WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #4

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Oct 31 1 59 PM '96

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Division of Health TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code § 16-5J-10

AMENDMENT TO AN EXISTING RULE: YES X NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 57

TITLE OF RULE BEING AMENDED: Clinical Laboratory Technician and Technologist Licensure and Certification

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED:

TITLE OF RULE BEING PROPOSED:

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Gretchen O. Lewis

Gretchen O. Lewis, Secretary

6-60

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Gaston Caperton
Governor

Gretchen O. Lewis
Secretary

Date: October 31, 1996

To: Administrative Law Division
Office of the Secretary of State

From: Kay Howard, Director
Regulatory Development

Re: Modified Rule, Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

The filing notice for and the modified rule, Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57, approved by the Legislative Rule-Making Review Committee are enclosed. Please also note the enclosed copy of a federal regulation newly adopted by reference in the modified rule, which has not been previously filed with your office.

KH/sm
Enclosures

cc: Legislative Rule-Making Review Committee

BUILDING 3, ROOM 265 CAPITOL COMPLEX CHARLESTON, WV 25305 (304) 558-3223

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register on the twenty-sixth day of February, one thousand nine hundred ninety-seven, relating to the division of health (child care centers, 64 CSR 21), is authorized.

(c) The legislative rule filed in the state register on the thirtieth day of August, one thousand nine hundred ninety-six, authorized under the authority of section twenty-three, article four-c, chapter sixteen, of this code, modified by the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-eighth day of February, one thousand nine hundred ninety-seven, relating to the division of health (emergency medical services, 64 CSR 48), is authorized.

(d) The legislative rule filed in the state register on the twenty-seventh day of November, one thousand nine hundred ninety-five, authorized under the authority of section five, article five-c, chapter sixteen, of this code, modified by the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-sixth day of February, one thousand nine hundred ninety-seven, relating to the division of health (residential board and care homes, 64 CSR 65), is authorized.

(e) The legislative rule filed in the state register on the fifth day of October, one thousand nine hundred ninety-five, under the authority of section ten, article five-j, chapter sixteen, of this code, modified by the director of the department of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the thirty-first day of October, one thousand nine hundred ninety-six, relating to the department of health (clinical laboratory technician and technologist licensure and certification, 64 CSR 57), is authorized until July 1, 1998: *Provided,* That the director of the department of health review, revise and propose, within the statutory deadline and in accordance with the provisions of article three, chapter twenty-nine-a of this code, a rule for legislative consideration during the legislative session of one thousand nine hundred ninety-eight with the following amendments:

"On page one, subsection 2.2.2, following the semicolon, by striking the word 'or';

On page one, by inserting a new 2.2.3, to read as follows: '2.2.3. Any respiratory care provider licensed within the state providing diagnostic testing within the scope of his or her professional license who performs moderate complexity testing as defined by CLIA, pursuant to 42 CFR 493.17; or';

'On pages one and two, by renumbering the subsequent subdivision,.' "

And,

"On page 6, subsection 7.2, after the word 'Personnel', by striking the period and inserting in lieu thereof the following: 'or by the International Society for Clinical Laboratory Technology.' "

§64-5-2. Commissioner of human services.

The legislative rule filed in the state register on the thirtieth day of August, one thousand nine hundred ninety-six, under the authority of section four, article two-b, chapter forty-nine, of this code, modified by the commissioner of human services to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-seventh day of February, one thousand nine hundred ninety-seven, relating to the commissioner of human services (certification requirements for family day care facilities, 78 CSR 18), is authorized.

§64-5-3. Child support enforcement commission.

(a) The legislative rule filed in the state register on the thirtieth day of August, one thousand nine hundred ninety-six, under the authority of section ten, article two, chapter forty-eight-a of this code, modified by the child support enforcement commission to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-eighth day of February, one thousand nine hundred ninety-seven, relating to the child support enforcement commission

MODIFIED PROPOSED RULE

WEST VIRGINIA LEGISLATIVE RULE
DIVISION OF HEALTH

CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION

64 CSR 57

199_

Modified Proposed Rule Approved
by the
Legislative Rule-Making Review Committee

October 14, 1996

WEST VIRGINIA LEGISLATIVE RULE
DIVISION OF HEALTH
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION
64 CSR 57

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MODIFIED PROPOSED RULE - TITLE 64
WEST VIRGINIA LEGISLATIVE RULE
DIVISION OF HEALTH
SERIES 57
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION

§64-57-1. General.

1.1. Scope. -- This legislative rule sets forth standards and procedures for the certification and licensing of laboratory technicians and laboratory technologists as clinical laboratory practitioners and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory practitioners by health care facilities.

1.2. Authority - W. Va. Code § 16-5J-10.

1.3. Filing Date -

1.4. Effective Date -

§64-57-2. Application and Enforcement

2.1. Application - Except as otherwise provided in this rule, this legislative rule applies to

2.1.1. Clinical laboratory practitioners employed as such in West Virginia, including individuals employed as clinical laboratory practitioners in agencies or organizations exempted from licensure as a laboratory under the provisions of W. Va. Code § 16-5J-7, i.e., county health departments organized under W. Va. Code § 16-2-1 et seq. or § 16-2A-1 et seq.; primary health care centers having tax exempt status and receiving contributions which are deductible to the contributor under provisions of federal law; or any laboratory operated solely for research or teaching purposes; and

2.1.2. Clinical laboratory consultants, directors, and supervisors in West Virginia.

2.2. This rule does not apply to:

2.2.1. Any individual who performs only laboratory tests published in the Federal Register as waived under CLIA by the Centers for Disease Control under the provisions of § 42 CFR 493.7;

2.2.2. Any physician, dentist, nurse practitioner, nurse midwife or physician assistant, licensed within this State working within the scope of his or her professional license, who performs only provider-performed microscopy procedures as found at § 42 CFR 493.19 (a) - (d); or

2.2.3. Any individual who performs laboratory tests only on himself or herself or

members of his or her family.

2.3. Enforcement - This rule is enforced by the secretary of the West Virginia department of health and human resources.

§64-57-3. Definitions.

3.1. CLIA - Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public Health Service Act (Title 42 United States Code Section 263a).

3.2. Clinical Laboratory - Any facility or place, however named, for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings.

3.3. Clinical Laboratory Consultant - A person who:

3.3.1. Meets the qualifications for:

3.3.1.a. Moderate complexity testing technical consultant found at 42 CFR § 493.1411;

3.3.1.b. Moderate complexity testing clinical consultant found at 42 CFR § 493.1417; or

3.3.1.c. High complexity testing clinical consultant found at 42 CFR § 493.1455.

3.4. Clinical Laboratory Director - A person who:

3.4.1. Provides overall management and direction of a clinical laboratory; and

3.4.2. Meets the qualifications for directors of:

3.4.2.a. Moderate complexity testing laboratories found at 42 CFR § 493.1405;

3.4.2.b. High complexity testing laboratories found at 42 CFR § 493.1443; or

3.4.2.c. Waived clinical laboratories found at 42 CFR § 493.35.

3.5. Clinical Laboratory Practitioner - A laboratory technician or a laboratory technologist. The term "clinical laboratory practitioner" includes laboratory technicians and laboratory technologists, but does not include: clinical laboratory practitioner trainees; clinical laboratory directors, consultants, or supervisors whose job tasks do not include processing specimens, or performing or reporting laboratory tests; or physicians licensed under W. Va. Code § 30-3-1 et seq. or § 30-14-1 et seq. who perform laboratory tests only on their own patients.

3.6. Clinical Laboratory Practitioner Trainee - A person who is in a training program designed for his or her qualification as a clinical laboratory practitioner or who has successfully completed such a training program and has applied for, but not yet received a clinical laboratory practitioner license.

3.7. Clinical Laboratory Supervisor - A person who meets the qualifications for:

3.7.1. A high complexity testing technical supervisor found at 42 CFR § 493.1449;

3.7.2. A high complexity testing general supervisor found at 42 CFR § 493.1461; or

3.7.3. A high complexity testing cytology general supervisor found at 42 CFR § 493.1469.

3.8. Contact Hours - The actual number of hours an individual participates in continuing education. Ten (10) contact hours equal one (1) continuing education unit.

