

(d) *Remands*—(1) *Secretary's action*. When a court remands an NCD matter to the Secretary because the record in support of the NCD is incomplete or otherwise lacks adequate information, the Secretary remands the case to HCFA in order to supplement the record.

(2) *Remand to HCFA*. HCFA supplements the record with new or updated evidence, including additional information from other sources, and may issue a revised NCD.

(3) *Final Actions*. (i) The proceedings to supplement the record, are expedited.

(ii) When HCFA does not issue a revised NCD, it returns the supplemented record to the court for review.

(iii) When HCFA issues a revised NCD, it forwards the case to an ALJ who issues a new decision applying the revised NCD to the facts of the claim(s) under consideration. The ALJ's decision is subject to DAB review and, ultimately, judicial review.

#### **PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS**

B. Part 417 is amended as set forth below:

1. The authority citation for part 417 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e-5, and 300e-9); and 31 U.S.C. 9701.

2. Section 417.634 is revised to read as follows:

#### **§ 417.634 Departmental Appeals Board (DAB) review.**

Any party to the hearing, including the HMO or CMP, who is dissatisfied with the hearing decision, may request the DAB to review the ALJ's decision or dismissal. Regulations beginning at 20 CFR 404.967 regarding SSA Appeals Council Review are applicable to DAB review for matters addressed by this subpart.

#### **PART 473—RECONSIDERATIONS AND APPEALS**

C. Part 473 is amended as set forth below:

1. The authority citation for part 473 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 473.46, paragraph (a) is revised to read as follows:

#### **§ 473.46 Departmental Appeals Board (DAB) and judicial review.**

(a) The circumstances under which the DAB will review an ALJ hearing decision or dismissal are the same as those set forth at 20 CFR 404.970, ("Cases the Appeals Council will review").

\* \* \* \* \*

#### **D. Technical Amendments.**

#### **§§ 405.711, 405.712, 405.714, 405.715, 405.716, 405.720, 405.722, 405.750, 405.807, 405.841, 405.871 [Amended]**

1. In §§ 405.711, 405.712, 405.714, 405.715, 405.716, 405.720, 405.722, 405.750(a), 405.807(b), and 405.871, the following changes are made:

a. The words "Social Security Administration" are removed wherever they appear, and "SSA" is added in their place.

b. The words "Health Care Financing Administration" are removed wherever they appear, and "HCFA" is added in their place.

#### **§ 405.708, 405.812, 405.832, 405.842, 417.612, 417.626 [Amended]**

2. In §§ 405.708(a) and (b), 405.812, 405.832(a), 405.842(b), 417.612(a) and 417.626 the word "final" or the words "final and" are removed wherever they appear.

#### **§§ 405.722, 405.747, 417.632 [Amended]**

3. Sections 405.722, 405.747, and 417.632(b) are amended by removing the term "presiding officer" wherever it appears and adding, in its place, "ALJ".

#### **§ 405.821 [Amended]**

4. In § 405.821, paragraph (c), is amended by removing the parenthetical phrase "(see § 405.801)".

#### **§ 405.831 [Amended]**

5. In § 405.831, the heading is amended by adding the words "at carrier hearing" before the word "and".

#### **§ 405.832 [Amended]**

6. In § 405.832, paragraph (c)(1) is amended by removing the reference to "section 1842(b)(3)(c)" and adding in its place, "section 1842(b)(3)(C)".

#### **§ 405.841 [Amended]**

7. In § 405.841, paragraph (b) is amended by removing the parenthetical reference "(see 20 CFR 404.958)" and adding in its place the parenthetical reference "(see 20 CFR 404.988(b) and 404.989)".

#### **§ 473.38 [Amended]**

8. In § 473.38 the following changes are made:

(a) The heading is amended by removing the word "Finality" and adding in its place "Effect".

(b) In paragraph (a), the words "final and" are removed.

#### **§ 473.48 [Amended]**

9. a. In § 473.48, in paragraphs (a)(1) and (a)(2), the word "final" is removed and "binding" is added in its place.

b. In paragraph (b), the word "final" is removed.

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

Dated: March 7, 1997.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 97-12263 Filed 5-9-97; 8:45 am]

BILLING CODE 4120-01-P

### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Health Care Financing Administration**

#### **Centers for Disease Control and Prevention**

#### **42 CFR Part 493**

[HSQ-237-FC]

RIN 0938-AH84

#### **Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Requirements—Extension of Certain Effective Dates for Clinical Laboratory Requirements Under CLIA**

**AGENCY:** Centers for Disease Control and Prevention (CDC) and Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule extends certain effective dates for clinical laboratory requirements in regulations published on February 28, 1992, and subsequently revised December 6, 1994, that implemented provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This rule extends the phase-in date of the quality control requirements applicable to moderate and high complexity tests and extends the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

These effective dates are extended to allow the Department additional time to issue revised quality control requirements and to ensure laboratory directors are able to complete certification requirements. These effective date extensions do not reduce

the current requirements for quality test performance.

