DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AH25

Veterans Education: Establishing Eligibility Under the Montgomery GI Bill—Active Duty

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Vocational Rehabilitation and Education regulations to reflect the statutory requirement that individuals seeking to establish eligibility for educational assistance under the Montgomery GI Bill—Active Duty through a combination of active duty service and service in the Selected Reserve must enter the Selected Reserve within one year of discharge from active duty.

EFFECTIVE DATE: December 18, 1989, the date this requirement became effective.

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer, Assistant Director for Policy and Program Administration, Education Service, Veterans Benefits Administration (202) 273–7187.

SUPPLEMENTARY INFORMATION: The Secretary of Veterans Affairs hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), the amended regulations, therefore, are exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604. This final rule merely reflects statutory requirements. Further, the final rule affects only individuals, and does not directly affect small entities.

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: March 21, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 21, subpart K is amended as set forth below.

PART 21—VOCATIONAL REHABILITATION AND EDUCATION

Subpart K—All Volunteer Force Educational Assistance Program (New GI Bill)

1. The authority citation for part 21, subpart K continues to read as follows:

Authority: 38 U.S.C. chapter 30, Pub. L. 98–525, 38 U.S.C. 510(a).

2. In § 21.7042 paragraph (b)(4) and its authority citation are revised to read as follows:

§ 21.7042 Basic eligibility requirements.

* * * * *

(b) * * *

(4) Except as provided in paragraph (b)(7) of this section, after completion of active duty service, the individual must serve at least four continuous years of service in the Selected Reserve. An individual whose release from active duty service occurs after December 17, 1989, must begin this service in the Selected Reserve within one year from the date of his or her release from active duty. During this period of service in the Selected Reserve the individual must satisfactorily participate in training as prescribed by the Secretary concerned.

(Authority: 38 U.S.C. 3012(a)(1); Pub. L. 100–689, Pub. L. 101–237)

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[FR Doc. 95–9990 Filed 4–21–95; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 493

[HSQ–216–FC]

RIN 0938–AG71

CLIA Program; Categorization of Tests and Personnel Modifications

AGENCY: Health Care Financing Administration (HCFA) and Public Health Service (PHS), HHS.

ACTION: Final rule with comment period.

SUMMARY: In this rule we are responding to some of the comments on categorization of tests and personnel requirements received in response to rules published on February 28, 1992 and January 19, 1993. (In a future rule, we will be responding to the remaining comments.) We are revising our regulations to: Allow dentists and midlevel practitioners to perform tests in the ''physician-performed'' microscopy (PPM) subcategory of moderate complexity procedures (we now call the subcategory ''provider-performed''); include three additional tests in PPM; and expand provisions relating to general supervisor and high complexity testing personnel.

DATES: *Effective date:* These regulations are effective April 24, 1995.

Comment date: Comments on the addition of three PPM tests will be considered if we receive them at the appropriate address, as provided under **ADDRESSES**, no later than 5 p.m. on June 23, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ–216–FC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201,

or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–216–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

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783–3238 or by faxing to (202) 275–6802. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Rosemary Bakes-Martin, (404) 488–7655, for questions regarding the addition of the three PPM tests; Rhonda S. Whalen, (404) 488–7655, for questions regarding personnel; and Judy Yost, (410) 597–5907, for certificate, fee, and inspection issues.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings must meet certain requirements to perform the examination. Many of the requirements are based on the complexity of the tests performed. There are currently three test categories: Waived, moderate complexity, including the subcategory of physician-performed microscopy, and high complexity.

Following the publication on February 28, 1992 (57 FR 7002) of the initial regulations implementing CLIA, HHS established a Clinical Laboratory Improvement Advisory Committee (CLIAC) to advise and make recommendations on technical and scientific aspects of the regulations. The CLIAC is composed of individuals involved in the provision of laboratory services, use of laboratory services, development of laboratory testing devices or methodologies, and others as approved by HHS. In addition, HHS has designated the following four CLIAC subcommittees: cytology; personnel; proficiency testing, quality control and quality assurance; and test categorization.

The CLIAC meets as needed, but not less than once a year. So far, the CLIAC has met in October, 1992, February, May, August, and December, 1993, and March and September, 1994. The subcommittee on test categorization has met in January and June, 1993; the subcommittee on cytology has met in December, 1993; and the subcommittee on proficiency testing, quality control, and quality assurance has met in March and September, 1994.

Following publication of the February 28, 1992 regulations, we received approximately 16,000 letters from professional organizations and individuals that provided around 71,000 comments. In response to public comments received concerning certain physician performed microscopy procedures, we requested the CLIAC to evaluate the categorization of these tests. As a result, we developed a new subcategory of moderate complexity testing, called physician-performed microscopy (PPM) procedures, and published the requirements concerning the subcategory in a rule on January 19, 1993 (58 FR 5215).

In this rule, we address the comments we received concerning the application of certain personnel requirements and comments concerning categorization of PPM tests. One area of commenter concern was that currently employed supervisors and high complexity testing personnel continue to be qualified. Another area of concern was that our requirements would diminish access to services, particularly in rural and underserved areas, leading to recommendations that we expand the PPM procedures subcategory to include dentists and midlevel practitioners.