3.9. Department - The West Virginia department of health and human resources.

3.10. Health Care Facility - An entity subject to licensure as a:

3.10.1. Birthing center under W. Va. Code § 16-2E-1 et seq.;

3.10.2. Hospital or extended care facility operated in connection with a hospital, or an ambulatory surgical facility, or an ambulatory health care facility, including a medical adult day care center under W. Va. Code § 16-5B-1 et seq.;

3.10.3. Nursing home or personal care home under W. Va. Code § 16-5C-1 et seq.;

3.10.4. Residential board and care home under W. Va. Code § 16-5C-1 et seq. and § 16-5H-1 et seq.;

3.10.5. Hospice under W. Va. Code § 16-5I-1 et seq.;

3.10.6. Clinical laboratory under W. Va. Code § 16-5J-1 et seq.;

3.10.7. Hospital, center or facility for the care and treatment of the mentally ill or mentally retarded, or for the prevention of such disorders under W. Va. Code § 27-9-1 et seq.; or

3.10.8. Group residential facility for the developmentally disabled or behaviorally disabled under W. Va. Code § 27-17-1 et seq.

3.11. Laboratory Technician - A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory.

3.12. Laboratory Technologist - A person whose job tasks include specimen processing,

laboratory test performance, or laboratory test reporting in a clinical laboratory.

3.13. Laboratory Test - The biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

§64-57-4. Incorporation by Reference.

The following provisions of the October 1, 1994, edition of 42 CFR Part 493, Laboratory Requirements, as amended in the April 24, 1995 edition of the Federal Register (60 FR 20035), and as further amended and published by January 1, 1997, are hereby incorporated by reference:

4.1. 42 CFR § 493.7;

4.2. 42 CFR § 493.19 (a) - (d);

4.3. 42 CFR § 493.35;

4.4. 42 CFR § 493.1363.

4.5. 42 CFR § 493.1405;

4.6. 42 CFR § 493.1411;

4.7. 42 CFR § 493.1417;

4.8. 42 CFR § 493.1423;

4.9. 42 CFR § 493.1443;

4.10. 42 CFR § 493.1449;

4.11. 42 CFR § 493.1455;

4.12. 42 CFR § 493.1461;

4.13. 42 CFR § 493.1469;

4.14. 42 CFR § 493.1483; and

4.15. 42 CFR § 493.1489.

§64-57-5. Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees.

5.1. No person shall perform any clinical laboratory practitioner tasks in West Virginia, except as specified in this rule, unless the person is licensed by the secretary as a clinical laboratory practitioner.

5.2. A clinical laboratory practitioner trainee may perform tasks related to laboratory tests only under the personal and direct supervision of: a licensed clinical laboratory practitioner; or a clinical laboratory director, consultant or supervisor.

§64-57-6. Licensure Requirements, Duration, Renewal.

6.1. Applicants for a clinical laboratory practitioner license shall submit to the secretary:

6.1.1. A completed application form supplied by the secretary with the documentation of qualifications required by this rule;

6.1.2. If employed in a clinical laboratory, a current job description and a statement identifying the specialty or specialties of laboratory tests for which the applicant has been trained and is currently competent to perform, except as specified in this rule. The required job description and statement of competency shall be signed and provided to the applicant by the applicant's clinical laboratory director. The attestation shall be partially based on the applicant's performance, if any, in proficiency testing programs; and

6.1.3. The licensure fee shown on the application as authorized by W. Va. Code.

6.2. The secretary shall grant a clinical laboratory practitioner license to applicants who:

6.2.1. Are certified as a clinical laboratory practitioner under Section 7 of this rule or are exempt from certification under Section 8 of this rule; and

6.2.2. Comply with the requirements of Section 6.1 of this rule.

6.3. An applicant for renewal of either a current or an expired license shall submit the application, information and licensure fee required by Section 6.1 of this rule and evidence that the applicant has completed at least ten (10) contact hours (one (1) continuing education unit) of educational activities commensurate with the level of complexity of testing the individual performs from a program or programs approved by the secretary, since the issuance of his or her current or expired license, as applicable. Acceptable continuing educational activities include, but are not limited to, activities such as: lectures, seminars, workshops, formal classes, in-service programs or correspondence courses.

6.4. The secretary shall renew a license if the applicant complies with the requirements of Section 6.3 of this rule.

6.5. A clinical laboratory practitioner license expires the earlier of:

6.5.1. One (1) year after issuance; or

6.5.2. The expiration of the individual's certification or exemption from certification as a clinical laboratory practitioner.

§64-57-7. Certification .

A person seeking certification as a clinical laboratory practitioner shall, at the time of application for initial licensure as a clinical laboratory practitioner, also apply for certification on the form provided by the secretary and submit documentation sufficient to establish that he or she meets one (1) of the following qualifications for certification:

7.1. He or she is certified as a medical laboratory technician or technologist by the American Medical Technologists or the American Society of Clinical Pathologists;

7.2. He or she is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel;

7.3. He or she was performing clinical laboratory practitioner tasks in a clinical laboratory in West Virginia on July 7, 1989; or

7.4. He or she meets the qualifications, except for State licensure, for:

7.4.1. Testing personnel found at 42 CFR § 493.1423, for persons performing moderate complexity tests;

7.4.2. Testing personnel found at 42 CFR § 493.1489, for persons performing high complexity tests;

7.4.3. Cytotechnologists found at 42 CFR § 493.1483, for persons performing cytological examinations; or

7.5. He or she is certified under any other applicable federal program.

§64-57-8. Exemption from Certification.

8.1. A person seeking an exemption from certification as a clinical laboratory practitioner shall submit a request for exemption from certification on a form provided by the secretary. The request shall include a statement signed by the director of the clinical laboratory in which the applicant is employed of: the type and number of the laboratory's CLIA certificate, and which of the qualifications for exemption established by this rule the applicant meets.

The request shall include a document which identifies the type and number of CLIA certificate of the laboratory in which the person is employed and states the exemption qualification found in Section 8.2 of this rule which applies to the person seeking the exemption. The document shall be signed by the clinical director of the laboratory.

8.2. The secretary shall exempt a person from certification as a clinical laboratory practitioner if:

8.2.1. He or she is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

8.2.2. His or her laboratory director states that the person applying for exemption from certification meets the qualifications, except for State licensure, for:

8.2.2.a. Testing personnel found at 42 CFR § 493.1423: Provided, That the applicant shall submit with his or her application documentation that he or she has at least a high school diploma, a general education development certificate (GED), or an equivalent approved by the State department of education, and has had training designed to provide him or her the following with respect to the specific tests he or she will perform:

8.2.2.a.(1). The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

8.2.2.a.(2). The skills required for implementing all standard laboratory procedures;

8.2.2.a.(3). The skills required for performing each test method and for proper instrument use;

8.2.2.a.(4). The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

8.2.2.a.(5). A working knowledge of reagent stability and storage;

8.2.2.a.(6). The skills required to implement the quality control policies and procedures of the laboratory;

8.2.2.a.(7). An awareness of the factors that influence test results; and

8.2.2.a.(8). The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results, and Provided further: That, in the event that the individual is to perform additional tests, he or she shall submit to the secretary documentation of training related to the additional tests in the skills, knowledge, and awareness as required by Sections 8.2.2.a(1) through 8.2.2.a(8) of this rule; or

8.2.2.b. For persons performing cytotechnoligical examinations, the qualifications for cytotechnologists found at 42 CFR § 493.1483.

§64-57-9. Expiration of Certification and Exemption.

An individual's certification or exemption from certification as a clinical laboratory practitioner expires when the person holding the certification or the exemption no longer meets the qualifications stated in this rule for certification or for exemption from certification.

§64-57-10. Reciprocity.

The secretary may issue a clinical laboratory practitioner license or certification to a person who holds a license or certification from another jurisdiction which has licensure or certification requirements at least as stringent as the requirements of this rule. Applicants for reciprocity shall submit the license application fee and a statement from their licensing or certifying jurisdiction that they are in good standing with their application.

§64-57-11. Limitations on Certification, License and Use of Titles by Health Care Facilities.

11.1. Licensure or certification as a clinical laboratory practitioner does not authorize the person to perform laboratory tests unless his or her clinical laboratory director has determined that the person is qualified by education, training or experience to perform such tests.

11.2. Health care facilities shall not use the terms clinical laboratory practitioner, laboratory or medical technician or laboratory or medical technologist, or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory practitioner.

§64-57-12. Revocation and Non-issuance of Clinical Laboratory Practitioner Certifications.

