

practitioners, nurse midwives, and physician assistants, be included in the PPM subcategory. The CLIAC suggested that these midlevel practitioners be permitted to perform PPM procedures under the supervision of a physician or to function independently in States that authorize individual practice.

In view of the CLIAC recommendation and the CDC evaluation that nurse midwives, nurse practitioners and physician assistants receive sufficient training to properly perform and interpret the microscopic examinations currently included in the PPM subcategory, we are adding midlevel practitioners to the PPM subcategory. We define them in § 493.2 as nurse practitioners, nurse midwives and physician assistants, licensed by a State if such licensing is required.

As a result of the comments received, we also considered the inclusion of dentists in the PPM subcategory. After evaluating the education and training that dentists receive in clinical laboratory procedures, we concluded that dentists, with either a Doctor of Dental Medicine (DDM) or Doctor of Dental Surgery (DDS) degree, are qualified to perform the examinations in the PPM subcategory and we are adding dentists as persons who may perform PPM procedures.

Upon evaluation of the education and training of emergency personnel, registered nurses, licensed practical nurses, and medical assistants, we determined that these practitioners do not receive sufficient training to properly perform and interpret the microscopic examinations currently included in the PPM subcategory. For this reason, we are not adding them as persons who may perform PPM procedures.

Changes to the Regulations

To accommodate the above additions, we are changing the name from "physician-performed microscopy procedures" to "provider-performed microscopy procedures."

To be consistent with other personnel requirements, we are moving the personnel requirements for the PPM subcategory, formerly located at § 493.16(e)(2) (§ 493.16(e)(3) is redesignated as § 493.19(e)(2)), to subpart M. At § 493.1355, we are specifying the condition requirements for laboratory director of PPM procedures, with director qualification requirements located at § 493.1357 and director responsibilities at § 493.1359. To the director responsibility requirements, we are adding the requirement limiting the number of laboratories that an individual can

direct to five, which was inadvertently not included in previous regulations; currently, directors of laboratories performing other moderate complexity testing may only direct five. The condition requirements for testing personnel performing PPM procedures are now located at § 493.1361, while testing personnel qualifications are located at § 493.1363 and responsibilities are at § 493.1365.

We are also making numerous conforming changes to part 493 to accommodate the revision to include midlevel practitioners and dentists. We are revising the following additional sections and headings: §§ 493.2—definition of "CLIA certificate—certificate for physician-performed microscopy procedures" by adding "dentist" and "midlevel practitioner", and revising "physician" (for consistency to include doctors of osteopathy and to require the physician to be licensed in the State in which the laboratory is located); 493.20(b); 493.25(c) (redesignated from 493.25(d)); heading for subpart C; 493.43 heading; 493.45(a)(2); 493.47; 493.49(a)(3); 493.53 heading and introductory paragraph; 493.638; 493.639(b); 493.643(a); 493.646(a); 493.1776 heading and paragraphs (a) (3) and (4) and (b); 493.1814(b)(3); 493.1834(b) and (f)(2)(iii); and 493.1836(c) (2) and (3).

2. General Discussion of General Supervisor and High Complexity Testing Personnel Comments

In response to the personnel requirements contained in the final regulations published February 28, 1992, we received approximately 55,000 comments from individuals and organizations. The qualification requirements for general supervisor and high complexity testing personnel received the most extensive comments. Approximately 8,000 comments concerned general supervisor, 14,000 comments related to high complexity testing personnel and more than 10,000 comments pertained to testing personnel, with the complexity of testing not specified. Some commenters indicated that the regulations were too stringent, while others thought the requirements were too lenient. Among the commenters who thought that the minimum qualifications should be raised, there was a general consensus that the increase in requirements should be prospective and that the regulations should include alternative qualifying pathways to avoid affecting currently employed individuals adversely. Many commenters were concerned that the regulations would eliminate the jobs of many laboratory employees who possess

extensive work experience but lack the requisite degree or formal laboratory training. This would particularly exacerbate the shortage of qualified laboratory personnel in rural and underserved areas and limit patient access to testing.

In evaluating the many comments, we sought advice from the CLIAC concerning whether changes were needed in the regulations pertaining to general supervisor and high complexity testing personnel. Many individuals and organizations provided detailed information and suggestions to CLIAC about the qualifications that should be required for supervision and performance of high complexity testing. The CLIAC recommended revising the regulations to recognize currently employed individuals who do not meet the qualifications contained in the final regulations but who have clinical laboratory training and extensive laboratory experience.

We acknowledge that extensive experience can qualify individuals to competently perform these functions. Therefore, in response to the comments provided to the regulations published February 28, 1992, and to the CLIAC advice, and to mitigate the impact of the regulations on currently employed people, especially those in rural and underserved areas, we are making in this regulation the changes necessary to provide alternative qualification pathways.

We are revising the general supervisor (§ 493.1461) and high complexity testing personnel (§ 493.1489) requirements to: qualify individuals currently performing high complexity testing and those currently employed general supervisors if they have the requisite laboratory training or experience; recognize 50-week U.S. military medical laboratory training programs and accredited laboratory training programs; and establish equivalent requirements for the associate degree. More specific comments and responses concerning revisions to the regulations to create alternative qualifications for general supervisor and high complexity testing personnel follow.

We also are making conforming cross-reference changes to §§ 493.1463 and 493.1495.

3. Specific Comments and Responses General Supervisor Qualifications

Comment: Although many commenters agreed that the minimum requirement for general supervisor should be an associate degree in clinical laboratory science or medical laboratory technology, others indicated that the