II. Responses to Comments

A. Categorization: Physician-Performed Microscopy Procedures

As stated earlier, we established a new subcategory of moderate complexity testing called ''physician-performed microscopy (PPM) procedures'' in revisions to the CLIA regulations, published in the **Federal Register** on January 19, 1993. In response to the regulation establishing PPM, we received approximately 2,200 comments from professional organizations and individuals. A significant number of these comments addressed the tests categorized as PPM procedures, including requests that some of these tests be waived, or that additional tests be added to the list of PPM procedures. Some commenters asked that PPM be expanded to include specific tests related to a particular medical specialty or practice. Conversely, other commenters were opposed to adding additional tests or criteria to PPM, and felt that this subcategory should remain very limited.

Comments and Responses

Comment: A number of commenters stated that PPM is too restrictive, and that all of the PPM procedures should be categorized as waived tests. Some commenters specifically stated that wet mounts and urine sediment examinations should not be in PPM but should be waived tests.

Response: Tests included in PPM are moderate complexity microscopic examinations that do not meet the criteria for waiver because they are not simple procedures; they require training and specific skills for test performance. Personnel performing these tests must be proficient in the use of a microscope and must be able to detect and identify cellular elements present in a specimen, both of which require substantial training, experience, and specific knowledge to be accurately performed. To differentiate significant elements in a specimen from debris or artifacts requires a high level of interpretive skills. In fact, personnel requirements for this subcategory of moderate complexity testing are more stringent than for other moderate complexity testing due to the nature of testing in PPM. Examinations of wet mount preparations and urine sediment were included in PPM because they meet the PPM criteria. These microscopic examinations are performed during a patient's physical examination on specimens that are labile or not appropriate to send to another laboratory for analysis. In addition, controls are generally not available to monitor the complete testing process for these procedures. Therefore, only limited activities are suitable for inspection.

Comment: Several commenters expressed confusion as to which examinations are considered ''wet mount examinations''.

Response: We are revising the description of ''wet mount examinations'' at § 493.19(c)(1) (formerly § 493.16(c)(1)), to clarify what we mean by wet mount preparations. Although we provided the examples of vaginal, cervical or skin specimens as part of the wet mount definition, we never intended to limit wet mount examinations to only these specimens. By revising the definition of this test, we are not making any changes in what was originally intended for this group of examinations. They are moderate complexity microscopic examinations performed on any direct specimen that may be suspended in a drop of water or saline. They are performed using a microscope, which is limited to bright-field or phase-contrast, in order to recognize the presence or absence of bacteria, fungi, parasites, and human cellular elements (including red and white blood cells, epithelial cells, etc.) and to differentiate these from artifacts. They are not procedures in which definitive identification or enumeration is made or any staining is performed.

Comment: A number of commenters requested that additional tests be added to PPM. Microscopic tests that were suggested include synovial fluid analysis, qualitative and quantitative semen analysis, nasal smears or sputum for eosinophils or basophils, wet mount examination of prostatic fluid or secretions, stools for leukocytes, scabies examinations, Gram stain, Tzanck preparations, white blood cell counts and leukocyte differentials, microscopic examinations of hair morphology, dark-field examinations and molluscum smears. A number of non-microscopic procedures were also requested, including microbiology cultures, serum glucose and BUN levels, qualitative drug screens, a variety of serologic tests, and miscellaneous tests performed using hand-held or elementary instrumentation.

Other organizations and professionals were opposed to adding tests or criteria to PPM. Two organizations suggested explicit language to limit procedures included in PPM to specific microscopic examinations and exclude any testing that involves automated instrumentation or biochemical reactions.

Response: Tests in PPM are limited to specific microscopic examinations that are moderately complex procedures and meet the criteria for PPM. Most of the tests named by commenters for addition to PPM do not meet these established criteria. However, nasal smear examinations for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility) do meet the criteria for inclusion in PPM. They are all moderate complexity microscopic examinations that are performed during the course of a patient examination. They are performed on labile specimens, require very limited specimen processing and handling, and controls are not available to monitor the entire testing process. Fecal leukocyte examinations and qualitative semen analyses are actually forms of wet mount examinations. The CLIAC recommended that these three examinations be included in PPM, and HHS agrees with CLIAC that these procedures meet the PPM criteria. The other examination that the CLIAC recommended be added to PPM, the wet mount examination of expressed prostatic secretions, is now included in PPM because it meets the clarified definition of wet mounts in § 493.19(c)(1). Tests that the CLIAC reviewed, and recommended not be included in PPM, are the Gram stain, quantitative semen analysis, histodermatology slides, white blood cell (WBC) differential, and polarization of synovial fluid for crystals. These examinations do not meet the criteria for inclusion in the PPM subcategory. The quantitative semen analysis, histodermatology slides, and polarization of synovial fluid for crystals are all high complexity procedures. Although some Gram stains and WBC differentials are categorized as moderate complexity, these examinations do not meet the additional criteria required for inclusion in PPM. They are not performed on labile specimens, and quality control materials are readily available for Gram stains and WBC differentials. Both of these examinations are performed on specimen preparations that must be stained in order to differentiate and identify cellular elements. These staining procedures require multiple, critical steps. Therefore, HHS concurs with the CLIAC recommendations that these tests not be included in the PPM subcategory, and has not added these tests to the list of PPM examinations.

