while still providing for the reasonable needs of navigation.

The SR 1 vertical lift bridge (Galliano-Tarpon bridge), mile 30.6, has averaged 383 bridge openings a month for vessel traffic over the past two years. This average out to less than 13 openings per day at the bridge. While statistics are not readily available for the other bridge, given its close proximity to the Tarpon bridge, its average opening should be similar or slightly lower as it is upstream of the SR 1 vertical lift bridge (Galliano-Tarpon bridge).

The SR 1 vertical lift bridge (Galliano-Tarpon bridge), mile 30.6, is owned and operated by the Louisiana Department of Transportation and Development (LDOTD). LDOTD has no objection to the modification of the operating schedule for the bridge.

The SR 1 ponton bridge (Cote Blanche bridge), mile 33.9, is owned and operated by Lafourche Parish. Lafourche Parish has no objection to the modification of the operating schedule for the bridge.

Discussion of Rules

The rule amends the existing regulation to adjust the time when the two bridges need not open for the passage of vessels. The regulations presently states that the draws of the SR 1 bridge, mile 30.6, and the SR 1 bridge, mile 33.9, both near Cutoff, shall open on signal except that, from 2 p.m. to 3 p.m., and from 4:30 p.m. to 5:30 p.m. Monday through Friday except Federal holidays, the draws need not open for the passage of vessels. The amended regulation modifies the times that the bridges need not open for the passage of vessels.

The modification to the regulation facilitates the movement of the school bus traffic while still providing for the reasonable needs of navigation. The amended regulation will require the draws of the SR 1 bridge, mile 30.6, and the SR 1 bridge, mile 33.9, both near Cutoff, shall open on signal except that, from 2:30 p.m. to 3:30 p.m., and from 4:30 p.m. to 5:30 p.m. Monday through Friday except Federal holidays, the draw need not open for the passage of vessels.

Regulatory Evaluation

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget under that Order has not reviewed it. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considers whether this final rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include (1) small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and (2) governmental jurisdictions with populations of less than 50,000.

The amended regulation adjusts the hours that the bridges need not open for the passage of vessels by 30 minutes. Any impact the adjustment may have on small entities is not substantial. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This final rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612 and has determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under Figure 2–1 CE #32(e) of the NEPA Implementing Procedures, COMDINST M16475.IC, this final rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard is amending Part 117 of Title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 105 Stat. 5039.

2. Amend § 117.465 to revise paragraph (a) to read as follows:

§ 117.465 Lafourche Bayou.

(a) The draws of the SR 1 bridge, mile 30.6, and the SR 1 bridge, mile 33.9, both near Cutoff, shall open on signal except that, from 2:30 p.m. to 3:30 p.m., and from 4:30 p.m. to 5:30 p.m. Monday through Friday except Federal holidays, the draws need not open for the passage of vessels.

* * * * *

Dated: September 28, 1998.

Paul J. Pluta,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 98–27573 Filed 10–13–98; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Centers for Disease Control and Prevention

42 CFR Part 493

[HCFA–2024–FC]

RIN 0938–AI94

Medicare, Medicaid, and CLIA Programs; 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, and May 12, 1997, 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 determine whether changes are needed in the qualification requirements for individuals with doctoral degrees to serve as directors of laboratories performing high complexity testing. These effective date extensions do not reduce the current requirements for quality test performance.

DATES: *Effective Date:* October 14, 1998.

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 December 14, 1998.

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: HCFA–2024–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: HCFA2024FC@hcfa.gov. For e-mail comment procedures see the beginning of **SUPPLEMENTARY INFORMATION**. For further information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT:

Rhonda S. Whalen (CDC), (770) 488–8155.

Diane Milstead (HCFA), (410) 786–3531.

SUPPLEMENTARY INFORMATION:

E-Mail, Comments, Procedures, Availability of Copies, and Electronic Access

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 HCFA–2024–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).

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) 512–7800 (or toll free at 1–888–293–6498) or by faxing to (202) 512–2250. 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**.

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I. Background

On February 28, 1992, we published in the **Federal Register** (57 FR 7002) final regulations with an opportunity for public comment. These regulations set 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 of testing performed. 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, and on May 12, 1997, we published in the **Federal Register** (59 FR 62606 and 62 FR 25855, respectively) final rules with opportunity for comment. These rules 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 May 12, 1997 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 May 12, 1997 rule and on advice from the Clinical Laboratory Improvement Advisory Committee (CLIAC) 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 July 31, 1998, to December 31, 2000, 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 July 31, 1998, to December 31, 2000, the date for laboratories to meet certain CLIA quality control requirements by following manufacturers' FDA CLIA-cleared test system instructions.
- We are extending from July 31, 1998, to December 31, 2000, 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 July 31, 1998, 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 July 31, 1998, 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. These resources were not available due to financial and other constraints of the program.

