing” to bring the lawsuit. Judge Hogan did not rule on the merits of AAB’s case [although he indicated he probably would have ruled against AAB].

To date, the CLIA program has never covered embryology laboratories, or andrology tests performed as part of an assisted reproductive technology procedure.

The 1992 CLIA ’88 regulations also dramatically changed how CLIA-covered laboratories were licensed by designating four categories of laboratory tests: high complexity, moderate complexity, physician-performed microscopy (later changed to “provider-performed” microscopy), and waived.

Anticipating that these categories would become engrained in laboratory nomenclature, in September 1992 ABB changed its director and supervisor certification acronyms as follows:

BLD (Bioanalyst Laboratory Director) became **MCLD** (Moderate Complexity Laboratory Director).

CLD (Clinical Laboratory Director) became **HCLD** (High Complexity Clinical Laboratory Director).

And a new category, **BCLD** (Bioanalyst Clinical Laboratory Director), was created for “generalist” high complexity clinical laboratory directors.

In May 1992, ABB designated 12 specialties/disciplines for ABB certification:

1. Bacteriology (including mycobacteriology)
2. Mycology
3. Parasitology
4. Virology
5. Immunology/Serology
6. Hematology (including flow cytometry)
7. Immunohematology
8. Routine Chemistry (including urinalysis)
9. Endocrinology
10. Toxicology
11. Andrology
12. Embryology

Clinical Molecular Biology (later changed to Molecular Diagnostics) was added on May 7, 1993. On May 13, 1995, bacteriology, mycology, parasitology, and virology were combined into one discipline: Microbiology, and Immunohematology was discontinued. [Historical footnote: on that date, May 13, 1995, ABB approved a subscription to America Online so that ABB could establish an email address.] Endocrinology eventually merged into Immunology; Toxicology was merged into Chemistry; and Public Health Microbiology was added in 2009, yielding the current 8 specialties/disciplines:

1. Microbiology
2. Chemistry
3. Hematology
4. Immunology
5. Andrology
6. Embryology
7. Public Health Microbiology
8. Molecular Diagnostics

On May 7, 1993, ABB began certifying Clinical Consultants (CC) and Technical Supervisors (TS) using the CLIA '88 regulations as a guideline.

On November 5, 1993, ABB divided its director examinations into two parts: Part 1 - General Knowledge and Part 2 - Technical Disciplines. ABB's original General Knowledge examination, which was unique among director certifying boards (and still is), included the following subject areas:

- Laboratory Administration
- Laboratory Finances
- QA, QC, Proficiency Testing
- Standard Operating Procedure Manuals
- Employer/Employee Relations
- Recordkeeping
- Safety
- Hygiene
- Licensure/Accreditation
- Data Processing/Laboratory Information Systems
- Marketing
- Statutes/Regulations, including Fire Codes, Hazardous Waste Disposal, OSHA, etc.

In 1995, ABB certification was recognized in Tennessee; it was already recognized in Florida, but new regulations left out ABB's recognition.

In May 1996 Dr. Pennell Painter suggested that ABB, on a state-by-state basis, seek to have ABB's certification recognized in all state licensure laws for director certification. ABB's efforts were successful, and as of November 2000 the following 15 states specifically mentioned ABB certification in their state laboratory personnel regulations:

- Alabama
- Alaska
- Connecticut
- Florida
- Georgia
- Hawaii
- Kentucky
- Maine
- Massachusetts
- Nevada
- New Jersey
- Oregon
- Pennsylvania
- Rhode Island
- Tennessee

Thirty-three other states used the CLIA regulations (where ABB is recognized), leaving only two states: California and New York that did not recognize ABB.

In July 1996 ABB petitioned California's Laboratory Field Services for a specialty director's license for andrology and embryology. And in 1998, ABB requested that New York's

CLEP program include ABB in its list of recognized boards. ABB wrote to New York's CLEP program on June 10, November 17, and December 2, 1998, and May 1999 requesting recognition of ABB, but received no answer as of May 24, 1999.

ABB's efforts to gain approval from state licensing agencies continued. On May 24, 1999, Florida approved ABB's director examination in Hematology. On November 21, 2004, Florida approved ABB's examination in Andrology and Embryology. In January 2006 Florida approved ABB's examination in Molecular Diagnostics. And in August 2010 Florida approved ABB's director examination in Public Health Microbiology. Currently, all ABB examinations are approved in Florida.

