

as a qualification requirement for individuals having a doctoral degree to serve as high complexity laboratory directors. These commenters emphasized the role of board certification in ensuring that individuals have specific training and experience, as well as uniform and broad-based clinical knowledge, skills and competencies. In addition, at the CLIAC meeting held on January 30, 2002 through January 31, 2002, CLIAC expressed strong support for board certification for laboratory directors and suggested the recent efforts of the boards to provide more flexible routes to certification would allow more individuals to meet the certification requirements. CLIAC and other commenters also felt that the documentation of continuing education required for retaining board certification is essential in ensuring that individuals maintain the professional abilities needed to direct laboratories that provide services in the multifaceted, constantly changing high complexity testing category. The few comments opposed to board certification indicated certification does not ensure the performance of individuals and that employee skill validation is the responsibility of the employer. These commenters also noted the absence of evidence documenting that certified individuals perform better than noncertified individuals.

Response: We agree with the comments supporting board certification and are maintaining the former requirements at § 493.1443(b)(3)(i) requiring board certification as one of the pathways for qualifying individuals with a doctoral degree as directors of laboratories performing high complexity testing. Although certification does not provide absolute assurance that individuals will effectively fulfill the responsibilities required of directors, it is a recognized benchmark of competency and an appropriate mechanism for qualifying individuals to serve as laboratory directors. In addition, the ongoing continuing education required by each of the HHS-approved boards to retain certification helps ensure these individuals maintain a current knowledge base.

Comment: A State Health Department and one laboratory professional organization requested that all HHS-approved boards and the criteria for board approval be listed in the regulations. One of these commenters asked whether the phrase “* * * be certified and continue to be certified * * *” included in the proposed rule at § 493.1443(b)(3)(i) means that HHS will

require board recertification when required by an HHS-approved board. In addition, a few commenters disagreed with board recertification.

Response: A total of eight certification boards have been approved by HHS. Four boards are listed in the former regulations at § 493.1443(b)(3)(i): The American Board of Medical Microbiology; the American Board of Clinical Chemistry; the American Board of Bioanalysis; and the American Board of Medical Immunology. On July 8, 1996, we published a notice in the **Federal Register** (61 FR 35736), that announced HHS approval of two boards: The American Board of Histocompatibility and Immunogenetics and the American Board of Medical Genetics. In this final rule, we are announcing HHS-approval of two additional boards: the National Registry for Clinical Chemistry at the doctoral level and the American Board of Forensic Toxicology. However, in this final rule, we are deleting the reference at § 493.1443(b)(3)(i) to the specific boards approved by HHS. Currently, all HHS-approved boards are listed on the Internet at <http://www.cms.hhs.gov/cliadirc/con.asp>. In the future, boards approved by HHS will also be listed in Appendix C of the State Operations Manual (CMS Pub. 7), subpart M. Removing the list of approved boards from the regulations and placing the list in Appendix C will allow greater flexibility to update the list of HHS-approved boards.

In response to the comments suggesting that the criteria for determining HHS-approval of certification boards be included in the regulations, we do not believe that regulations, which specify standards that must be met by covered entities, should include details of an administrative process. All boards approved by HHS have been determined to have comparable certification requirements. In the “Conditions for Coverage of Services of Independent Laboratories” published in the September 19, 1974 **Federal Register** (39 FR 33693), the laboratory director qualification requirements included provisions for qualifying individuals with a doctoral degree. One option was certification by one of three boards (American Board of Medical Microbiology, the American Board of Clinical Chemistry, and the American Board of Bioanalysis). Subsequently, all boards approved by HHS have been determined to have certification requirements comparable to those three boards originally recognized. Any board may request HHS approval by submitting their request for board

certification to CMS. This information will be evaluated to determine if the board’s certification requirements are comparable to those currently approved boards.

With respect to requiring recertification, it was always the intent of the former regulations, that individuals with a doctoral degree qualifying under § 493.1443(b)(3)(i) must be, and continue to be, certified by an HHS-approved board. If a board requires recertification and an individual fails to recertify and loses board certification, this individual would no longer meet the director qualification requirement at § 493.1443(b)(3)(i). In this final rule, and as proposed in the December 28, 2001 proposed rule, we are revising the language at § 493.1443(b)(3)(i) for clarification.

Comment: A number of comments agreed with the second provision (at proposed § 493.1443(b)(3)(ii)) allowing individuals having a doctoral degree, who are serving or have served as directors of laboratories performing high complexity testing under the current regulations’ phase-in provision, to continue to qualify without obtaining board certification. However, a few commenters felt this provision should be temporary, with a date specified by which board certification would be required to maintain qualification. One commenter urged that a date be established (and not extended) to conclude this qualification provision. A State Health Department interpreted the requirements in this provision to mean that a total of 4 years of experience is required, and that the training and experience and director and/or supervisory experience cannot be gained concurrently. This commenter also suggested this experience be postdoctoral experience.

Response: We agree the second proposed qualification provision is needed to allow (“grandfather”) individuals who have served or are currently serving as directors of high complexity testing to continue to serve. We also agree that a date needs to be specified to conclude this qualification pathway and the training and experience requirements clarified; however, we do not agree that the training and experience must be postdoctoral. We believe laboratory training and experience obtained while an individual is working toward obtaining a doctoral degree is pertinent and appropriate, and should be considered as meeting the requirement.

In this final rule, at § 493.1443(b)(3)(ii), we are specifying February 24, 2003, as the effective date