Following the publication of the December 1994 and May 12, 1997 final rules, we received comments that the current quality control requirements are not appropriate for some test methodologies and a comprehensive quality control regulation should be developed to address ''today's'' quality control needs. While a final rule addressing quality control issues raised by these commenters is under development, it will not be completed by July 31, 1998. Commenters raised issues that stressed the need to ensure that the quality control requirements are practical and flexible enough to accommodate different testing sites and test systems that range from current methodologies to new and emerging technologies, so as to not impede access. We must also, as the comments suggest, base the requirements on technical considerations as well as their impact on patient care.

To assist us in determining the types of quality control requirements necessary to monitor laboratory test performance, we will also consider advice provided by the CLIAC, as well as information obtained from a public meeting held in September 1996 for manufacturers and others to make presentations on quality control.

Concurrently, the FDA process for product clearance, an integral part of the CLIA quality control requirements published in 1992, is undergoing comprehensive changes (see **Federal Register** notices published January 21, 1998 (63 FR 3142) and February 2, 1998 (63 FR 5387)).

Due to the complexity of the issues that must be addressed, we are extending the July 31, 1998, sunset date for quality control standards in § 493.1202 to December 31, 2000, and extending the effective date for § 493.1203 from July 31, 1998, to December 31, 2000, to allow laboratories to continue to meet current regulations until we make further determinations regarding these requirements. We are extending the effective dates for these sections to December 31, 2000, to ensure that we have sufficient time to publish final rules concerning quality control. Extending the dates will allow sufficient time for publication of final regulations. Subsequent to the publication of the final regulations and prior to the actual implementation of the revised requirements, we must develop new surveyor guidelines, design new survey forms, reprogram the CLIA data system, conduct surveyor training, and inform and educate the laboratory community, CLIA exempt States and accreditation organizations. Time must be allocated for CLIA exempt States and approved accreditation organizations to review their requirements and determine whether they must make changes to maintain their overall equivalency with the CLIA requirements. CLIA exempt States may need to make changes to their State laws. Accreditation organizations may also need time to revise policies and requirements and have them approved by their organizations for adoption. Our implementation delay will provide States and accreditation organizations the time needed to make changes to their program requirements and for their subsequent review by CDC and HCFA. Failure to provide sufficient time for education and implementation could cause confusion and interfere with the laboratory community's continued compliance with CLIA requirements and jeopardize the continued equivalency of CLIA exempt States and accreditation organizations.

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 July 31, 1998. The phase-in 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.

As stated previously in the preamble to the December 1994 final rule, a number of comments to the February 1992 final rule suggested that board certification not be a mandatory requirement for currently employed individuals. In addition, CLIAC 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 December 31, 2000. This extension will allow time for review of the qualifications required for laboratory directors to determine whether modifications should be made for inclusion in the final rule being developed to address other CLIA personnel 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 July 31, 1998, to December 31, 2000.

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.

The revisions in this final rule are essential, because if the 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 actively working to revise these same quality control requirements. While this activity has begun, the issues

we are addressing are many and complex, particularly in light of changing technologies. Since we will be revising the quality control requirements in rulemaking that should occur in the reasonably near future, to impose more stringent requirements now is unreasonable, unnecessary, and confusing. With respect to the personnel standards addressed in this rule, if the date is not extended, those individuals qualified as laboratory directors under the phase-in requirements based on their doctoral degree and laboratory training and work experience would no longer qualify to serve as directors of laboratories performing high complexity testing. Since we are considering revisions to the regulations which would allow individuals with a doctoral degree to qualify under alternative provisions that would recognize their laboratory training and experience, we would not want to disenfranchise these currently employed directors at this time. Extending the dates governing laboratory director qualifications will provide the opportunity for us to determine whether alternative provisions should be developed to qualify individuals with a doctoral degree who have laboratory training and experience, but do not have board certification. 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. 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.

Also, because current regulations will expire on the July 31, 1998, 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 this rule. 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 July 31, 1998, allow adequate time for addressing all concerns with respect to revising 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.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in annual expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. The final rule has no consequential effect on State, local, or tribal governments. We believe the private sector costs of this rule fall below these thresholds, as well.

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

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, part 493 is amended 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)).

§ 493.1202 [Amended]

2. In § 493.1202, in the section heading, remove ''July 31, 1998.'' and add in its place ''December 31, 2000.''.

§ 493.1203 [Amended]

3. In § 493.1203, in the section heading, remove ''July 31, 1998.'' and add in its place ''December 31, 2000.''.

§ 493.1443 [Amended]

4. Section 493.1443 is amended as set forth below:

a. In § 493.1443(b)(3)(ii) introductory text, remove ''July 31, 1998,'' and add in its place ''December 31, 2000,''.

b. In § 493.1443(b)(3)(ii)(C), remove ''July 31, 1998,'' and add in its place ''December 31, 2000,''.

(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: May 20, 1998.

Claire V. Broome,

Acting Director, Centers for Disease Control and Prevention.

Dated: May 20, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: August 5, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–27523 Filed 10–13–98; 8:45 am]

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