A clinical laboratory practitioner license, certification, or exemption from certification, shall not be issued or shall be revoked if the applicant for or holder thereof:

12.1. Has misrepresented material facts in an application or has assisted another person in doing so;

12.2. Does not meet requirements for licensure, certification, or exemption from certification; or

12.3. Has been convicted of a felony involving laboratory practices.

§64-57-13. Hearings.

13.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory practitioner certification or license, by a holder thereof or by a health care facility. The request shall specify the grounds relied upon as a basis for the relief requested.

13.2. Hearings shall be conducted in accordance with the provisions of W. Va. Code § 29A-5-1 et seq., and Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia Administrative Rules, 64 CSR 1.

§64-57-14. Severability.

The provisions of this rule are severable. If any provision of this rule is held invalid, the remaining provisions remain in effect.

consent order for the substance and determined that the information available was sufficient to make a reasoned evaluation of the health effects of the substance. EPA concluded that, for the purposes of TSCA section 5, the substance will not present an unreasonable risk and consequently revoked the section 5(e) consent order. The proposed revocation of SNUR provisions for the substance designated herein is consistent with the revocation of the section 5(e) order.

In light of the above, EPA is proposing a revocation of SNUR provisions for this chemical substance. When this revocation becomes final, EPA will no longer require notice of any person's intent to manufacture, import, or process this substance. In addition, export notification under section 12(b) of TSCA will no longer be required.

III. Comments Containing Confidential Business Information

Any person who submits comments claimed as CBI must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR part 2. Any party submitting comments claimed to be confidential must prepare and submit a public version of the comments that EPA can place in the public file.

IV. Rulemaking Record

The record for the rule which EPA is proposing to revoke was established at OPPTS-50608 (P-92-341). This record includes information considered by the Agency in developing the rule and includes the test data that formed the basis for this proposal.

A record has been established for this rulemaking under docket number OPPTS-50608C (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE-B607, 401 M St., SW., Washington, DC 20460

Electronic comments can be sent directly to EPA at:

ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

V. Regulatory Assessment Requirements

EPA is proposing to revoke the requirements of the rule. Any costs or burdens associated with the rule will also be eliminated when the rule is revoked. Therefore, EPA finds that no costs or burdens must be assessed under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 605(b)), or the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements, Significant new uses.

Dated: September 1, 1995

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

§ 721.3254 [Removed]

2. By removing § 721.3254.

[FR Doc. 95-22731 Filed 9-12-95; 8:45 am]

BILLING CODE 6560-60-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 493

[HSQ-225-P]

RIN 0938-AG99

Public Health Service; CLIA Program; Categorization of Waived Tests

AGENCY: Health Care Financing Administration (HCFA) and Public Health Service (PHS), HHS.

ACTION: Proposed rule.

SUMMARY: In this rule we are proposing criteria we would use to determine whether to categorize specific laboratory tests as waived from certain requirements of the Clinical Laboratories Improvement Amendments of 1988. We also propose revisions to requirements that laboratories performing waived tests must meet.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 13, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Centers for Disease Control and Prevention, Public Health Service, Department of Health and Human Services, Attention: HSQ-225-P, 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 address:

CDC/Washington, Room 714-B, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ-225-P. 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 p.m. (phone: (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC

20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

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 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**.

FOR FURTHER INFORMATION CONTACT: Rosemary Bakes-Martin, (404) 488–7655, for questions regarding the criteria for waived test categorization and the requirements for data submission; and Judy Yost, (410) 786–3531, for certificate and inspection issues.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 353 of the Public Health Service (PHS) Act (42 U.S.C. 263a), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings must meet certain requirements to perform the examination. On February 28, 1992 (57 FR 7002), we published regulations to implement CLIA at 42 CFR part 493. Many of the requirements are based on the complexity of the tests performed. There are currently three test categories: waived, moderate complexity and high complexity.

In accordance with the law, HHS established a Clinical Laboratory Improvement Advisory Committee (CLIAC) to advise and make recommendations on technical and scientific aspects of the regulations. The CLIAC is composed of individuals involved in the provision of laboratory services, use of laboratory services, development of laboratory testing devices or methodologies, and others as approved by HHS. In addition, HHS has designated four CLIAC subcommittees that focus on the following areas: cytology, personnel, proficiency testing, quality control and quality assurance; and test categorization.

We received approximately 16,000 letters from professional organizations and individuals that provided approximately 71,000 comments in response to publication of the February 28, 1992 regulations. Through this proposed rule, we are responding to the approximately 1,100 comments concerning the categorization of waived tests, specifically the subjectiveness of the waived criteria and the failure of tests to be granted waiver status.

These commenters were responding to our regulations at § 493.15 that merely excerpt the statutory language without elaboration and list nine tests or examinations that meet the statutory criteria and are waived. That section further provides that revisions to the list of waived tests approved by HHS will be published in the **Federal Register** in a notice with opportunity for public comment. As currently defined in the regulation, waived tests are simple laboratory examinations and procedures that—

(1) Are cleared by the Food and Drug Administration (FDA) for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

The specified tests that are listed in the regulation are:

(1) Dipstick or tablet reagent urinalysis (non-automated) for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen;

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

After evaluating the comments concerning waived tests, we sought advice in February 1993 from the CLIAC concerning the criteria for waiver and the process for considering whether specific tests should be placed in the waived category. The CLIAC agreed that the criteria should be better defined and recommended that the Centers for Disease Control and Prevention (CDC) clarify the criteria and process for categorizing waived tests and suggested that a moratorium be placed on adding tests to the waived category until the criteria were better defined. In response to the CLIAC recommendation, CDC initially established a moratorium on considering tests for waiver while we were developing the notice of proposed rulemaking to revise the CLIA regulations for waived categorization.

In response to public concern, on December 19, 1994, the moratorium was lifted, and CDC notified all manufacturers and producers of moderate complexity test systems that it will consider for waiver any test that meets the statutory criteria and for which the manufacturer or producer applies for waiver in accordance with the CLIA regulations published February 28, 1992. CDC enclosed guidelines (included in this rule as proposed test system characteristics and field studies) that can be used to verify the accuracy and precision of testing devices and demonstrate that the test meets the statutory criteria for waiver. The guidelines were included to assist applicants in applying for waiver; however, all requests will be considered as long as they include valid scientific studies to verify that the test meets the statutory criteria for waiver.

II. The Revision Process

Under the statute, waived tests are defined as "* * * simple laboratory examinations and procedures that, as determined by the Secretary, have an insignificant risk of an erroneous result * * *." The statute contains additional language to describe the types of examinations and procedures to be included in the waived category; that is, tests that have "* * * been approved by the FDA for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly." The law also specifies that waived tests are exempt from the CLIA health and safety standards, including personnel, patient test management, quality control, proficiency testing, quality assurance, and routine inspections requirements.

In the preamble of the CLIA regulations published February 28, 1992, in the Federal Register (57 FR 7002), we stated that FDA clearance of a test for home use could not be used as a sole criterion for qualifying as a

waived test. We have continued to review the section of the statute pertaining to waived tests and believe now that the better view of the statute is that the waived criteria set out at 42 U.S.C. 263a(d)(3)(A), (B), and (C) were intended by the Congress to represent the kinds of tests that are "simple laboratory examinations and procedures which * * * have an insignificant risk of an erroneous result." Therefore, any test system cleared by the FDA for home use will, upon receipt of a request for waiver from the manufacturer, be waived under CLIA.

With regard to the other two criteria for waiver, we believe that a critical factor to be considered is the implicit statutory mandate that waived testing be easily performed and provide accurate results. Therefore, in order for a test to be categorized as waived, it must *both*: (1) Be simple; and (2) have an insignificant risk of an erroneous result. In this rule, we are proposing to clarify the statutory criteria by specifying performance characteristics and studies designed to demonstrate that any test system categorized as waived would be simple, easy to perform, and essentially error-free. We believe that conformance to these criteria would reduce the possibility of the test producing an erroneous result and, thus, assist in determining whether the test system could pose a reasonable risk of harm to a patient if performed incorrectly.

We are proposing that, to be exempt from CLIA and categorized as waived, in accordance with the law, all test systems either be cleared by the FDA for home use or meet the requirements in CLIA to ensure that the test procedure is simple and not prone to error.

In response to the CLIAC recommendation, CDC developed a protocol to follow when requesting that tests be placed in the waived category. The protocol describes basic specifications for verifying that the test system meets the performance characteristics defined by the criteria. CDC proposed that, upon request of HHS as specified in § 493.2001, the CLIAC would review applications for waiver, in accordance with the waived criteria, and make recommendations to HHS concerning waiver status.