A major victory occurred on November 22, 2009, when California approved all ABB director examinations (except Embryology) for California's Bioanalyst (generalist) laboratory director's license. [California intended to approve ABB's Embryology examination after the California legislature authorized a "specialty" license for embryology laboratory directors. Although several attempts were made to do this, none were successful.] This was especially important because ABB's first executive director, Lucien Hertert (who lived in California) coined the term "bioanalyst," the term California still uses for a licensed clinical laboratory director. Even so, it took over 40 years for ABB to be recognized in California.

And in New York, ABB repeatedly tried to obtain recognition throughout the 1990s and 2000s, but these efforts were not successful. Part of the problem stemmed from three lawsuits the American Association of

Bioanalysis (AAB) filed against the New York Health Department during those years that resulted in New York State refunding, to New York licensed laboratories, over \$23 million in overcharges for laboratory permits. ABB is continuing its pursuit of recognition in New York.

On May 17, 2004, John Boffa, HCLD, was elected chair of ABB, becoming only the second chair of ABB. Mr. Boffa served as chair until May 2013, when Brooks Keel, Ph.D., HCLD, was elected ABB's third chair. In June 2014 Mr. Boffa was elected ABB's "Chairman Emeritus" in recognition of his many contributions to ABB.

ABB made many efforts over the years to collaborate with other laboratory associations, especially IVF societies in other countries. A number of meeting/conversations were held with ALPHA [the European Assisted Reproductive Technology (ART) society] and Red Latinoamericana de Reproducción Asistida (the Latin American ART society) to develop a common international certification program for andrologists/embryologists. ALPHA eventually decided to develop its own certification program, but ABB was partially successful with Red.

On October 14, 2011, ABB's first Spanish language Embryology examinations were administered in Orlando, Florida, but only to applicants who lived and worked outside the United States. Several Andrology and Embryology Review Courses were also conducted in Argentina using a Spanish Review Book, and one ABB Spanish-language examination was administered in Buenos Aires, Argentina, on November 14, 2012. However,

the level of interest was not sufficient to sustain the program, which relied heavily on the volunteer work of Jorge Blaquier, M.D., and his daughter, Isabel Blaquier. Ms. Blaquier, who was very instrumental in the organization and coordination of the review course and ABB certification examination held in Buenos Aires, passed away unexpectedly on September 22, 2012.

In 2012 Kelly Athayde Wirka, M.Sc., TS(ABB), and Christine Silva Allen, Ph.D., M.Sc., TS(ABB), translated AAB's *Andrology & Embryology Review Course Manual* into Portuguese (a tremendous amount of work), but AAB and ABB were not successful in arranging an Andrology & Embryology Review Course and ABB examination in Brazil.

In the 21st century, ABB added several new certifications:

- On November 18, 2001, the first examination in Clinical Molecular Biology [changed to Molecular Diagnostics on November 9, 2003] was administered in Philadelphia, Pennsylvania, prior to the Association of Molecular Pathology (AMP)]. John Hughes, Ph.D.; Linda Sabatini, Ph.D., HCLD(ABB); Dolores Lamb, Ph.D., HCLD(ABB); and Daniel Farkas, Ph.D., HCLD(ABB) guided development of this examination.
- On April 29, 2002, ABB approved an Embryology Laboratory Director (ELD) certification. The ELD was created as an international embryology director certification, i.e., it differed from an HCLD in embryology by not focusing on U.S.

statutes/regulations, instead using practices that were generally recognized in many countries.

- On June 29, 2009, ABB's Public Health Laboratory Director (PHLD) certification in Microbiology was approved by CLIA.

In 2016, ABB entered into discussions with the Association of Medical Laboratory Immunologists (AMLI) to provide a director-level Immunology examination after the American Board of Medical Laboratory Immunology (ABMLI) [the fourth director certifying board recognized in 1992 by CLIA] announced that its Immunology examination would be discontinued after August 2017.

In 2017 ABB and AMLI reached an agreement to work together, using ABB's Immunology examination, to replace ABMLI's Immunology examination. That collaboration begins this year.

Looking forward, ABB is expecting updates/revisions to the CLIA '88 regulations, which have not had a major overhaul since 1992, and the impact of new molecular-based technologies (e.g. Next-Gen Sequencing, Bioinformatics, and CRISPR) on clinical laboratory testing.

ABB expects that huge changes and developments are just down the road. We welcome the help and advice of current (and future) ABB Diplomates and Certificants in meeting these challenges.

Mark S. Birenbaum, Ph.D.

Administrator