Comment: Several organizations requested that tests relevant to specific medical specialties, including pediatrics, internal medicine, family practice, rheumatology, and infectious disease, be added to PPM for physicians with appropriate training.

Response: The CLIAC considered a proposal by HHS to expand PPM to include additional medical specialty-specific microscopic examinations when performed by physicians with specialty training. The CLIAC recommended that PPM not be expanded to include medical specialty-specific procedures, due to the difficulty in establishing a mechanism to assure adequate training and competency in performing each of these specialized procedures. HHS agrees with this recommendation and we have not added medical specialty-specific procedures to PPM; however, physicians may continue to perform these procedures in accordance with the applicable requirements for the level of complexity in which the test is categorized.

Comment: One organization stated that, in order to contain costs, physicians should be able to perform essential laboratory tests in their offices without restrictions and recommended that a free-standing physician category be established with the range of tests performed in each laboratory based on the physician's specialty, training and experience. The organization indicated that there should be no specific test list; any testing other than cytopathology would be included in this category. Testing could be performed by the physician, or by other personnel under the direction and control of the physician. Quality control and proficiency testing would be required, and laboratories would be subject to on-site inspections if it was suspected that they were not in compliance with the regulations.

Response: The CLIA regulations were developed in an effort to ensure the quality of laboratory services in every testing situation and assure that accurate and reliable testing is available to all patients. To do this, minimum requirements were established for laboratory testing that, in accordance with the law, depend on the complexity of the procedures being performed and are independent of the testing location. As test procedures become more complex, more stringent testing requirements are imposed. PPM contains a unique group of microscopic procedures that are routinely performed in the course of a patient examination. They are tests for which it is difficult to enforce regulatory requirements because biological controls that monitor the entire testing process are not readily available and because the inspection process would interfere with a patient examination. The PPM subcategory was established to exempt physicians (and, as discussed below, mid-level practitioners and dentists are now included) from the requirement for routine inspections if the PPM procedures are the only tests, in addition to waived tests, that they perform. Physicians, mid-level practitioners, and dentists are not prohibited from performing other laboratory procedures in their offices or clinics. However, for procedures that can be regulated through an inspection process, routine inspections are required, since this is one mechanism to assure that the quality of testing is maintained.

Changes to the Regulations

In this regulation, we have moved the PPM subcategory, formerly located at § 493.16, to a new § 493.19.

In the list of PPM procedures now located at § 493.19(c), we are changing the description of wet mounts at § 493.19 (c)(1) to clarify the types of examinations that are included in this procedure. Also, to the list of PPM procedures, we are adding three tests: nasal smears for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

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

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

requirement should be an associate degree with area of study not specified. Some commenters said that requirements equivalent to the associate degree should be established. Several commenters indicated that individuals having a bachelor of arts or education degree with a specified number of science courses should be qualified.

Response: We agree with the commenters who suggested the establishment of requirements equivalent to the associate degree with appropriate study in the sciences because we believe individuals who have completed the requisite courses and training are qualified to supervise high complexity testing. In this regulation, we are defining the following as equivalent to the academic requirements for an associate degree: 60 semester hours, which must include either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and twelve semester hours of courses in chemistry, biology or medical laboratory technology, or any combination. In addition, individuals must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours specified above) or three months of documented training in each specialty in which the individual performs high complexity testing. We are specifying the equivalent requirements for the associate degree under high complexity testing personnel, which are adopted by cross-reference to the general supervisor requirements. Therefore, individuals who do not have a degree or who have a bachelor's degree that is not in a science can now qualify as a general supervisor if they meet the equivalency requirements for an associate degree and have at least two additional years of laboratory training or experience in high complexity testing.

Comment: Many commenters recommended qualifying medical laboratory technicians without an associate degree to serve as general supervisor. Some commenters recommended qualifying individuals, including certified laboratory assistants, who received training in an accredited hospital or approved technical school training program. Other commenters recommended qualifying individuals with military training.

Response: We agree with the commenters that the regulations should recognize individuals who were serving as a general supervisor of high complexity testing on or before September 1, 1992 (the effective date of the CLIA personnel regulations) but do not have an associate degree, or equivalent, provided they have completed an accredited clinical laboratory training program. We believe individuals having this training and experience have the appropriate qualifications to serve as a general supervisor. Therefore, we are adding a provision to the general supervisor qualification requirements to qualify individuals who, on or before September 1, 1992, were serving as a general supervisor of high complexity testing. The individual must on or before April 24, 1995, have completed a 50-week U.S. military medical laboratory training program or have graduated from a medical laboratory or clinical laboratory training program accredited by the Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation or other organization approved by HHS. To help assure equivalency to other qualification pathways, individuals having this type of training are required to have two additional years of laboratory training or experience in high complexity testing in order to qualify as general supervisor. This additional training or experience may be acquired before or after completing the accredited or U.S. military medical laboratory training program.

Comment: Several commenters misread the regulations and thought that individuals qualified under regulations published March 14, 1990 (55 FR 9576) were required to obtain an associate degree.

Response: Individuals who qualified as general supervisors under the previous Federal regulations are qualified under these regulations and are not required to obtain an associate degree.

Comment: Some commenters recommended that all laboratory personnel currently employed as general supervisors be qualified through a ''grandfather'' provision.

