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.

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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.