**DATES:** These regulations are effective on May 12, 1997.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on July 11, 1997.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Centers for Disease Control and Prevention, Department of Health and Human Services, Attention: HSQ-237-FC, 4770 Buford Hwy., NE., MS F11, Atlanta, Georgia 30341-3724.

If you prefer, you may deliver your written comments (1 original and 3 copies) to the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HSQ237FC@hcfa.gov. E-mail comments must include the full name and address of the sender. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ-237-FC. Written 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 5:00 p.m. (phone: (202) 690-7890).

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**FOR FURTHER INFORMATION CONTACT:** Rhonda S. Whalen (CDC), (770) 488-7655.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On February 28, 1992, we published final regulations with an opportunity for public comment in the **Federal Register**, at 57 FR 7002, setting forth the requirements for laboratories that are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These regulations established uniform requirements for all laboratories regardless of location, size, or type. In developing the regulations, we included requirements that would ensure the quality of laboratory services and be in the best interest of the public health. We recognized that a rule of this scope required time for laboratories to understand and to implement the new requirements. Therefore, certain requirements were phased-in and given prospective effective dates. We also planned to address the comments we received on the February 28, 1992 rule and make modifications, if necessary, in a subsequent final rule.

On December 6, 1994, we published a final rule with opportunity for comment in the **Federal Register** at 59 FR 62606. This revision to the February 28, 1992 final rule included provisions that extended the phase-in of the quality control requirements applicable to moderate and high complexity tests and the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing. These changes were made due to the resource constraints that had prevented the Department of

Health and Human Services from establishing the process to review manufacturers' test system quality control instructions for CLIA compliance and the inability of many laboratory directors to complete certification requirements within the time period originally specified.

##### **II. Revisions to the Regulations**

The date extensions provided by the December 6, 1994 rule have proven to be inadequate for the reasons set forth below. In addition, based on our evaluation of comments submitted in response to the December 6, 1994 rule and on advice from the Clinical Laboratory Improvement Advisory Committee (CLIA) concerning the quality control requirements appropriate to ensure quality testing and the qualification requirements for laboratory directors, we have found it necessary to make the following revisions to our regulations:

- We are extending from September 1, 1996 to July 31, 1998 the current phase-in quality control requirements for moderate and high complexity tests. The phase-in quality control requirements for unmodified, moderate complexity tests cleared by the Food and Drug Administration (FDA) (through 510(k) or premarket approval processes, unrelated to CLIA), are less stringent than the requirements applicable to high complexity and other moderate complexity tests.
- We are extending from September 1, 1996 to July 31, 1998 the date for laboratories to meet certain CLIA quality control requirements by following manufacturers' FDA CLIA-cleared test system instructions.
- We are extending from September 1, 1996 to July 31, 1998 the date by which individuals with doctoral degrees must obtain board certification to qualify as director of a laboratory that performs high complexity tests.

These revisions are discussed in more detail below.

##### **A. Quality Control Requirements**

42 CFR § 493.1202 contains the quality control requirements applicable to moderate and high complexity tests and allows a laboratory that performs tests of moderate complexity, using test systems cleared by the FDA through the section 510(k) or premarket approval processes, until September 1, 1996 to comply with the quality control provisions of part 493 subpart K by meeting less stringent quality control requirements, as long as the laboratory has not modified the instrument, kit, or test system's procedure.

Section 493.1203, effective beginning September 1, 1996, establishes a mechanism for laboratories using commercial, unmodified tests to fulfill certain quality control requirements by following manufacturers' test system instructions that have been reviewed and determined by the FDA to meet applicable CLIA quality control requirements. Implementation of this review process, however, depended upon the availability of sufficient additional resources necessary to meet the projected workload.

Comments received on the February 1992 final rule expressed opposition to the quality control phase-in provision. Following the publication of the December 1994 final rule, we received additional comments indicating continued concerns about the quality control phase-in. A final rule addressing quality control issues raised by commenters on the February 1992 and December 6, 1994 rules is still under development. Therefore, we are extending the September 1, 1996 sunset date for quality control standards in § 493.1202 to July 31, 1998 and extending the effective date for § 493.1203 from September 1, 1996 to July 31, 1998 to allow laboratories to continue to meet current regulations until we make further determinations regarding these requirements. To assist us in determining the types of quality control requirements necessary to monitor laboratory test performance, we have solicited advice from the CLIA and, in addition, we held a two-day public meeting in September 1996 for manufacturers and others to make presentations on quality control.

We recognize that these revisions may have substantive implications for those laboratories performing only unmodified, moderate complexity testing previously cleared through the FDA's section 510(k) or premarket approval processes. We are, therefore, maintaining the provisions for these tests, as listed in § 493.1202(c), until July 31, 1998. We expect to revise the existing quality control regulations by this date.

#### *B. Laboratory Director Qualifications*

Section 493.1443(b)(3) provides that a director of a laboratory performing high complexity testing, who has an earned doctoral degree in chemical, physical, biological, or clinical laboratory science from an accredited institution, must be certified by a board recognized by the Department as of September 1, 1996. The phase-in, revised from 2 to 4 years, was designed to allow the Department adequate time to review requests for approval of certification programs and

to ensure that a laboratory director with a doctoral degree had sufficient time to successfully complete the requirements for board certification.