Response: We agree with the commenters and the CLIAC recommendation that regulations should include provisions to allow currently employed supervisors who have pertinent laboratory experience to continue their employment. We are adding a provision to the general supervisor requirements to qualify high school graduates, or equivalent, who, on or before September 1, 1992, were serving as a general supervisor and have at least ten years of laboratory training or experience in high complexity testing, including at least 6 years of supervisory experience in high complexity testing within the last 10 years because we believe this amount of experience is appropriate to qualify individuals as general supervisors and is commensurate with the general supervisor responsibility requirements.

Comment: A few commenters agreed with the responsibilities for general supervisor, while a few commenters disagreed. Most of the commenters who disagreed with the responsibilities were opposed to requiring the general supervisor to be onsite when high complexity tests are performed by personnel who do not have at least an associate degree. Conversely, many commenters indicated that an individual with an associate degree should be allowed to perform high complexity testing only when a technologist or supervisor is onsite.

Response: In the revised regulation published in the **Federal Register** on January 19, 1993, we changed the requirement for onsite supervision to require 24-hour review of any high complexity testing performed by personnel who do not have at a minimum an associate degree and were performing high complexity testing on or before January 19, 1993. However, in the January 19, 1993 regulation, we retained the onsite supervision requirement for those high school graduates, or equivalent, who began performing high complexity testing after January 19, 1993. In this regulation, we are not changing the requirements for onsite supervision or 24-hour review. However, we believe individuals who have completed accredited or 50-week U.S. military medical laboratory training programs or have academic qualifications equivalent to the associate degree are qualified to perform high complexity testing. Therefore, we are revising the regulations to qualify as high complexity testing personnel individuals having these qualifications. Individuals who qualify under these new provisions may perform high complexity testing without onsite supervision or 24-hour review.

We do not agree with the commenters that onsite supervision should be required for high complexity testing performed by individuals having an associate degree; such a requirement would be unnecessarily burdensome and could exacerbate personnel shortages and limit patient access to testing. It should be emphasized that these are minimum requirements that do not restrict laboratories from establishing their own policies requiring higher personnel qualifications. In all cases, the laboratory director is responsible for ensuring that all testing

personnel have the necessary education and training or experience required for test performance.

Testing Personnel Qualifications (High Complexity)

Comment: Numerous commenters believed an associate degree in laboratory science or medical laboratory technology should be the minimum education requirement. Several commenters suggested recognizing associate degrees in fields other than clinical laboratory science or medical laboratory technology, with others suggesting equivalent requirements be established for the associate degree.

Response: Currently, the qualification requirements for high complexity testing personnel contain provisions that prospectively require high school graduates to obtain an associate degree. As mentioned above, in evaluating the comments received concerning high complexity testing personnel, we sought the advice of the CLIAC about the appropriateness of the qualifications required. The CLIAC recommended that the associate degree be established as the minimum education requirement and, in addition, that equivalent academic requirements be established for the associate degree. In this regulation, we are adding a provision to qualify individuals who have completed specific college courses but do not have an associate degree or who have an associate degree that is not in medical laboratory technology or a laboratory science. As previously mentioned, we have defined requirements equivalent to the associate degree (60 semester hours that must include 24 semester hours of medical laboratory technology courses *or* 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology and twelve semester hours of courses in chemistry, biology or medical laboratory technology, or any combination); individuals qualifying under the equivalency provisions also must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours) or three months of documented training in each specialty in which the individual performs high complexity testing. The laboratory training may be acquired before, during or after completing the academic requirements.

Comment: Many commenters recommended recognizing medical laboratory technicians without an associate degree. Commenters also recommended qualifying individuals, including certified laboratory assistants, who received training in an accredited hospital or technical school training program. A large number of commenters suggested qualifying individuals with military training.

Response: We agree with the commenters that, in addition to the revisions made to the general supervisor requirements, revisions are needed in the qualification requirements for high complexity testing personnel to recognize individuals who have completed a nondegree clinical laboratory training program and, therefore, have equivalent training. Therefore, we are adding to the high complexity testing personnel requirements, a provision to qualify individuals who, on or before April 24, 1995 have completed a 50-week U.S. military medical laboratory training program or have graduated from a medical laboratory or clinical laboratory training program accredited by the Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation or other organization approved by HHS.

Comment: A number of commenters recommended that the regulations be revised to qualify all currently employed high complexity testing personnel. Other commenters said currently employed high school graduates, who were trained on the job, should be allowed to continue performing high complexity testing but only under supervision.

Response: We agree with the CLIAC recommendation that the regulations should be revised to alleviate the impact on currently employed personnel. We also believe that high school graduates with appropriate training, who were performing high complexity testing on or before April 24, 1995 have obtained sufficient work experience to allow them to continue performing testing with supervisory oversight. Therefore, we are revising the regulations to allow these individuals to continue performing high complexity testing even after September 1, 1997 (the current limit) and do not require that they obtain additional training or education. However, performance of any high complexity testing by these individuals must be in accordance with the supervision requirements discussed below.

Comment: A few commenters agreed with the responsibility requirements for high complexity testing personnel, while numerous commenters disagreed. The majority of the commenters who disagreed were opposed to requiring onsite supervision when individuals who do not have an associate degree perform high complexity testing.