The proposed clarifications to the criteria for waiver addressing simplicity and accuracy and the proposed process to follow when requesting waived categorization were presented to the CLIAC test categorization subcommittee and subsequently to the full committee. The CLIAC endorsed the clarifications as well as the process for requesting waived categorization and recommended that the CLIA regulations be revised to incorporate the changes.

The CLIAC further recommended that all tests currently on the waived list be subject to the new clarifications to the criteria to determine if they should remain in the waived category. The committee thought that the method previously used to place tests in the waived category was too subjective and was concerned that some of the tests may not be sufficiently error-free to justify their continued waived status.

III. Proposed revisions

Clarified Criteria

In this regulation, we propose to delete § 493.15, which contains the current criteria for waived tests and a process to announce revisions to the list. In its place, we would: Clarify the waived criteria (outlined below), incorporate the clarification into our regulations at a new § 493.7, and place the remaining provisions, appropriately revised to reflect the new procedures, at § 493.9.

Following the recommendation from the CLIAC that we clarify the criteria for waiver, a number of resources, such as FDA protocols for defining tests suitable for home use and the National Committee for Clinical Laboratory Standards protocols for method evaluations, were used as reference materials. Since one of the main concerns of commenters on our previous CLIA rulemaking centered around the subjectiveness and ambiguity of applying the statutory criteria to categorize the tests as waived, we used information from these sources to clarify what we mean by "simple" and "not prone to error" as a mechanism to define the statutory phrase "have an insignificant risk of an erroneous result". We believe that test systems must possess certain characteristics that would make them easier to use and they also must be able to demonstrate a level of accuracy and precision that would ensure the correct test result is generated regardless of the user's level of expertise.

Below we have listed test system properties that we believe illustrate simplicity and ease of use. The test system:

- Uses direct unprocessed specimens, requires no specimen manipulation before analysis or analyst intervention during analysis, and provides direct readout of results. Quantitative tests must be fully automated while qualitative tests are limited to simple reagent impregnated devices that produce only a positive or negative result;
- Contains fail-safe mechanisms rendering no results when the results are outside of the reportable range or when the test system malfunctions;
- Requires no invasive test system troubleshooting, or electronic or mechanical maintenance; and
- Contains instructions written at a comprehension level no higher than seventh grade. Instructions would have to include step-by-step system operation and maintenance procedures; reagent preparation and storage; and calibrator and control preparation, storage, frequency of assay, and action to be taken if control or calibrator results are out of range.

We would consider a test for waiver if the test system has these characteristics. However, we are interested in receiving comments on alternative test system characteristics or approaches to define the statutory criterion related to test system simplicity.

The test system characteristics that we are proposing are designed to limit the amount of operator intervention or interpretive skill required to perform the test. Limiting operator intervention should prevent analysts without previous laboratory training or experience from inadvertently disrupting the analytic process and thus introducing human error into the testing procedure. The requirement for a fail-safe mechanism would prevent untrained operators from unknowingly accepting or utilizing incorrect results. In view of the fact that no previous training or experience is required before performing waived tests, test systems in the waived category should not require invasive troubleshooting or electronic or mechanical maintenance since these processes rely on the use of interpretive skills to make judgement decisions. We also believe that an "easy to use" test system must have instructions that are written at a comprehension level that would provide reasonable assurance that all likely users, regardless of background, training, or experience, would be able to read and understand the step-by-step procedures required to correctly perform testing. We are suggesting that a seventh grade comprehension level is appropriate to define the waived criteria because waived tests will not be subject to any personnel requirements and because waived tests must be simple and capable of providing accurate test results when performed by non-professional testing personnel. Inasmuch as the considerations for waiver are similar to those for FDA clearance of home-use products, and FDA requires that package inserts for

home-use tests be written at the seventh grade comprehension level, we are proposing that waived test system instructions be written at the same comprehension level.

Submission Requirements

To define test systems that are simple, easy to use, and not error prone, we are proposing that field studies be conducted to scientifically assess the accuracy and precision of the test. In this regulation, we are proposing basic criteria for manufacturers and producers to use in configuring these field studies.

The studies are designed to ensure that the test system generates consistent results regardless of the environment in which the testing is performed.

Specifically, we are proposing that these studies:

- Evaluate among-operator imprecision;
- Evaluate within-site imprecision at a minimum of three sites; and
- Evaluate among-site imprecision.

We are proposing to place no restrictions on the number of study participants or sites except for specifying that the within-site studies should be performed at a minimum of three sites. We believe it is appropriate to provide this flexibility in study design, which allows applicants to determine the number of participants and sites that are adequate to produce measures of performance that are both statistically valid and defensible. Also, the appropriateness of the number of study participants and sites might vary depending upon the analyte or test method.

Additionally, in this rule, we are proposing that the studies prove the test system's clinical reliability by demonstrating accuracy at all relevant medical decision points. To verify the credibility of the data, we are proposing in this rule that the number of participants and sites and the sampling process be adequate to produce measures of performance that are both statistically valid and defensible (estimates must support valid confidence limits for all statistical parameters). We are proposing that the studies be performed at non-laboratory sites to ensure that all users, professionals as well as lay persons, can perform waived testing with the same competence. We are proposing that the study participants have no previous laboratory experience or training to ensure that individuals used for study purposes have education, training and experience that is at a level no higher than that of the lowest trained persons anticipated to perform the test. We welcome comments and suggestions on the types of studies proposed in this rule and comments on our proposals for data submission.

Because waived tests would not be subject to any quality control requirements and we would not routinely conduct inspections of laboratories performing only waived tests, we propose to require the laboratory to notify the producer or manufacturer of the test system of any performance that does not meet the specifications as outlined in the test system instructions and would require the producer or manufacturer to include in the test system instructions the address and phone number of the person to contact. If the manufacturer or producer of the test system does not resolve the problem, we would require the laboratory to notify PHS of the problem.

We also would require that test system instructions include a statement to inform the laboratory that if the laboratory modifies or alters the test system instructions in any way (for example, changes in specimen type or sample amount), the test no longer meets the requirements for waiver and is considered to be high complexity and, thus, must meet all the applicable CLIA requirements in 42 CFR part 493.

Review Process

To ensure that tests categorized as waived are simple, accurate and essentially error-free, we would require that waived tests meet the clarified criteria. Once the final rule responding to the comments received to this proposed rule is published, we plan to evaluate requests for waiver, in accordance with the data submittal requirements and process for requesting waived categorization that would be included under § 493.7, and to apply the new requirements to currently waived tests. However, it should be noted that when the CLIA regulations are revised to incorporate changes to the waiver process, we expect that the review process for waived categorization of devices having similar test methodologies could be simplified. For example, if a test system employs the same methodology as a device that has been granted waiver in accordance with the final regulations, submission of studies showing accuracy and precision equivalency between the applicant test system and the waived test should be sufficient. These studies must reflect data that are adequate to produce measures of performance that are statistically valid and defensible and estimates must support valid confidence limits for all parameters.

In this rule, we are proposing that, after waiver has been granted, any change or modification by the maunfacturer or producer to the test system that could affect the test accuracy or reliability (that is, procedural changes that would now require operator intervention during the analytic process or method changes that require performance studies to reevaluate test validity) be resubmitted for evaluation and review. Changes to a test system that would not affect test performance, such as those made to improve component appearance or durability, would not have to be resubmitted.

The Department's purpose in issuing this proposed rule is to clarify the criteria for determining which tests should be waived. In this regard, there may be alternative formulations that would result in more, or fewer, waived tests. In this proposed rule, we specifically request comments concerning:

- Which proposed criteria might be modified (and how), as well as comments in support of the provisions contained in this proposed rule;
- The impact on patient access to care if these criteria are finalized;
- The health implications of any recommended changes, including not only the possibility of erroneous test results but also likely effects on patient health if additional testing is discouraged or encouraged (for example, by providing such testing in a doctor's office); and
- The potential that these criteria may or may not have for driving new technology toward more safe and accurate testing.

In addition, we are interested in receiving comments and suggestions about how we might include in the waived categorization process considerations related to the benefits to the public of categorizing tests as waived. Although the statute does not specify this as a criterion for waiver, we recognize this as a significant factor affecting access to care.

