DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Centers for Disease Control and Prevention

42 CFR Part 493

[CMS–2094–P]

RIN 0938–AK83

Medicare, Medicaid, and CLIA Programs; Qualification Requirements for Directors of Laboratories Performing High Complexity Testing

AGENCY: Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise and expand the qualification requirements by which an individual with a doctoral degree may qualify to serve as a director of a laboratory that performs high complexity testing.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 28, 2002.

ADDRESSES: Mail written comments (one original and three copies) to the following addresses:

Centers for Disease Control and Prevention, Department of Health and Human Services, Attention: CMS–2094–P, 4770 Buford Hwy., NE., MS F11, Atlanta, Georgia 30341–3724; and

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2094–P, P.O. Box 8018, Baltimore, MD 21244–8018

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8018.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–2094–P.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

For information on ordering copies of the **Federal Register** containing this document and electronic access, *see* the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Rhonda S. Whalen (CDC), (770) 488–8155. Cecelia Hinkel (CMS), (410) 786–3531.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

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 C5–12–17 of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. To schedule an appointment to review public comments, phone: (410) 786–9994.

Availability of Copies and Electronic Access

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This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The Website address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

On February 28, 1992, we published a final rule with comment period in the **Federal Register** (57 FR 7002). The regulation set forth the requirements for laboratories that are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The regulation established uniform requirements for all laboratories regardless of location, size, or type of testing performed. In developing the regulation, we included requirements that we believed 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 implement the new requirements. Therefore, certain requirements were given prospective effective dates.

The February 28, 1992 rule extended the timeframe to allow a director of a laboratory performing high complexity testing to be certified by a board approved by the Department of Health and Human Services (HHS). This extension allowed time for laboratory directors who were not board certified to complete the certification requirements and for HHS to review and approve certification boards. Until December 31, 2002, individuals with a doctoral degree and 2 years of laboratory training or experience and 2 years of experience directing or supervising high complexity testing would be qualified to be directors of laboratories performing high complexity testing.

The final rules with comment period published on December 6, 1994 in the **Federal Register** (59 FR 62606), May 12, 1997 in the **Federal Register** (62 FR 25855), October 14, 1998 in the **Federal Register** (63 FR 55031), and December 29, 2000 in the **Federal Register** (65 FR 82941) extended the date by which an individual with a doctoral degree was required to be board certified in order to qualify as a director of a laboratory that performs high complexity testing. These date extensions were established to allow additional time for laboratory directors who were not board certified to complete certification requirements.

Following the publication of the February 28, 1992 rule, many individuals expressed concern about making board certification a mandatory requirement for directors of laboratories performing high complexity testing. In response to the publication of the date extension regulations, we received comments suggesting that we develop alternative provisions to qualify individuals with a doctoral degree on the basis of laboratory training or experience, instead of requiring board certification.

II. Provisions of the Proposed Rule

Upon consideration, we realize that individuals currently serving as laboratory directors are qualified based on training and experience, and have demonstrated the level of competency necessary to direct laboratories performing high complexity testing.

Therefore, we are proposing to revise and expand the qualification requirements at § 493.1443(b)(3). The proposed change provides three alternatives for an individual to meet in order to be qualified to serve as a director of a laboratory performing high complexity testing.

First, an individual who holds an earned doctoral degree and is certified by an HHS-approved board is qualified.

Second, an individual who is or has been the director of a laboratory performing high complexity testing before January 1, 2003, and holds an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and has 2 years of laboratory training or experience, or both; and 2 years experience directing or supervising high complexity testing will be qualified.

Finally, an individual who holds an earned doctoral degree but has never been the director of a laboratory performing high complexity testing must have at least 6 years of laboratory training or experience, or both; including 2 years of experience directing or supervising high complexity testing.

We are particularly interested in receiving comments on the appropriate combination of education and experience needed to ensure competency in directing a laboratory performing high complexity testing in the absence of board certification.

III. Response to Comments

Because of the large number 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 major comments in the preamble of that document.

IV. Regulatory Impact Statement

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This rule is not a major rule, and we do not anticipate that these provisions will have an impact of $100 million or more in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $10 million or less annually. 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. This analysis must conform to the provisions of section 603 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 100 beds.

This rule applies only to the qualifications of individuals hired to direct laboratories performing high complexity testing and does not have any direct impact on laboratories. In addition, the rule would allow high complexity laboratory directors who have a doctoral degree and laboratory experience but are not certified by an HHS-approved board two options to maintain their director qualifications. These options would ensure that currently employed laboratory directors including those directors of State public health laboratories would continue their laboratory director services. The essential participation of these public health laboratories in the homeland defense effort would be compromised without the options provided in this rule. In the absence of this proposed change, the experienced individuals who have a doctoral degree without board certification and are serving as directors of laboratories performing high complexity testing would be ineligible to continue serving in their current positions, further exacerbating the existing shortage of qualified personnel in clinical and public health laboratories.