Response: As previously mentioned above under the discussion of qualifications of the general supervisor, in the regulation published in the **Federal Register** on January 19, 1993, we changed the requirement for onsite supervision to only require 24-hour review of any high complexity testing performed by personnel who do not have an associate degree and who were performing high complexity testing on or before January 19, 1993. The onsite supervision requirement was retained only for those high school graduates, or equivalent, who began performing high complexity testing after January 19, 1993. In this regulation, we are not changing the requirements for onsite supervision or 24-hour review. However, we believe individuals who have completed accredited or U.S. military laboratory training programs or have qualifications equivalent to the associate degree and have appropriate laboratory training are qualified to perform high complexity testing without supervision. Therefore, we are revising the qualification requirements for high complexity testing personnel to allow individuals having these qualifications to perform high complexity testing without onsite supervision or 24-hour review.

III. Other Revisions

We are making the following technical changes in addition to those discussed above:

- We are making minor editorial changes to improve clarity and remove redundancies. This includes removing §§ 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634.
- We are revising the definition of ''certificate of registration'' in § 493.2 to exclude reference to laboratories that are exempt from CLIA requirements because they are licensed by a HCFA-approved laboratory licensure program: these laboratories are not required to obtain a registration certificate.
- From the definition of ''physician'' in § 493.2 we are deleting the phrase ''or equivalent degree'' as there are no degrees equivalent to doctor of medicine, osteopathy or podiatric medicine.
- To §§ 493.35(d)(2) and 493.37(b)(2) we are adding a requirement that a laboratory seeking a certificate of waiver must permit announced inspections by HHS (as well as unannounced) because it was inadvertently omitted from the January 19, 1993 rule.
- In §§ 493.35(d)(2)(iv), 493.49(b)(2)(iv), 493.1776(a)(4) and 493.1776(b)(4)(iv), we indicate that we will collect information during

inspections to determine the ''appropriateness'' of tests, rather than their ''addition, deletion or continued inclusion''.

- In § 493.602 we clarify Federal validation survey activity to include accredited laboratories and change ''State-exempt'' to ''CLIA exempt'' to agree with references that were changed in previous regulations.
- In §§ 493.638, 493.639, and 493.645(c), we revise the text so that it more accurately reflects what costs fees do and do not cover; for example, they do cover the cost of categorizing tests.
- In the title of § 493.645 and paragraph (a) we are changing the word ''licensure'' to ''laboratory'' and, in paragraph (a), ''State-exempt'' to ''CLIA-exempt'' to conform to changes made in previous regulations.

IV. Waiver of Delay in Effective Date

We find good cause to waive the usual 30-day delay in effective date for most of the revisions. Those persons who become qualified under the revised regulations are no less qualified now than they will be in 30 days. Hence, it serves no purpose to delay our regulations. Other revisions are very technical in nature and to delay their effective date is also unnecessary. Also, under the provisions of the current regulations, revisions of the list of PPM tests may be done outside of a rulemaking process through publication of a **Federal Register** notice that does not require a 30 day delay. As indicated earlier, we also will consider comments received on the addition of three new PPM procedures. Therefore, we find good cause to waive the delay in effective date of this rule.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Collection of Information Requirements

The portions of §§ 493.7, 493.35, 493.39, 493.43, 493.53, 493.55, and 493.57 of this document that have been revised contain information collection and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These reporting and recordkeeping requirements are not effective until a notice of OMB's approval is published in the **Federal Register**. The information collection requirements concern the performance of recordkeeping. The respondents who will provide the information include any entity performing laboratory testing used for assessment, diagnostic or treatment purposes. Public reporting burden for this collection of information is estimated to be 61 hours per laboratory per year.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

VII. Regulatory Impact Statement

Background

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all laboratories are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

General

This rule modifies CLIA regulations published February 28, 1992 and January 19, 1993. There are approximately 157,000 entities enrolled under CLIA that may be affected by the provisions of this rule. The significance of the effect will vary depending on the volume and complexity of tests performed; whether the entity employs midlevel practitioners to perform provider-performed microscopy (PPM) procedures; and whether employees meet the personnel requirements contained in the February 28, 1992 regulations. While we cannot estimate the number of entities that may make changes in their laboratory testing practices as a result of this rule, we believe the modifications to the CLIA program will benefit the affected entities in several ways. This rule will help to ease implementation of the CLIA program at no loss to public health and safety by offering alternative qualification standards for laboratory employees who would be adversely affected by the original personnel requirements. It also increases patient access to laboratory services, especially in rural and underserved areas, by expanding the list of personnel qualified to conduct certain laboratory tests. In addition, it reduces the regulatory burden for laboratories by enabling them to provide an expanded menu of tests under a PPM certificate without incurring the costs associated with obtaining a certificate of compliance.

Categorization of Tests

Expanding the list of PPM procedures may affect a laboratory's choice of certificate. Laboratories with certificates for PPM are not subject to costs associated with the routine inspections required under a certificate of compliance. Therefore, laboratories holding a certificate of compliance that change to a certificate for PPM will have a decrease in compliance costs and the number of inspections. Certificate of waiver laboratories choosing to expand their test menu to include PPM procedures and obtain a certificate of PPM will have increased certificate fees, as well as additional costs inherent in meeting applicable requirements, such as personnel and proficiency testing. The current biennial fee for a certificate of waiver is $100, as compared to $150 for a certificate for PPM. Although the cost of obtaining a certificate for PPM is more than for a certificate of waiver, it is less than the cost associated with a certificate of compliance.