After the comments to this rule are evaluated and a final rule is published, we plan to follow the CLIAC recommendation that PHS reevaluate tests that were previously categorized as waived against any new regulatory criteria. If changes to the previously waived tests are necessary, we plan to publish a notice in the Federal Register soliciting comments on the proposed changes.

Waived Test List

In this rule, we propose to delete the generic list of waived tests from

§ 493.15. However, at § 493.7(c)(3), we would retain the provision, currently at § 493.15(d), to publish the names of the tests that are waived in a Federal Register notice with an opportunity for public comment. In addition, for consistency with the test categorization provisions in § 493.17(c)(1)(ii), we would make waived categorization effective on the date of notification to the applicant. Any entity that is notified of approval of its waiver application must be aware, however, that we may rescind this waiver approval and recategorize the test should comments we receive convince us that our initial waiver decision was inappropriate.

Summary of Proposed Changes to the Regulation

We propose to remove § 493.15 in its entirety. The criteria currently in § 493.15(b) for determining whether a given test can be categorized as waived would now be in a new § 493.7 and in greater detail. The requirements applicable to certificate of waiver laboratories (formerly at § 493.15(e)) would be expanded and placed in a new § 493.9.

In § 493.9, we would continue to require laboratories to follow the manufacturer's or producer's instructions when performing waived tests and to meet the requirements in subpart B of part 493. In line with the clarifications provided to the statutory criteria for categorizing tests as waived, we also would state that if a laboratory does not follow the manufacturer's or producer's instructions or makes a modification in the test system, the laboratory would no longer meet the requirements for certificate of waiver and the modified test, as performed by the laboratory, would be considered high complexity until otherwise categorized. If a laboratory or manufacturer desires official categorization of the modified test, it must submit a written request to PHS. Categorization of the modified product should occur within 30 days after PHS receives the request. In addition, laboratories would be required to report to PHS any performance problems not resolved by the producer or manufacturer of the test.

We would also make technical conforming changes to the following sections and headings because of our revisions concerning waived tests: §§ 493.2; 493.20(c); 493.25(d); 493.35 (a) and (d); 493.37(b)(1) and (g); 493.39 introductory paragraph and paragraph (a); 493.45 (a)(2) and (a)(3); 493.47(a)(2); 493.49 introductory paragraph and (b)(2)(iv); 493.53(a); 493.1775(b)(4)(iii) through (v), and (c).

IV. 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. 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 comments in the preamble to that document.

V. Collection of Information Requirements

The proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Section 493.7: This section outlines the criteria a manufacturer must follow in order to have a test considered to be a "waived" test. These include but are not limited to test system characteristics, instructions, field studies and the evaluation of data.

Section 493.9: This section outlines the requirements for laboratories performing waived tests. These include following the manufacturers' instructions and reporting to PHS performance problems not resolved by the manufacturer.

Sections 493.35, 493.39, 493.49, 493.53: Sections 493.35 through 493.63 are currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. The information is gathered on form number HCFA-R–26. These sections outline the requirements for a laboratory to follow to submit application forms for CLIA certification. The requirements include laboratory notification to HHS of changes to the types of tests performed or changes in ownership, name, location or director.

Section 493.1775: Section 493.1775 is currently approved under OMB approval number 0938–0612 with an expiration date of February 28, 1998. This section sets forth conditions and standards for inspection of laboratories. The burden associated with inspections consists of retrieving the records and documentation requested by the inspector, participating in the entrance and exit interviews, responding to the statement of deficiencies that may result from the inspection and documenting any corrective actions taken that are appropriate to the plan of correction for the deficiencies cited.

When OMB approves those provisions not currently approved we will publish a notice in the Federal Register to that affect.

Description of Respondents

Section 493.7: Small businesses or organizations, businesses or other for profit, non-profit institutions, who manufacture laboratory tests.

Sections 493.9, 493.35, 493.39, 493.49, 493.53; 493.1775: Small businesses or organizations, businesses or other for profit, non-profit institutions, state and local governments, federal agencies.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR sections	Annual No. of responses	Annual frequency	Average burden per response	Annual burden per hours
493.35, 493.39, 493.49, 493.53	28,700	1	.25 hr	7,175
493.1775	1,280(a)	1	4 hrs	2,560
493.7	20	1	168 hrs	3,360
493.9	<20	(b)	(b)	(b)

[a] Based on receiving complaints on 2 percent of waived laboratories (64,000) resulting in the survey of 1,280 waived laboratories with complaints in a two year period.

[b] Laboratories are responsible for following manufacturers' instructions when performing waived tests. Whenever a problem is encountered by the laboratory that is not resolved by the manufacturer, the laboratory must notify PHS. This should be an infrequent occurrence (manufacturers generally resolve problems identified by laboratories)

The agency has submitted a copy of the proposed rule to OMB for its review of these information collections. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Comments should be sent to HCFA, HSQB, MPAS, C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850 and to the OMB official whose name appears in the ADDRESSES section of this preamble.

VI. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all laboratories and manufacturers and producers of laboratory test systems are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary 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 50 beds.

As a result of our evaluation of comments received on the test categorization portion of the February 28, 1992 regulations implementing CLIA and as a result of additional consultation with the CLIAC, we are proposing to clarify the criteria and process used to categorize laboratory tests as waived. Manufacturers and producers of laboratory test systems specifically suggested that the types of information and data to be submitted when requesting waived categorization be more clearly defined in order to ensure that the criteria are applied accurately and uniformly to all laboratory tests. The proposed expansion of the waived criteria and development of a process protocol would provide for consistent application of detailed standards in order to ensure that tests categorized as waived are either cleared by the FDA for home use or are simple to use, produce accurate results when testing is performed, and preclude any reasonable risk of harm to patients as a result of testing errors. Of course, manufacturers and producers would be required to submit specific information and data demonstrating that their test system meets the criteria for waived categorization. In some cases, manufacturers or producers of test systems might have to conduct additional studies to obtain the information required; however, much of the data is similar to that currently required by the FDA for clearance of products. In accordance with the law, this rule would provide that any test system cleared by the FDA for home use will, upon application by the manufacturer, be waived from CLIA. We anticipate that manufacturers and producers ultimately will benefit in the form of increased sales and distribution of tests categorized as waived.

Currently, almost one-half of all laboratories hold certificates of waiver. These laboratories would obviously benefit from an improved test categorization process that yields more waived tests. Any increase in the number of waived tests would benefit laboratories by reducing the regulatory burden, since laboratories limiting their services to waived test performance are not subject to the CLIA health and safety standards (including proficiency testing, quality control, personnel, recordkeeping and quality assurance requirements). Certificate of waiver laboratories are required only to register and follow manufacturers' and producers' instructions for test performance. In addition, increasing the number of waived tests would enable laboratories to provide an expanded test menu without incurring the higher fees associated with a regular CLIA certificate. The availability of an expanded test menu at less cost also may encourage new entities to begin providing services, thereby increasing access to health care, particularly in underserved and rural areas. Consumers of laboratory services would benefit from an enhanced range of laboratory services that have been determined to be safe and produce accurate results.

We have developed these clarifications to the waived criteria in an effort to improve the process of approving tests for waiver. We believe that using the better defined criteria would result in more tests being waived if for no other reason than because the improved waiver process should drive the technology toward simpler tests that would then be widely available (because of waived status). However, we realize that the number of tests waived could vary depending upon the revisions to the waiver process. Depending on how many more or fewer tests receive a waiver, there could be significant effects on patient health (due to more or less patient access to testing, as well as more or fewer test errors) and impact on manufacturers, producers and laboratories. We request comments on alternatives that might produce higher benefits or lower costs, taking into account all effects. We particularly solicit comments that can provide quantitative estimates of likely effects on patient health resulting from different waived criteria and, hence, waived tests.

As indicated above, we believe that over time the effect of this rule will be to expand the universe of waived tests, to the benefit of patients, laboratories, manufacturers, and producers. However, we are unable to quantify these likely long run effects because they depend on market decisions, research results, and technological change that cannot be predicted.

In the short run, we would not expect substantial effects. Currently there are nine waived tests and about 250 individual test systems or products representing nine analytes or specific types of procedures that have been approved as waived tests. Assuming that the final rule does not depart substantially from the proposed criteria, the great majority of individual tests would continue to be eligible for the waiver category. We expect that laboratories would continue to have a wide range of products/test systems available and would therefore not lose waiver status. At most, only a few products might not meet the clarified waived criteria and any such test system's manufacturer or producer would have the option of improving test accuracy.