Therefore, we are proposing certifying that this rule will not have significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We do not anticipate these provisions will have an impact of $110 million or more in any 1 year. This proposed rule has no consequential effect on State, local, or tribal governments. Therefore, we have not prepared a regulatory impact analysis.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that this proposed rule would not have a substantial effect on State, local, or tribal governments.

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.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV, part 493 as set forth below:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues 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)).

2. In § 493.1443, paragraph (b) introductory text is republished, and paragraph (b)(3) is revised to read as follows:

§ 493.1443 Standard; Laboratory director qualifications.

* * * * *

(b) The laboratory director must—

* * * * *

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—

(i) On or after January 1, 2003, be certified and continue to be certified by a board approved by HHS;

(ii) Before January 1, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least—

(A) Two years of laboratory training or experience, or both; and

(B) Two years of experience directing or supervising high complexity testing; or

(iii) Have at least 6 years of laboratory training or experience, or both; including 2 years experience directing or supervising high complexity testing.

* * * * *

(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: July 23, 2001.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention.

Dated: August 30, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 11, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–31722 Filed 12–27–01; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 54 and 69

[CC Docket Nos. 00–256, 96–45; DA 01–2916]

Multi-Association Group (MAG) Plan for Regulation of Interstate Services of Non-Price Cap Incumbent Local Exchange Carriers and Interexchange Carriers; Limited Extension of Time for Filing Comments and Replies in Rate-of-Return Access Charge Reform Proceeding

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of time.

SUMMARY: In this document, the Commission extends the time by 45 days for filing comments and reply comments in the Rate-of-Return Access Charge Reform proceeding. Certain members of the Multi-Association Group (MAG) requested an extension of time for filing comments. This proceeding seeks additional comment on proposals for incentive regulation, proposed changes to the ''all-or-nothing'' rule, pricing flexibility for rate-of-return carriers, and merging the Long Term Support mechanism into the new Interstate Common Line Support mechanism.

DATES: Comments are due on or before February 14, 2002, and reply comments are due on or before March 18, 2002.

ADDRESSES: Parties who choose to file comments by paper should send comments to Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 12th St., SW; TW-A325, Washington, DC 20554. Comments filed through the Commission's Electronic Comment Filing System (ECFS) can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html*.

FOR FURTHER INFORMATION CONTACT: Marvin F. Sacks at (202) 418–2017 (Common Carrier Bureau).

SUPPLEMENTARY INFORMATION: On November, 8, 2001, the Commission released the Second Report and Order and Further Notice of Proposed Rulemaking (''FNPRM'') in CC Docket Nos. 00–256 and 96–45, FCC 01–304, published at 66 FR 59761, November 30, 2001. Certain members of the Multi-Association Group (MAG) requested an extension of time for filing comments in the FNPRM. This proceeding seeks additional comment on proposals for incentive regulation, proposed changes to the ''all-or-nothing'' rule, pricing flexibility for rate-of-return carriers, and merging the Long Term Support mechanism into the new Interstate Common Line Support mechanism. When filing comments and reply comments, parties should reference CC Docket Nos. 00–256 and 96–45, and conform to the filing procedures contained in this FNPRM. The complete text is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW, Washington, DC, and also may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW, CY–B402, Washington, DC 20554. The FNPRM is also available via the Internet at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–01–304A1.pdf*.

Federal Communications Commission.

Jack Zinman,

Deputy Division Chief, Competitive Pricing Division.

[FR Doc. 01–31864 Filed 12–27–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH96

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the Northern Great Plains Breeding Population of the Piping Plover; Reopening of Public Comment Period and Notice of Availability of Draft Economic Analysis

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of public comment period and notice of availability of economic analysis.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of the draft economic analysis for the proposal to designate critical habitat for the northern Great Plains breeding population of the piping plover (*Charadrius melodus*), under the Endangered Species Act of 1973, as amended. We also are providing notice of the reopening of the public comment period for the proposal to designate critical habitat for this species, and the associated draft environmental assessment, to allow all interested parties to comment. Comments previously submitted need not be resubmitted as they have already been incorporated into the public record and will be fully considered in the final rule. Comments submitted during this comment period also will be incorporated into the public record and will be fully considered in the final rule.

DATES: The comment period is opened and will close on January 28, 2002. Any comments that are received after the closing date may not be considered in the final decision on this proposal.

ADDRESSES: You may submit written comments and information to Piping Plover Comments, South Dakota Ecological Services Field Office, U.S. Fish and Wildlife Service, 420 South Garfield Avenue, Suite 400, Pierre, South Dakota 57501, or by facsimile to 605–224–9974.

You may hand-deliver written comments to our South Dakota Field Office at the address given above.