Provider-Performed Microscopy Procedures

All providers performing microscopy examinations in conjunction with patient evaluations may be affected by the expansion of the subcategory of microscopy procedures to include midlevel health care practitioners and dentists. Many midlevel practitioners routinely perform patient examinations and associated laboratory testing, and in some States, are authorized to practice independently. Because there is such a wide variety of settings in which these services are offered, we cannot quantify the percentage of tests done by each type of health professional. However, there are no data to indicate that the quality of their tests results is not at least equivalent to the tests performed

by physicians. As a result of this expansion, patient access to care and services will increase, particularly in rural and underserved areas where there are shortages of physicians and, as many commenters pointed out, midlevel practitioners are the only health care providers available.

Personnel Requirements

As a result of our evaluation of the 32,000 comments received on the general supervisor and testing personnel requirements contained in the February 28, 1992 regulations, and after consultation with the CLIAC, we are revising the regulations to mitigate the impact of the regulations on currently employed individuals. Adding alternative qualification standards to the general supervisor and high complexity testing personnel requirements enables currently employed individuals with equivalent training and experience to continue to qualify for these positions. As stated in the impact analysis that accompanied the February 28, 1992 regulations, we recognize that flexibility is needed by the laboratory industry to effectively take advantage of the personnel resources available to it, and it was not our intention to disenfranchise anyone currently employed. By providing equivalent qualification standards, we will increase the available pool of qualified laboratory personnel which will enable laboratories to meet the certification requirements without compromising the health and safety of patients. We expect many laboratories to benefit from this revision to the regulations, especially those in rural and underserved areas who are experiencing personnel shortages and the resultant limited patient access to laboratory services.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 493

Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 493 is amended as set forth below:

PART 493—LABORATORY PROCEDURES

1. The authority citation for part 493 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

2. Section 493.2 is amended by revising the definition of ''CLIA certificate'' and ''physician'' and adding in alphabetical order definitions of ''Dentist'' and ''Midlevel practitioner'' to read as follows:

§ 493.2 Definitions.

* * * * *

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with § 493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in § 493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA (indicating that the laboratory is deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with § 493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by HCFA or its agent; or in accordance with § 493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.37, to a laboratory to perform only the waived tests listed at § 493.15(c).

* * * * *

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

* * * * *

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

* * * * *

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

* * * * *

3. In § 493.3, the introductory text of paragraph (a) is republished and paragraph (a)(1) is revised to read as follows:

§ 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

* * * * *

4. A new § 493.5 is added to read as follows:

§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

§ 493.10 [Removed]

5. Section 493.10 is removed.

§ 493.16 [Redesignated as § 493.19]

6. Section 493.16 is redesignated as § 493.19 and is revised to read as follows:

§ 493.19 Provider-performed microscopy (PPM) procedures.

(a) *Requirement.* To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) *Criteria.* Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

(c) *Provider-performed microscopy (PPM) examinations.* A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) *Revisions to criteria and the list of PPM procedures.*

(1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the **Federal Register** as a notice with an opportunity for public comment.

(e) *Laboratory requirements.* Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and P of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

7. Section 493.20 is revised to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at § 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, M, and P of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e) and 493.1775.

8. In § 493.25, paragraphs (c) and (d) are redesignated as (d) and (c), respectively, and paragraphs (b), (c) and (d) are revised to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, P, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, P, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at § 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, M, and P are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e) and 493.1775.

9. In § 493.35, paragraphs (a) and (d) are revised to read as follows:

§ 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

* * * * *

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in § 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in § 493.15.

* * * * *

10. In § 493.37, the introductory text of paragraph (b) is republished and paragraphs (b)(2) and (g) are revised to read as follows:

§ 493.37 Requirements for a certificate of waiver.

* * * * *

(b) Laboratories issued a certificate of waiver—

* * * * *

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

* * * * *

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

11. In § 493.39, the introductory paragraph is republished and paragraph (a) is revised to read as follows:

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

* * * * *

12. The heading of subpart C is revised to read as follows:

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

13. In § 493.43, the heading and paragraph (a) are revised to read as follows:

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests, must file a separate application for each laboratory location.

* * * * *

14. In § 493.45, a new introductory paragraph is added, the introductory paragraph (a) is republished, paragraph (a)(3) is removed, and paragraphs (a)(1), (a)(2), (d), and (f) are revised to read as follows:

§ 493.45 Requirements for a registration certificate.

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in § 493.15(c) or specified as PPM procedures.

* * * * *

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

* * * * *

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

* * * * *

15. In § 493.47, the heading, paragraph (a), the introductory text of paragraphs (b) and (c), paragraph (c)(2), and paragraphs (d) and (e) are revised to read as follows:

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

* * * * *

(c) Laboratories issued a certificate for PPM procedures are subject to—

* * * * *

(2) The applicable requirements of this subpart and subparts H, J, K, M, and P of this part; and

* * * * *

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

16. Section 493.49 is revised to read as follows:

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at § 493.1840(a) (4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

17. In § 493.51, the introductory paragraph of paragraph (a) is republished and the heading, the section's introductory paragraph and paragraphs (a)(5), (b) and (c) are revised to read as follows:

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

* * * * *

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

18. In § 493.53, the heading, the introductory paragraph, and paragraph (a) are revised to read as follows:

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under § 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

* * * * *

19. The introductory text of § 493.55(a) is revised to read as follows:

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—

* * * * *

20. In § 493.57, the introductory paragraph and paragraph (b) are revised to read as follows:

§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

* * * * *

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of § 493.49.