This proposed rule would clarify the process and criteria for categorizing waived tests and possibly result in changes in the list of waived tests. Proper realignment of the fee schedule, if necessary, would follow implementation of this rule.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities or

the operations of a substantial number of small rural hospitals. We do request comments, however, on possible adverse effects on affected entities and will consider these carefully in formulating the final rule.

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 would be 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), 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. In § 493.2, in the definition of "CLIA certificate" the introductory text is republished and paragraph (2) and (5) are revised to read as follows:

§ 493.2 Definitions.

* * * * *

CLIA certificate means any of the following types of certificates issued by HCFA or its agent:

* * * * *

(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, tests approved by PHS as waived under § 493.7.

* * * * *

(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 tests approved by PHS as waived under § 493.7.

* * * * *

3. A new § 493.7 is added to read as follows:

§ 493.7 Waived tests.

(a) *Requirement.* For a test to be included in the waived category, the test system must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems must be simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. Test systems cleared by the FDA for home use meet the criteria specified in this section and will be approved for waiver following submission of the manufacturer's or producer's request for waiver approval.

(1) For quantitative tests, methods must be simple (easy to use) and accurate as evidenced by the following items:

(i) Test systems that have the following characteristics:

(A) Are fully automated or self-contained.

(B) Use only direct unprocessed specimens.

(C) Require no specimen manipulation before the analytic phase of operation.

(D) Require no operator intervention during the analytic phase.

(E) Provide a direct readout of results; that is, require no calculations or conversions.

(F) Contain fail-safe mechanisms that render no result when the test system malfunctions and initiate fail-safe mechanisms rendering no test result when the result is outside the reportable range.

(G) Require no invasive test system troubleshooting to be performed by testing personnel and include no electronic or mechanical maintenance to be performed by testing personnel.

(ii) Test system instructions that are written at a comprehension level no higher than the seventh grade (as demonstrated by accepted academic standards) and that address the following items:

(A) Analytical skills required of personnel performing the test.

(B) Attributes or limitations of the physical environment or conditions for test performance.

(C) Requirements for specimen collection, handling, storage and preservation.

(D) Reportable range for patient results.

(E) Reference range (normal values).

(F) Step-by-step protocols that include, as appropriate, the following items:

(*1*) Instrument or test system operation and test performance instructions.

(*2*) Test system maintenance procedures.

(*3*) Preparation and storage of reagents, calibrators, controls or other materials used in testing.

(*4*) Control procedures, including the type of materials, suggested concentrations, and frequency of assay.

(*5*) Calibration procedures, including the number and type of materials and frequency of assay.

(*6*) Acceptable ranges for any control or calibration material included with the test system.

(*7*) Action to be taken when calibration or control results do not meet the acceptable range of values.

(*8*) Description of course of action to be taken when the test system becomes inoperable.

(iii) Field studies that meet the following criteria:

(A) Are performed at nonlaboratory sites.

(B) Include study participants who have no previous laboratory experience or training. The number of participants and sites selected must be adequate to produce measures of performance that are both statistically valid and defensible.

(C) Demonstrate that the manufacturer's or producer's written instructions are the only protocols required to perform the test accurately and reliably.

(D) Demonstrate that the test system produces accurate results under the testing conditions and within the physical environment specifications defined in the test system instructions.

(E) For those tests that employ calibration, demonstrate that calibration is stable over the calibration frequency interval or that a fail-safe mechanism rendering no result is initiated when the test system is out of calibration.

(iv) Data from field studies that meet the following criteria:

(A) Are generated from protocols that address the points described in paragraph (b)(1)(iii) of this section.

(B) Are adequate to produce measures of performance that are both statistically valid and defensible (estimates must support valid confidence limits for all statistical parameters).

(C) Evaluate performance at all medical decision points and relevant upper and lower limits of the reportable range using at least three concentrations of the analyte being tested.

(D) Evaluate among-operator imprecision using test results of all study participants.

(E) Evaluate within-site imprecision using test results generated at each site by an adequate number of participants to produce measures of performance that are statistically valid and defensible. Testing must be performed at a minimum of three independent study sites.

(F) Evaluate among-site imprecision at an adequate number of sites to produce

measures of performance that are statistically valid and defensible.

(G) Demonstrate that the total amount of imprecision, which includes all components contributing to imprecision as demonstrated by studies described in paragraphs (b)(1)(iv) (D), (E) and (F) of this section, is less than one-fourth of the reference range for the analyte divided by the mean of the reference interval.

(v) Method accuracy studies demonstrating that the test system is not affected by systematic error when—

(A) Using reference materials assayed by study participants that produce data that prove there is no statistically significant difference between the test results and the value of the reference materials;

(B) Using patient samples instead of reference materials, proving that there is no statistically significant difference between test results obtained on patient and reference materials due to the effects of the sample matrix; and

(C) Using patient samples containing substances that commonly cause interference, confirming there is no introduction of error due to the presence of these substances.

(2) For qualitative tests, methods must be simple (easy to use) and accurate as evidenced by the following items:

(i) Test systems that have the following characteristics:

(A) Use only direct unprocessed specimens.

(B) Require no specimen manipulation before performing the testing procedure.

(C) Contain no procedural steps beyond adding a sample to a reagent impregnated device.

(D) Require no specimen manipulation during the procedure.

(E) Require a well-defined distinct endpoint that is limited to positive or negative interpretation.

(F) Contain fail-safe mechanisms that render no result when the test system malfunctions.

(ii) Test system instructions that are written at a comprehension level no higher than the seventh grade (as demonstrated by accepted academic standards) and that address the following items, as appropriate:

(A) Analytical skills required of personnel performing the test.

(B) Attributes or limitations of the physical environment or conditions for test performance.

(C) Requirements for specimen collection, handling, storage and preservation.

(D) Patient result reporting.

(E) Reference range (normal values).

(F) Step-by-step protocols that include, as appropriate, the following items:

(*1*) Test performance instructions.

(*2*) Preparation and storage of reagents, calibrators, controls or other materials used in testing.

(*3*) Control procedures, including the type of materials and frequency of assay.

(*4*) Calibration procedures, including the number and type of materials and frequency of assay.

(*5*) Acceptable ranges for any control or calibration material included with the test system.

(*6*) Action to be taken when calibration or control results do not meet the acceptable range of values.

(*7*) The correct interpretation of test endpoints.

(*8*) Description of course of action to be taken when test endpoints cannot be determined.

(iii) Field studies that meet the following requirements:

(A) Are performed at nonlaboratory sites.

(B) Include study participants who have no previous laboratory experience or training. The number of participants and sites selected must be adequate to produce measures of performance that are both statistically valid and defensible.

(C) Demonstrate that the manufacturer's or producer's written instructions are the only protocols required to perform the test accurately and reliably.

(D) Demonstrate that the test system produces accurate results under the testing conditions and within the physical environment specifications defined in the test system instructions.

(E) For those tests that employ calibration, demonstrate that calibration is stable over the calibration frequency interval or that a fail-safe mechanism rendering no result is initiated when the test system is out of calibration.

(iv) Data from field studies that meet the following requirements:

(A) Are generated from protocols that address the points described in paragraph (b)(2)(iii) of this section.

(B) Are adequate to produce measures of performance that are both statistically valid and defensible.

(C) Confirm that study participants are able to read the test endpoint with the same precision as laboratory professionals.

(D) Confirm that the performance of study participants is essentially the same as laboratory professionals when testing samples at or near the cutoff and at sufficient distance above and below the cutoff to confirm precision at all analytical decision points.

(E) Demonstrate minimal among-operator imprecision using results of all study participants.

(F) Demonstrate minimal within-site imprecision using test results generated at each site by an adequate number of participants to produce measures of performance that are statistically valid and defensible. Testing must be performed at a minimum of three independent study sites.

(G) Using results generated by study participants, on aliquots of a single testing material, demonstrate minimal among-site imprecision at an adequate number of sites to produce measures of performance that are statistically valid and defensible.

(v) Method accuracy studies demonstrating that there is no statistically significant difference between observed values and expected values at the cutoff point when—

(A) The test values are compared to a quantitative result such as the value of a reference material or the presence or absence of a particular biologic component;

(B) Confirming that there are no significant equivocal test results on either side of the cutoff;

(C) Comparing results between study participants and laboratory professionals on samples with values at the cutoff;

(D) The test is performed on patient samples instead of reference materials, confirming there is no introduction of error due to sample matrix; and

(E) Samples contain substances that commonly cause interference, confirming there is no introduction of error due to these substances.