In 1992, we expected that an adequate number of certification boards would apply and be approved. On that basis, we required board certification by September 1, 1994. This date was extended to September 1, 1996 due to much slower progress than anticipated. While the Department has announced the approval of two additional certification boards in a **Federal Register** notice published July 8, 1996, at 61 FR 35762, additional requests for board approval are currently under review. We believe a further extension of the September 1, 1996 date is in order.

As stated previously in the preamble to the December 1994 final rule, a number of commenters on the February 1992 final rule suggested that board certification not be a mandatory requirement for currently employed individuals. In addition, CLIA has suggested, and we are still considering, the development of alternative provisions to qualify currently employed individuals with a doctoral degree on the basis of laboratory training or experience, in lieu of requiring board certification.

We are extending the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing to July 31, 1998. This extension will allow time for the approval of additional boards, and to remove the inadvertent disqualification of doctoral-degreed individuals with laboratory training and experience as high complexity laboratory directors. Between the present time and the July 1998 date, we will review the qualifications required for laboratory directors to ensure that they are appropriate and determine whether modifications should be made for inclusion in the final rule being developed to address other CLIA issues raised by commenters on the February 1992 final rule.

In summary, we are extending the phase-in period in § 493.1443(b)(3) from September 1, 1996 to July 31, 1998.

#### **III. Waiver of Proposed Rulemaking and Delayed Effective Date**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of

the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

These revisions are essential, because if these dates for quality control requirements are not extended, many laboratories performing moderate complexity testing will be faced unnecessarily with meeting more stringent and burdensome quality control requirements at a time when we are considering revisions to these same quality control requirements. Since we plan to publish revised quality control requirements in future rulemaking, to impose more stringent requirements when these regulations are currently under review is unreasonable. With respect to the personnel standards addressed in this rule, if the date for board certification of individuals with doctoral degrees is not extended, those individuals qualified as laboratory directors through their doctoral degree and certification by a board currently under review by us could be disenfranchised until they have an opportunity to be certified by an approved board. Although these directors have shown competency through certification by a professional board, we have not yet completed our review of all boards that have applied. Extending the date under these regulations governing laboratory director requirements will provide the opportunity for completion of these reviews without forcing the removal of individuals who have already shown their ability to fulfill the tasks we ask of laboratory directors. Accordingly, we believe that it is impracticable, unnecessary, and not in the public interest to engage in proposed rulemaking and believe there is good cause for doing so and to issue this final rule with a 60-day comment period. Also, because the September 1, 1996 date has caused these regulations to expire, additional urgency has been placed on the implementation of this rule. We, therefore, believe there is good cause to waive a delay in the effective date of these rules. To do otherwise would create unnecessary confusion among laboratories in understanding the requirements they must meet with respect to quality control and laboratory director qualifications. It could also impose unnecessary burdens on laboratories and hardships on individuals affected by these requirements.

#### IV. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify 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.

In addition, section 1102(b) of the Act requires us 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. That 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.

Extending the phase-in periods will continue the quality control requirements in effect prior to September 1, 1996, allow additional time to make further determinations regarding revision to the quality control requirements, and not change costs, savings, burden, or opportunities to manufacturers, laboratories, individuals administering tests, or patients receiving the tests.

For these reasons, we have determined, and the Secretary certifies, that this regulation does not result in a significant impact on a substantial number of small entities and does not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

#### 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. However, we will consider all comments we receive on the date extensions described in this rule by the date and time specified in the **ADDRESSES** section of this preamble,

and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

#### List of Subjects in 42 CFR Part 493

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

42 CFR chapter IV is amended as follows:

#### PART 493—LABORATORY REQUIREMENTS

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), and the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), and the sentence following 1395x(s)(11) through 1395x(s)(16)).

##### § 493.1202 [Amended]

2. In § 493.1202, in the section heading, remove “September 1, 1996.” and add in its place “July 31, 1998.”

##### § 493.1203 [Amended]

3. In § 493.1203, in the section heading, remove “September 1, 1996.” and add in its place “July 31, 1998.”

##### § 493.1443 [Amended]

4. Section 493.1443 is amended as set forth below:

a. In § 493.1443(b)(3)(ii) introductory text, remove “September 1, 1996,” and add in its place “July 31, 1998.”

b. In § 493.1443(b)(3)(ii)(C), remove “September 1, 1996,” and add in its place “July 31, 1998.”

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

Dated: December 17, 1996.

**David Satcher,**

*Director, Centers for Disease Control and Prevention.*

Dated: December 20, 1996.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

Dated: January 28, 1997.

**Donna E. Shalala,**

*Secretary.*

[FR Doc. 97-12271 Filed 5-9-97; 8:45 am]

BILLING CODE 4120-01-P

#### FEDERAL EMERGENCY MANAGEMENT AGENCY

#### 44 CFR Part 67

#### Final Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Final rule.

**SUMMARY:** Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**EFFECTIVE DATE:** The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated in the table below.

**ADDRESSES:** The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Frederick H. Sharrocks, Jr., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646-2796.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR Part 67.

FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR Part 60.