Other Revisions to the Regulations

Currently, PPM procedures are subsumed in the category of moderate complexity, with changes made to moderate complexity testing requirements as needed. To aid readers in finding requirements pertinent to their needs, we have created a discrete subcategory of requirements for PPM procedures, by breaking out the requirements for PPM as necessary.

Currently, a laboratory that meets the requirements to perform high or moderate complexity tests is issued a "certificate". We also have certificates for PPM procedures. For clarity, to distinguish between the generic use of the word certificate and the type of certificate issued to a laboratory that performs tests of moderate or high complexity, or both, we are changing "certificate" (for tests of moderate or high complexity, or both) to "certificate of compliance." This is the certificate that will be issued following the determination of successful compliance with the CLIA regulations for testing that includes moderate and/or high complexity. Where necessary, we make revisions concerning each specific certificate and/or subcategory (including waived tests). We are changing, as required, references to specific certificates to refer to "appropriate" certificates.

We make these technical changes in the following existing sections and headings: §§ 493.2, definition of "certificate" under "CLIA certificate"; 493.3(a)(1); 493.5(a)(2) and (c) (formerly 493.10); 493.20(a) and (b); 493.25(c) (formerly 493.25(d)); subpart C heading; 493.43 heading and paragraph (a); 493.45 introductory paragraph and paragraphs (a)(1), (2) and (3) (the last is deleted) and (d) and (f); 493.49; 493.51 heading, introductory paragraph, and paragraphs (b) and (c); 493.55(a); 493.57 introductory paragraph and subparagraph (b)(1)(ii); 493.511(h); 493.521(j); 493.602; 493.638; 493.639(b); 493.643(d); 493.645 heading and paragraph (c) (redesignated from paragraph (a)(2)); 493.646(a); 493.649(a) and (b); subpart H heading; 493.803(a); 493.807 heading; subheading preceding 493.821; subpart I heading; subpart J heading; 493.1101, including the heading; subpart K heading; 493.1201 heading; subpart M heading; subpart P heading; 493.1701, including heading; 493.1777 heading, introductory paragraph and paragraphs (a) and (g); 493.1814(b)(3); 493.1834(b) and (f)(2)(iii); 493.1836(c)(2) and (3); and 493.2001.

B. Personnel

1. Physician-Performed Microscopy Procedures

Comment: Approximately 68 percent of the 2,200 comments received in response to the regulation establishing PPM addressed personnel requirements, especially expansion of the PPM subcategory to include other health care practitioners. The comments were divided between individuals who suggested expansion of PPM to include other health care professionals and those commenters who believed that PPM should be limited to physicians. While national laboratory organizations and individual laboratory professionals commented that PPM should be limited to physicians, professional organizations representing physicians and midlevel health care practitioners stated that PPM should be expanded to include other health care providers. We also received comments requesting that dentists be included in PPM to allow them to perform wet mount examinations as part of their dental evaluations.

Several commenters representing physicians and midlevel health care practitioners included information and responded to questions posed in the preamble to the January 19, 1993, **Federal Register** rule creating the PPM subcategory. In that publication, we specifically asked commenters to comment on the type of health care professionals who usually perform the PPM tests as part of a physical examination, how often the tests are performed, and the quality, access and cost implications in establishing the PPM subcategory.

The commenters who responded to these questions stated that depending on the type of health care setting, physicians, or quite often nurse practitioners, nurse midwives, or physician assistants, perform physical examinations and the laboratory tests related to these examinations. In some cases, State laws authorize these midlevel practitioners to practice independently. These commenters added that, because of the variety of settings, it is impossible to estimate the percentage of testing done by each group of health professionals. However, they did say that many midlevel practitioners perform patient examinations and certain microscopic tests on a daily basis and in equal or greater numbers than physicians in some places. They also said that midlevel practitioners receive the training needed to perform these tests and the quality of their test results is at least equivalent to testing performed by

physicians. Commenters indicated that, in addition to the physicians and the midlevel practitioners listed above, emergency personnel, registered nurses, licensed practical nurses, and medical assistants perform PPM tests. Commenters indicated that although the cost of testing might vary, this was not related to who performed the test.

Lastly, the commenters stressed that the quality, cost and access implications of not including midlevel practitioners under the certificate for the PPM subcategory were extensive, especially in rural areas, among low-income populations, and in other areas where there is a shortage of physicians. In some of these settings, midlevel practitioners are the only available health care providers. Excluding these professionals from obtaining a certificate for the PPM subcategory has substantial cost implications. Since laboratories that have a certificate for the PPM subcategory are not subject to fees for routine inspections, the cost of providing services under the PPM certificate is lower than under a certificate of compliance. If facilities cannot afford to provide testing under a certificate of compliance, patient access to health care would be limited.

Response: In considering these comments, we sought the advice of the CLIAC. In an effort to provide an opportunity for public discussion and consideration of these issues, we scheduled two CLIAC meetings on the PPM subcategory. Presentations were made by HHS, and the public was invited to comment and provide information. The CLIAC recommended that individuals and organizations representing practitioners seeking to be included in the PPM subcategory submit documentation concerning the specific course work and the amount of training such individuals receive in the performance of microscopic examinations. Over 100 individuals and organizations responded to the request for information, with many of the commenters providing documentation of specific training curricula in microscopic procedures. The CLIAC asked CDC to evaluate the materials submitted. In reviewing the training programs of nurse midwives, nurse practitioners and physician assistants, CDC concluded that these practitioners, like physicians, perform the procedures currently included in the PPM subcategory in conjunction with patient evaluations, and the training they receive in microscopic examinations is comparable to that of physicians. The CLIAC considered this information and recommended that midlevel practitioners, defined as nurse