(c) *Waiver process*—(1) *Process for requesting waived status.* (i) Requests for waiver of tests must be submitted to PHS.

(ii) PHS reviews requests for waiver that meet the criteria specified in paragraph (b) of this section and the submission requirements under paragraph (c)(2) of this section.

(iii) The Clinical Laboratory Improvement Advisory Committee (CLIAC), as specified in subpart T of this part, conducts reviews upon request of HHS and makes recommendations to HHS concerning the waiver of tests.

(iv) Any change or modification to a test system by the manufacturer or producer that could affect the accuracy or reliability of the waived test must be resubmitted to PHS for evaluation and review. Until this review is completed and status is determined, the modified test is considered uncategorized and, in accordance with § 493.17(c)(4), is considered high complexity.

(v) A request for reconsideration of a test denied waived status is accepted for review if the request is based on information not previously submitted.

(2) *Submission requirements*—(i) Requests for waiver must meet the criteria described in paragraph (b) of this section. In the event that a request does not include complete information, the request is not reviewed and the manufacturer or producer of the test system is notified.

(ii) Data collection protocols and data submitted must be complete and data submitted must be statistically valid and meet the criteria described under paragraph (b) of this section.

(iii) Test system instructions must be complete and must include, as applicable, the items defined in paragraph (b)(1)(ii) of this section for quantitative tests and under paragraph (b)(2)(ii) of this section for qualitative tests. In addition, test system instructions must include the following statements:

(A) "Any modification by the laboratory to the test system or the PHS-approved test system instructions will result in the test no longer meeting the requirements for waived categorization. A modified test is considered to be high complexity and is subject to all applicable CLIA requirements contained in 42 CFR part 493."

(B) "The laboratory must notify the manufacturer or producer of this test system of any performance, perceived or validated, that does not meet the performance specifications as outlined in the instructions." The name, address and phone number(s) of the manufacturer's or producer's contact person(s) must follow this statement.

(iv) Using the criteria specified in paragraph (b) of this section, each test categorized as waived before [date of publication of final rule] will be reevaluated by PHS.

(3) *Notification of decision*—(i) PHS determines whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test.

(ii) PHS notifies the applicant of the waived categorization determination, whether denied or granted.

(iii) Waived categorization is effective as of the date of notification to the applicant.

(iv) PHS publishes additions and revisions periodically to the tests categorized as waived in the **Federal Register** in a notice with an opportunity for public comment. PHS reserves the right to reevaluate and recategorize a test based upon the comments it receives in response to the **Federal Register** notice.

4. A new § 493.9 is added to read as follows:

§ 493.9 Laboratories performing waived tests.

(a) A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts its test performance to one or more tests approved by PHS as waived under § 493.7.

(b) Laboratories issued a certificate of waiver must meet the following requirements:

(1) Follow the manufacturer's or producer's instructions for performing the test. If a laboratory does not follow the manufacturer's or producer's test system instructions, the laboratory no longer meets the requirements for a certificate of waiver and the modified test, as performed by the laboratory, is considered high complexity until otherwise categorized.

(2) Report to PHS any performance problems not resolved by the manufacturer or producer of the test.

(3) Meet the requirements in subpart B of this part.

§ 493.15 [Removed]

5. Section 493.15 is removed.

6. In § 493.20, paragraph (c) is revised to read as follows:

§ 492.20 Laboratories performing tests of moderate complexity.

* * * * *

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, M, and P of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.9(b) and 493.1775.

7. In § 493.25 paragraph (d) is revised to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, M, and P are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.9(b) and 493.1775.

8. In § 493.35, paragraphs (a) and (d) are revised to read as follows:

§ 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more tests approved by PHS as waived under § 493.7 must file a separate application for each laboratory location.

* * * * *

(d) *Access requirements.* Laboratories that perform one or more tests approved by PHS as waived under § 493.7 and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.9(b).

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not approved by PHS as waived under § 493.7.

(iv) To collect information regarding the appropriateness of tests approved by PHS as waived under § 493.7.

* * * * *

9. In § 493.37, the introductory text of paragraph (b) is republished and paragraphs (b)(1) and (g) are revised to read as follows:

§ 493.37 Requirements for a certificate of waiver.

* * * * *

(b) *Laboratories issued a certificate of waiver*—(1) Are subject to the requirements of this subpart and § 493.9(b); and

* * * * *

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not approved by PHS as waived under § 493.7 must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

10. In § 493.39, the introductory text and paragraph (a) are revised to read as follows:

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests approved by PHS as waived under § 493.7 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test not approved by PHS as a waived under § 493.7 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

* * * * *

11. In § 493.45, the introductory text of paragraph (a) is republished.

paragraph (a)(3) is removed, and paragraph (a)(2) is revised to read as follows:

§ 493.45 Requirements for a registration certificate.

* * * * *

(a) A registration certificate is required—

* * * * *

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests approved by PHS as waived under § 493.7 or specified as PPM procedures.

* * * * *

12. In § 493.47, paragraph (a) is revised to read as follows:

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests approved by PHS as waived under § 493.7.

* * * * *

13. In § 493.49, the introductory text of paragraphs (b) and (b)(2) are republished and the introductory text of the section and paragraph (b)(2)(iv) are revised to read as follows:

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or approved by PHS as waived under § 493.7. Moderate complexity tests may include those specified as PPM procedures.

* * * * *

(b) Laboratories issued a certificate of compliance—

* * * * *

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

* * * * *

(iv) To collect information regarding the appropriateness of tests approved by PHS as waived under § 493.7 or tests categorized as moderate complexity (including the subcategory) or high complexity.

* * * * *

14. In § 493.53, the introductory text is republished and paragraph (a) is revised to read as follows:

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not approved by PHS as waived under § 493.7 for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

* * * * *

15. In § 493.1775, the introductory text of paragraphs (b) and (b)(4) is republished and paragraph (b)(4)(iv) is redesignated as (b)(4)(v), a new (b)(4)(iv) is added, and paragraphs (b)(4)(iii) and (c) are revised to read as follows:

§ 493.1775 Condition: Inspection of laboratories issued a certificate of waiver.

* * * * *

(b) The laboratory may be required, as part of this inspection, to—

* * * * *

(4) Permit HHS or its designee upon request to review all information and data necessary to—

* * * * *

(iii) Determine whether the laboratory is performing tests not approved by PHS as waived under § 493.7;

(iv) Determine whether the laboratory is performing the test in accordance with the manufacturer's or producer's instructions; and

* * * * *

(c) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493. Requirements for the purposes of this section are located in subparts A and B or subpart D, if applicable, of this part.

* * * * *

Authority: Sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: May 18, 1995.

Philip R. Lee,

Assistant Secretary for Health

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: June 2, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95-22378 Filed 9-12-95; 8:45 am]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 80

[WT Docket No. 95-132; FCC 95-352]

Designate Sault Ste. Marie, Michigan; San Francisco, California, and Morgan City, Louisiana as a Radio Protection Area for Mandatory Vessel Traffic Services (VTS)

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has proposed rules to add Sault Ste. Marie, Michigan; San Francisco, California, and Morgan City, Louisiana to the United States Coast Guard (Coast Guard) designated radio protection areas for mandatory VTS and establish marine VHF Channel 12 as the VTS frequency for Sault Ste. Marie, Michigan; San Francisco, California; and Channel 11 as the VTS frequency for Morgan City, Louisiana. This action is in response to a request from the Coast Guard. The designation of Sault Ste. Marie, Michigan; San Francisco, California; and Morgan City, Louisiana as a VTS areas will allow the Coast Guard to manage vessel traffic in a more efficient manner.

DATES: Comments must be submitted on or before October 23, 1995; Reply comments on or before November 7, 1995.

FOR FURTHER INFORMATION CONTACT: James Shaffer, (202) 418-0680, Wireless Telecommunications Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making* FCC 95-352, adopted August 9, 1995, and released August 30, 1995. The full text of this *Notice of Proposed Rule Making* is available for inspection and copying during normal business hours in the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C. The complete text may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, Suite 140, Washington, D.C. 20037, telephone (202) 857-3800.

