encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance for CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

Application Submission and Deadlines

Preapplication Letter of Intent

A nonbinding letter of intent-to-apply is required from potential applicants. An original and two copies of the letter should be submitted to the Grants Management Officer, Grants Management Branch, CDC (see Applications for the address). It should be postmarked no later than July 15, 1997. The letter should identify the announcement number, name of principal investigator, and specify the activity(ies) to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information before the application is submitted. Notification may be provided by facsimile or postal mail to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E–18, Atlanta, GA 30305, facsimile (404) 842–6513.

Application

An original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mail Stop E–18, Atlanta, GA 30305, on or before August 15, 1997.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information, call (404) 332–4561. You will be asked to leave your name, address, and telephone number. Please refer to Announcement #774. You will receive a complete program description, information on application procedures and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E–18, Atlanta, GA 30305, telephone (404) 842–6801.

Programmatic technical assistance may be obtained from Christine Galavotti, Ph.D., Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4700 Buford Highway, NE., Mail Stop K–34, Atlanta, GA 30341–3724, telephone (770) 488–5245. The announcement will also be available on one of two Internet sites on the publication date: CDC's homepage at <http://www.cdc.gov>, or at the Government Printing Office homepage (including free access to the **Federal Register**) at <http://www.access.gpo.gov>. Other CDC Announcements are also listed on the Internet on the CDC homepage.

Please refer to Announcement Number 774 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000, (Full Report, Stock No.017–001–00474–0) or Healthy People 2000, (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction,'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: June 25, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–17123 Filed 6–30–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Goals for Working Safely With Mycobacterium tuberculosis in Clinical, Public Health, and Research Laboratories; Amendment To Extend Comment Period

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Extension of request for comments.

A notice requesting comments from all interested parties concerning goals for working safely with *Mycobacterium tuberculosis* in clinical, public health, and research laboratories was published in the **Federal Register** on April 28, 1997 (62 FR 23066).

This notice is amended as follows: On page 23066, first column, under the heading **DATES,** line 8, the date for submitting written comments to this notice has been extended from June 27, 1997, to July 27, 1997.

All other information and requirements of the April 28, 1997, **Federal Register** notice remain the same.

Dated: June 25, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–17125 Filed 6–30–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HSQ–243–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Exemption of Laboratories Licensed by the State of Washington

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces that laboratories located in the State of Washington that possess a valid license under the Medical Test Site Licensure Law, Chapter 70.40 of the Revised Code of Washington (RCW), continue to be exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) until April 30, 2001.

DATES: The continuance granted by this notice is effective until April 30, 2001.

FOR FURTHER INFORMATION CONTACT: Val Coppola, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHS Act), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet requirements established by the Department of Health and Human Services (HHS). Under the provisions of the sentence following section 1861(s)(14) and paragraph 1861(s)(16) of the Social Security Act, any laboratory that also wants to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the PHS Act. Subject to specified exceptions, laboratories must have a current and valid CLIA certificate to test human specimens and to be eligible for payment from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHS Act are contained in 42 CFR part 493.

Section 353(p) of the PHS Act provides for the exemption of laboratories from CLIA requirements in a State that applies requirements that are equal to or more stringent than those of CLIA. The statute does not specifically require the promulgation of criteria for the exemption of laboratories in a State. The decision to grant CLIA exemption to laboratories within a State is at the discretion of HCFA, acting on behalf of the Secretary of HHS.

Various regulations in 42 CFR part 493 subpart E implement section 353(p) of the PHS Act. Section 493.513 provides that HCFA may exempt from CLIA requirements, for a period not to exceed 6 years, all State licensed or approved laboratories in a State if the State meets specified conditions. Section 493.513(k) provides that we will publish a notice in the **Federal Register** announcing the names of States whose laboratories are exempt from meeting the requirements of part 493, describing the basis for granting the exemption, describing how the laboratory requirements are equal to or more stringent than those of CLIA, and specifing a term of approval not to exceed 6 years. On December 23, 1994 (59 FR 66314), we published a notice in the **Federal Register** announcing that the State of Washington had applied for exemption of its laboratories from CLIA requirements; that the evaluation of this application demonstrated that all requirements for exemption were met; and that Washington was granted an exemption.

