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

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 (or toll free at 1-888-293-6498) or by faxing to (202) 512-2250. The cost for each copy is $9. 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. 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: <A HREF="http://www.access.gpo.gov/nara/index.html">http://www.access.gpo.gov/nara/index.html</A>.

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 Sec. 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 
ever 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 Sec. 493.1443, paragraph (b) introductory text is
republished, and paragraph (b)(3) is revised to read as follows:

Sec. 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)

Jeffrey P. Koplan,
Director, Centers for Disease Control and Prevention.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Tommy G. Thompson,
Secretary.

[FR Doc. <strong>01</strong>-<strong>31722</strong>--<strong>Filed</strong> 12-27--<strong>01</strong>; 8:45 am]
BILLING CODE 4120--<strong>01</strong>--<strong>P</strong>