Summary of Notice of Proposed Rule Making

1. The Coast Guard filed a petition (RM-8500, 8592, 8598), Public Notice No. 2023 and 2057, requesting that the Commission amend Part 80 of the Rules, 47 CFR Part 80, to add Sault Ste. Marie, Michigan; San Francisco, California; and Morgan City, Louisiana to the Coast

ANALYSIS OF PROPOSED LEGISLATIVE RULE

Agency: Department of Health and Human Services

Subject: Clinical Laboratory Technician and Technologist Licensure and Certification- 67CSR57

PERTINENT DATES

Filed for public comment: June 23, 1995
Public comment period ended: October 5, 1995
Filed following public comment period: October 5, 1995
Filed LRMRC: October 5, 1995
Filed as emergency: n/a

Fiscal Impact: Estimated revenue, $100,000.00 per year, estimated annual cost first year, $111,626, and after first year, $145,384.00.

ABSTRACT

The proposed rule is new. The following is a section by section synopsis of the proposed rule.

Section 1 is the standard general section, setting forth the scope, authority, filing date and effective date of the proposed rule.

Section 2 provides that this rule applies to all clinical laboratory practitioners. County health departments, primary health care centers having tax exempt statue, laboratories operated by the federal government, laboratory operated purely for research or teaching purposes, or to individuals who perform tests on his or her self or members of his or her family are excluded from the provisions of this rule.

Section 3 is the definition section. Major definitions include:

Clinical laboratory practitioner is defined as a laboratory technologist or technician. Both of these types of practitioners are regulated under this rule.

Health care facility covered under this rule include: Hospitals, nursing, residential and personal care homes, Hospice programs, mentally illness facilities, and group residential facilities.

Section 4 incorporates federal laboratory requirements by reference.

Section 5 provides that no person may practice as a clinical laboratory practitioner unless licensed as a clinical laboratory practitioner.

Section 6 establishes licensure requirements. Applicants must submit a completed form to the director along with a licensure fee. Licenses shall be granted to all persons who submit this with proof of certification as a lab technician or technologist, or exemption therefrom. Ten hours of continuing education must be completed each year for all annual renewal applications.

Section 7 sets out certification requirements. Three nationally recognized programs are recognized along with a grandfather clause to allow those persons acting as practitioners by July 7, 1989 to be certified without meeting any training requirements.

Section 8 provides criteria for persons to receive exemptions for certification requirements.

Section 9 provides that certification or exemption from certification expires when the person holding the certification or exemption no longer meets the certification or exemption requirements.

Section 10 establishes reciprocity of other states licensees if that state has licensing requirements "at least comparable" to West Virginia's requirements.

Section 11 provides that in addition to the provisions of this rule, that clinical laboratory directors must determine that each clinical laboratory practitioner is qualified to perform tests before a clinical laboratory practitioner can conduct lab tests. This section also prohibits laboratories from using the term "clinical laboratory practitioner" for any person not licensed as a clinical laboratory practitioner.

Section 12 establishes criteria for revocation or denial of certification and licensure if the application has been falsified, the person fails to meet the requirements of this rule, or the person has been convicted of a felony involving lab practices.

Section 13 establishes criminal penalties for violating the provisions of this rule.

Section 14 provides administrative procedures to appeal for denial of licensure and permits by the Division.

AUTHORITY

Statutory authority: W.Va. Code, §16-5J-10 provides the following:

> (a) The director of the department of health shall promulgate rules and regulations for the licensure and certification of lab technicians and lab technologists. All such persons being so employed on the effective date of this article shall be automatically certified and exempt from this requirement: Provided, That any technologist and technician who is certified by the American medical technologists or the American society of clinical pathologists or the national certification agency for medical laboratory personnel or any federal certification program shall be considered certified.
>
> (b) All laboratory technicians or technologists shall pay an annual license fee of twenty-five dollars to the director of the department of health to cover the costs of licensure.
>
> (c) All rules and regulations required under this section or other provisions of this article may not be filed as emergency rules until after the set of rules is approved by the Legislature.
>
> (d) All fees and interest earned or collected by the department under this article shall be used to pay for the implementation of this article.

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

Yes.

1. Section 4 incorporates 42 CFR Part 93 in its entirety. This federal rule establishes requirements for testing laboratories as well as several other requirements that do not relate to qualifications for lab technicians and technologists. The rule needs to be amended to incorporate only those portions of Part 93 that specifically relate to this rule.

2. Section 6 provides that the licensing fee may be set by W.Va. Code or rule. W. Va. Code 16-5J-10 establishes the licensing

fee at $25.00. It will require a change in the statute to allow for the fee to be set by rule.

3. Section 13 establishes criminal penalties for violating this rule. There is no statutory authority to establish any penalties for violation of the provisions of this rule.

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

No, see above.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

Yes. The adoption of 42 CSR Part 493 violates the provisions of W.Va Code 16-5J-3 which establishes a different procedure for the adoption of laboratory rules.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

Yes.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

Yes.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

Yes. Counsel has several modifications to suggest.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISION OF THE CODE?

Yes.

VIII. OTHER.

Counsel has several changes to propose to the rule.

West Virginia Legislature

Legislative Rule-Making Review Committee

Room MB47-State Capitol
Charleston, West Virginia 25305
(304) 347-4840

Senator Mike Ross, Co-Chair
Delegate Vicki Douglas, Co-Chair

Debra A. Graham, Counsel
Joe Altizer, Associate Counsel
Marie Nickerson, Admr. Assistant

October 15, 1996

NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Ken Hechler, Secretary of State, State Register

TO: Gretchen Lewis, Secretary
Dept. of Health & Human Resources
Bldg. 3, Capitol Complex
Charleston, WV 25305

FROM: Legislative Rule-Making Review Committee

PROPOSED RULE: Clinical Laboratory Technician and Technologist Licensure and Certification

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule
   (a) as originally filed ____
   (b) as modified by the agency __X__

2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached. ____

3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached. ____

4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached. ____

5. Recommends that the rule be withdrawn; a statement of reasons for such recommendation is attached. ____

Pursuant to Code 29A-3-11(c), this notice has been filed in the State Register and with the agency proposing the rule.

cc: Kay Howard
Office of Regulatory Development
Irv Miller
701 Milford St.
Clarksburg, WV 26301

Senate Bill No. 181

(By Senator(s) Ross, Anderson, Macnaughtan, Boley and Buckalew)

[Introduced March 3, 1997; referred to the Committee on Health and Human Resources; and then to the Committee on the Judiciary.]

A BILL to amend article five, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, by adding thereto a new section, designated section two, relating to authorizing the department of health and human resources to promulgate a legislative rule relating to clinical laboratory technician and technologist licensure and certification.

Be it enacted by the Legislature of West Virginia:

That article five, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended by adding thereto a new section, designated section two, to read as follows:

ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND

64-57

HUMAN RESOURCES TO PROMULGATE LEGISLATIVE RULES.

§64-5-2. Department of health and human resources.

The legislative rule filed in the state register on the fifth day of October, one thousand nine hundred ninety-five, under the authority of section ten, article five-j, chapter sixteen, of this code, modified by the department of health and human resources to meet the objections of the legislative rule-making review committee and refiled in the state register on the thirty-first day of October, one thousand nine hundred ninety-six, relating to the department of health and human resources (clinical laboratory technician and technologist licensure and certification, 64 CSR 57), is authorized.

NOTE: The purpose of this bill is to authorize the Department of Health and Human Resources to promulgate a legislative rule relating to Clinical Laboratory Technician and Technologist Licensure and Certification.

This section is new; therefore, strike-throughs and underscoring have been omitted.

EHEC

H. B. 2343

Bill-DHHR, Clin Lab

(By Delegate(s) Douglas, Hunt, Compton, Faircloth, Linch and Riggs)

[Introduced March 3, 1997; referred to the Committee on Health and Human Resources then the Judiciary.]

A BILL to amend article five, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, by adding thereto a new section, designated section two, relating to authorizing the department of health and human resources to promulgate a legislative rule relating to clinical laboratory technician and technologist licensure and certification.

Be it enacted by the Legislature of West Virginia:

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ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND

64-57

HUMAN RESOURCES TO PROMULGATE LEGISLATIVE RULES.

§64-5-2. Department of health and human resources.

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NOTE: The purpose of this bill is to authorize the Department of Health and Human Resources to promulgate a legislative rule relating to Clinical Laboratory Technician and Technologist Licensure and Certification.

This section is new; therefore, strike-throughs and underscoring have been omitted.