* * * * *

21. In § 493.511, paragraph (h) is revised to read as follows:

§ 493.511 Removal of deeming authority and final determination review.

* * * * *

(h) After HCFA withdraws approval of an accreditation organization's deeming authority, the certificates of accreditation of all affected laboratories continue in effect for 60 days after the laboratory receives notification of the withdrawal of approval. HCFA may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for inspection to another approved accreditation organization or an application for the appropriate certificate to HCFA, the State agency, or other HCFA agent before the initial 60-day period ends.

* * * * *

22. Paragraph (j) of § 493.521 is revised to read as follows:

§ 493.521 Removal of CLIA exemption and final determination review.

* * * * *

(j) After HCFA withdraws approval of a State laboratory licensure program, the exempt status of licensed or approved laboratories in the State continues in effect for 60 days after the laboratory receives notification from the State of the withdrawal of HCFA's approval of the program. HCFA may extend this period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application to HCFA for the appropriate certificate before the initial 60-day period ends.

* * * * *

23. Section 493.602 is revised to read as follows:

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

§§ 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634 [Removed]

24. Sections 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634 are removed.

25. Section 493.638 is revised to read as follows:

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received. Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

26. Section 493.639(b) is revised to read as follows:

§ 493.639 Fee for revised certificate.

* * * * *

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under § 493.643(d) if it is necessary to determine compliance with additional requirements.)

27. In § 493.643, paragraphs (a) and (d) are revised to read as follows:

§ 493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

* * * * *

(d) *Additional fees.* (1) If after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

28. Section 493.645 is revised to read as follows:

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that

standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If a laboratory issued a certificate of accreditation has been inspected and followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(c) If, in the case of a laboratory that has been issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

29. Section 493.646(a) is revised to read as follows:

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

* * * * *

30. In § 493.649, paragraph (a) and the introductory paragraph of paragraph (b) are revised to read as follows:

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

* * * * *

31. The heading of subpart H is revised to read as follows:

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

32. Section 493.803(a) is revised to read as follows:

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing tests of moderate complexity (including the subcategory) and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

* * * * *

33. The heading of § 493.807 is revised to read as follows:

§ 493.807 Condition: Reinstatement of laboratories performing tests of moderate complexity (including the subcategory), high complexity, or any combination of these tests, after failure to participate successfully.

* * * * *

34. The undesignated center heading immediately preceding § 493.821 is revised to read as follows:

Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

35. The heading to subpart I is revised to read as follows:

Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

36. The heading for subpart J is revised to read as follows:

Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

37. Section 493.1101 is revised to read as follows:

§ 493.1101 Condition: Patient test management; moderate complexity (including the subcategory), or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards as they apply to the testing performed.

38. The heading to subpart K is revised to read as follows:

Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

39. The heading to § 493.1201 is revised to read as follows:

§ 493.1201 Condition: General quality control; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

40. The heading to subpart M is revised to read as follows:

Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing

41. New § 493.1351 is added to subpart M to read as follows:

§ 493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

42. Following § 493.1351, a new undesignated center heading and new §§ 493.1353, 493.1355, 493.1357, 493.1359, 493.1361, 493.1363, and 493.1365 are added to subpart M to read as follows:

Laboratories Performing Provider-Performed Microscopy (PPM) Procedures

§ 493.1353 Scope.

In accordance with § 493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§ 493.1355 through 493.1365.

§ 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1357 and provides overall management and direction in accordance with § 493.1359.

§ 493.1357 Standard; laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in § 493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(1) Be a physician, as defined in § 493.2.

(2) Be a midlevel practitioner, as defined in § 493.2, authorized by a State to practice independently in the State in which the laboratory is located.

(3) Be a dentist, as defined in § 493.2.

§ 493.1359 Standard; PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

(a) Direct no more than five laboratories; and

(b) Ensure that any procedure listed under § 493.19(c)—

(1) Is personally performed by an individual who meets the qualification requirements in § 493.1363; and

(2) Is performed in accordance with applicable requirements in subparts H, J, K, M, and P of this part.

§ 493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of § 493.1363 to perform the functions specified in § 493.1365 for the volume and complexity of testing performed.

§ 493.1363 Standard: PPM testing personnel qualifications.

Each individual performing PPM procedures must—

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(1) Be a physician, as defined in § 493.2.

(2) Be a midlevel practitioner, as defined in § 493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

(3) Be a dentist as defined in § 493.2 of this part.

§ 493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be—

(a) Personally performed by one of the following practitioners:

(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.

(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and

(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

§ 493.1401 [Removed]

43. Section 493.1401 is removed.

44. In § 493.1461, the introductory text of paragraph (c) and paragraph (c)(2) is revised, and new paragraphs (c)(4) and (c)(5) are added to read as follows:

§ 493.1461 Standard; General supervisor qualifications.

* * * * *

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must—

* * * * *

(2)(i) Qualify as testing personnel under § 493.1489(b)(2); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

* * * * *

(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—

(i) Meet one of the following requirements:

(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and—

(i) Be a high school graduate or equivalent; and

(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory

experience between September 1, 1982 and September 1, 1992.