II. Requirements for Granting CLIA Exemption

In order to determine whether we should grant or continue an existing CLIA exemption to laboratories within a State, we conduct a detailed and in-depth comparison of State and CLIA requirements to determine whether the State meets the requirements at § 493.513. In summary, the State must:

- Have laws in effect that provide for requirements that are equal to or more stringent than CLIA requirements;
- Have an agency that licenses or approves laboratories that meet State requirements which meet or exceed CLIA requirements, and, therefore, meet the condition level requirements of the CLIA regulations;
- Meet the requirements and be approved in accordance with § 493.515, Federal review of laboratory requirements of State laboratory programs;
- Demonstrate that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements;
- Permit HCFA or HCFA agents to inspect laboratories within the State;
- Require laboratories within the State to submit to inspections by HCFA or HCFA agents as a condition of licensure;
- Agree to pay the cost of the validation program administered by HCFA and the cost of the State's pro rata share of the general overhead to develop and implement CLIA as specified in §§ 493.645(b) and 493.646; and
- Take appropriate enforcement action against laboratories found by HCFA or HCFA agents not to be in compliance with requirements comparable to condition level requirements.

As specified in our regulations at § 493.515, our review of a State laboratory program includes (but is not necessarily limited to) an evaluation of:

- Whether the State's requirements for laboratories are equivalent to or more stringent than the condition level requirements;
- The State's inspection process requirements to determine:

—The comparability of the full inspection and complaint inspection procedures to those of HCFA;

—The State's enforcement procedures for laboratories found to be out of compliance with its requirements; and

—The ability of the State to provide HCFA with electronic data and reports with the adverse or corrective actions resulting from proficiency testing (PT) results that constitute unsuccessful participation in HCFA-approved PT programs and with other data HCFA determines to be necessary for validation and assessment of the State's inspection process requirements;

- The State's agreement with HCFA to ensure that the agreement obligates the State to:

—Notify HCFA within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or been in any way sanctioned;

—Notify HCFA within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;

—Notify each laboratory licensed by the State within 10 days of HCFA's withdrawal of the exemption;

—Provide HCFA with written notification of any changes in its licensure (or approval) and inspection requirements;

—Disclose any laboratory's PT results in accordance with a State's confidentiality requirements;

—Take the appropriate enforcement action against laboratories found by HCFA not to be in compliance with requirements comparable to condition level requirements and report these enforcement actions to HCFA;

—Notify HCFA of all newly licensed laboratories, including the specialties and subspecialties for which any laboratory performs testing, within 30 days; and

—Provide HCFA, as requested, inspection schedules for validation purposes.

III. Evaluation of the Washington Request for Continued CLIA Exemption

Washington has applied to HCFA for continued exemption of its laboratories from CLIA requirements.

We evaluated the request for continuation of the Washington CLIA exemption for equivalency against the three major categories of CLIA rules: the

implementing regulations, the enforcement regulations, and the deeming/exemption requirements.

We evaluated the application to verify Washington's assurance of continued compliance with the following subparts of part 493: Subpart A, General Provisions; Subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program; Subpart H, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; Subpart M, Personnel for Moderate and High Complexity Testing; Subpart P, Quality Assurance for Moderate or High Complexity Testing, or Both; Subpart Q, Inspection; and Subpart R, Enforcement Procedures.

Washington was found to continue to meet the requirements of Subparts A, E, H, M, P, Q, and R.

IV. Validation Inspections

The Federal validation inspections of CLIA-exempt laboratories, as specified in § 493.517, were conducted on a representative sample basis as well as in response to any substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections has been and will continue to be HCFA's principal tool for verifying that the laboratories located in and licensed by the State are in compliance with CLIA requirements.

HCFA staff of the Laboratory Survey Section, Division of Health Standards and Quality in the HCFA Regional Office in Seattle, Washington have conducted validation inspections of a representative sample (approximately 5 percent) of the laboratories inspected by the Washington Office of Laboratory Quality Assurance (LQA). The validation inspections were of the concurrent type; that is, HCFA surveyors accompanied Washington's surveyors, each inspecting against his or her agency's respective regulations. Analysis of the validation data revealed no significant differences between the State and Federal findings. The Washington inspection process covers all appropriate CLIA conditions and the State laboratory licensure requirements were found to meet or exceed CLIA requirements. The HCFA survey staff found the State inspectors highly skilled and qualified. The LQA is maintaining its workload at the proper level to assure that all laboratories within the State will be inspected in a 24-month cycle. All parameters monitored by HCFA staff to date indicate that the LQA is meeting all requirements under the CLIA exemption. This Federal monitoring will continue as an on-going process.

