

laboratory training during medical residency to be 17,400. In addition, ABMS reports 5,784 pathologists received board certification over the past 10 years. This number is consistent with the Accreditation Council for Graduate Medical Education's (ACGME) data indicating there are approximately 2,660 anatomical and clinical pathology residents enrolled through the current academic year (ending June 2002). These residents will be eligible for board certification over the next 4 years.

The total number of board-certified doctoral-degreed individuals is estimated to be 2,090 (American Board of Bioanalysis (ABB), American Board of Clinical Chemistry (ABCC), American Board of Forensic Toxicology (ABFT), American Board of Medical Genetics (ABMG), American Board of Medical Laboratory Immunology (ABMLI), American Board of Medical Microbiology (ABMM), and National Registry of Certified Chemists (NRCC)). In addition, one HHS-approved board reports an average of 8 individuals receiving certification annually, another board reports an average of 11 annually, and a third board reports 37 annually (AAB, ABCC, ABFT, ABMLI, ABMM, NRCC, personal communication, March 2002).

Based on the data provided by the HHS-approved boards, ABMS, and ACGME, we believe there will be a sufficient number of individuals available to fill the possible 750 high complexity laboratory director vacancies per year over the next 5 years. Moreover, only 5 percent of the COC high complexity laboratories currently employ a laboratory director with a doctoral degree. We believe the percentage of COA and Washington State high complexity laboratories employing a laboratory director with a doctoral degree may be about the same or lower. Therefore, we estimate that approximately 180 of the 958 COC, COA, and Washington State high complexity laboratories that employ a doctoral-degreed individual as a laboratory director may have to replace their director during the next 5 years (36 annually). We did not include the high complexity laboratories in New York because they require laboratory directors to have "specific" training or experience in the specialty(ies) of testing the laboratory performs.

Benefits

Impact

There will be no immediate impact because the second provision included in this final rule allows individuals who have served or are currently serving as

laboratory directors and have at least 2 years of training or experience, or both, and 2 years of experience directing or supervising high complexity testing to continue in their capacity without obtaining board certification. This provision circumvents the costly and disruptive burdens associated with currently employed individuals obtaining board certification and laboratories, which perform high complexity testing, replacing currently serving directors.

With regard to future impact, available data indicate there are ample numbers of qualified individuals available to fill the estimated annual high complexity laboratory director vacancies over the next 5 years. In addition, the CLIA regulations permit qualified individuals to direct up to five laboratories, which may further lessen the burden associated with replacing retiring laboratory directors. However, States and accrediting organizations may have more stringent qualification requirements for laboratory directors and affected laboratories would need to continue to meet these requirements.

Costs

The provisions in this final rule at § 493.1443(b)(3), will have no immediate costs, and we believe the costs over the next 5 years will be no greater than the costs laboratories performing high complexity testing currently experience when replacing directors.

Alternative Approaches

In the December 28, 2001 proposed rule, we considered qualifying individuals with a doctoral degree and 6 years of laboratory training and experience, or both (including 2 years experience directing or supervising high complexity testing), as directors of laboratories performing high complexity testing. While we offered this as an alternative qualification pathway, we agree with the majority of commenters and the CLIAAC recommendation that the provision is not commensurate with the responsibilities of a high complexity laboratory director or consistent with the qualification requirements and responsibilities specified for the other CLIA laboratory personnel categories. Moreover, we have determined that this qualification pathway is not needed to ensure a sufficient pool of qualified individuals to serve as high complexity laboratory directors and thus continued access to high complexity testing.

5. Miscellaneous Changes

The reorganization of this final rule reflects the flow of laboratory testing

(from receipt of the specimen through test performance, test reporting and systems' assessments), eliminates duplicative requirements, and rewords certain requirements. In response to comments received to previous rulemakings, wherever possible we have made changes to the regulations to reduce the burden and expense to laboratories. Also, in recognition of new and emerging technologies and methodologies, obsolete requirements have been deleted and a few new requirements have been added. Listed below are several of these revisions, not yet discussed in this impact analysis, which may result in some change in costs or burden for laboratories. While we believe the change in costs or burden, or both, will be relatively minor, lack of data and information makes these estimates either difficult or impossible to quantify.

Revisions Resulting in No Change in Burden and Costs

The FDA QC review process was intended to be implemented when the QC phase-in ended, but we established through our survey process that the review would be not be of benefit to laboratories. Because this review was not implemented, there is no impact.

- Records of test system performance specifications established or verified as required under § 493.1253 must be retained for the period of time the test system is in use. Because this information provides important data about the laboratory's test system performance (for example, accuracy, precision, and reportable range of patient results) that the laboratory is required (formerly at § 493.1109(g), now at § 493.1291(e)) to provide to clients upon request, laboratories should have already been maintaining this information. Therefore, there is no additional burden with this change.

- When a laboratory transcribes or enters test requisition or authorization information into a record or information system, it must ensure that the information is transcribed or entered accurately. Formerly at § 493.1701, laboratories were responsible for identifying and correcting problems and ensuring accurate, reliable, and prompt reporting of test results. Inaccurate transcription of test requisition or authorization information would be one example of a problem, if left uncorrected, that could interfere with both the reporting of test results and the accuracy of the results. For this reason, we believe this new requirement should have no impact on the laboratory's burden or costs.