* * * * *

§ 493.1463 [Amended]

45. In § 493.1463, all references to ''§ 493.1489(b)(4)'' are amended to read ''§ 493.1489(b)(5).''

46. In § 493.1489, the introductory text to the section and to paragraph (b) are republished, paragraphs (b)(2) and (b)(4) through (b)(6) are revised, and paragraph (b)(7) is added to read as follows:

§ 493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

* * * * *

(b) Meet one of the following requirements:

* * * * *

(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(*1*) 24 semester hours of medical laboratory technology courses; or

(*2*) 24 semester hours of science courses that include—

(*i*) Six semester hours of chemistry;

(*ii*) Six semester hours of biology; and

(*iii*) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(*1*) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

* * * * *

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or

(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5)(i) Until September 1, 1997—

(A) Have earned a high school diploma or equivalent; and

(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—

(*1*) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(*2*) The skills required for implementing all standard laboratory procedures;

(*3*) The skills required for performing each test method and for proper instrument use;

(*4*) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(*5*) A working knowledge of reagent stability and storage;

(*6*) The skills required to implement the quality control policies and procedures of the laboratory;

(*7*) An awareness of the factors that influence test results; and

(*8*) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

(ii) As of September 1, 1997, be qualified under § 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

(6) For blood gas analysis—

(i) Be qualified under § 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of § 493.1449 (b) or (l) to perform tissue examinations.

§ 493.1495 [Amended]

47. In § 493.1495, all references to ''§ 493.1489(b)(4)'' are amended to read ''§ 493.1489(b)(5).''

48. The heading to subpart P is revised to read as follows:

Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

49. Section 493.1701 is revised to read as follows:

§ 493.1701 Condition: Quality assurance; moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests.

Each laboratory performing moderate complexity (including the subcategory) or high complexity testing, or any combination of these tests, must establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

50. In § 493.1776, the introductory text of paragraphs (a), (b), and (b)(4) are republished and the heading and paragraphs (a)(3), (a)(4), (b)(1), (b)(4)(iii) and (b)(4)(iv) are revised to read as follows:

§ 493.1776 Condition: Inspection of laboratories issued a certificate for PPM procedures.

(a) HHS or its designee will conduct announced or unannounced inspections of any laboratory at any time during its hours of operation to—

* * * * *

(3) Determine whether the laboratory is performing tests in addition to procedures specified as PPM procedures; and

(4) Collect information regarding the appropriateness of tests specified as PPM procedures.

(b) The laboratory may be required, as part of this inspection, to—(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493. Requirements for the purposes of this section are located in subpart C or

subpart D, if applicable, and subparts H, J, K, M, and P of this part;

* * * * *

(4) Permit HHS or its designee upon request to review all information and data necessary to—

* * * * *

(iii) Determine whether the laboratory is performing tests in addition to procedures specified as PPM procedures; (iv) Collect information regarding the appropriateness of tests specified as PPM procedures; and

* * * * *

51. In § 493.1777, introductory text to the section is added and the heading and paragraphs (a) and (g) are revised to read as follows:

§ 493.1777 Condition: Inspection of laboratories requesting or issued a certificate of compliance.

Laboratories requesting or issued a certificate of compliance must permit an inspection to assess compliance with part 493 of this chapter. Testing in the subcategory of PPM procedures, may be included in the laboratory's routine or complaint inspection. PPM procedures are assessed for compliance with only the applicable requirements specific to the subcategory of testing.

(a) HHS or its designee may conduct unannounced or announced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory possessing a registration certificate before issuance of a certificate of compliance.

* * * * *

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory, or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate of compliance in accordance with subpart R of this part.

§ 493.1804 [Amended]

52. In § 493.1804(b)(2), the word ''ore'' is revised to read ''or''.

53. In § 493.1814, the introductory text of paragraph (b) is republished and paragraph (b)(3) is revised to read as follows:

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

* * * * *

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

* * * * *

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

* * * * *

54. In § 493.1834, the heading and introductory text of paragraph (f)(2) are republished and paragraphs (b) and (f)(2)(iii) are revised to read as follows:

§ 493.1834 Civil money penalty.

* * * * *

(b) *Scope.* This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

* * * * *

(f) *Accrual and duration of penalty—*

* * * * *

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

* * * * *

(iii) HCFA suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

* * * * *

55. In § 493.1836, the heading of paragraph (c) is republished and paragraphs (c)(2) and (c)(3) are revised to read as follows:

§ 493.1836 State onsite monitoring.

* * * * *

(c) *Duration of sanction.*

* * * * *

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

56. In § 493.2001, paragraph (e) and paragraph (e)(1) are revised to read as follows:

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

* * * * *

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategory) and high complexity;

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 23, 1994.

Philip R. Lee,

Assistant Secretary for Health.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 27, 1994.

Donna E. Shalala,

Secretary.

[FR Doc. 95–9953 Filed 4–21–95; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 61

[CC Docket No. 93–179, FCC 95–133]

Price Cap Rules for Local Exchange Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This action is taken to incorporate explicitly the ''add-back'' adjustment into the local exchange carrier (LEC) price cap rules. The explicit add-back rule will first be applied when the LECs file their 1995 access tariffs. It is intended that the explicit add-back rule will ensure that