The CLIA exemption of laboratories located in and licensed by Washington may be removed if we determine the outcome and comparability review of validation inspections are not acceptable as described under § 493.521 or if Washington fails to pay the required fee every 2 years as required under § 493.646.

V. Laboratory Data

In accordance with § 493.513(d)(2)(iii), Washington will continue to agree to provide us with changes to a laboratory's specialties or subspecialties based on the State's survey. Washington also will provide us with changes in a laboratory's certification status, such as a change from a regular certificate to a certificate of waiver.

VI. Required Administrative Actions

CLIA is intended to be a totally user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, we may not charge a fee to laboratories in the State. The State's share of the costs associated with CLIA must be collected from the State. Section 493.645 specifies that HHS will assess fees such that the costs of administering the CLIA program will be shared by all States including those that are CLIA exempt.

Washington must pay for:

- Costs of Federal inspection of laboratories in the State to verify that standards are enforced in an appropriate manner. The average Federal hourly rate is multiplied by the total hours required to perform Federal validation surveys within the State.
- Costs incurred for Federal investigations and surveys triggered by complaints that are substantiated. We will bill Washington on a semiannual basis.
- Washington's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, a portion of those services from which Washington received direct benefit or contributed to the CLIA program in the State. Thus, Washington is being charged for a portion of HCFA's direct and indirect costs as well as a portion of the costs incurred by the Centers for Disease Control and Prevention (CDC).

In order to estimate Washington's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.6 percent of the registered laboratories are in Washington. We determined that 1.6 percent of the applicable CDC and HCFA costs should be borne by Washington.

Washington has agreed to pay us the State's pro rata share of the overhead costs and anticipated costs of actual validation and complaint investigation surveys. A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

VII. Approval

HCFA grants continuance of the CLIA exemption for all specialties and subspecialties to all laboratories located in and licensed by the State of Washington effective July 1, 1997 to April 30, 2001.

VIII. 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 notice such as this would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all laboratories to be small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This notice announces the continuance of the exemption of laboratories licensed by the State of Washington from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The State has established that the quality of laboratory services continues to meet standards equivalent to or more stringent than those of the CLIA program and also has established that it has a comparable program to monitor and evaluate compliance with the standards. The effect of the continued exemption from CLIA requirements is that laboratories will remain under State, rather than Federal, regulation, with no discernible difference in the

operations of the programs. Consequently, we anticipate that our continuation of Washington's CLIA exemption will not affect the laboratories or the quality and availability of services provided.

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

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

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

Dated: May 30, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 97–17193 Filed 6–30–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Mapping Alcoholism Related Genes by Linkage Disequilibrium in Choctaw American Indians With Mixed Ancestry

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which provides for an opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

The Laboratory of Neurogenetics (LN), Division of Intramural Clinical and Biological Research, NIAAA, intends to conduct the study for 'Mapping Alcoholism Related Genes by Linkage Disequilibrium in Choctaw American Indians with Mixed Ancestry'.

The LN is authorized by Section 452 of Part G of Title IV of the Public Health Service Act (42 U.S.C. 288) as amended by the NIH Revitalization Act of 1993 (Pub. Law 103–43). The information proposed for collection in this study will be used by the NIAAA to expand the Choctaw Indian study by sampling people and families that exhibit a spectrum of Indian and non-Indian ancestry. This is possible because the Choctaw have approximately 100,000 enrolled members and 95% of them have some degree of non-Indian heritage. It is now recognized that admixed populations are useful for linkage analysis using a variety of techniques, including Mapping using Admixture Linkage Disequilibrium and Transmission Disequilibrium Test. This extension of NIAAA research on Choctaw American Indians will utilize the population structure in a unique way to determine the genetic basis of alcoholism and related psychiatric phenotypes. It will complement the current family and epidemiological approaches. In combination, these different approaches will yield one of the most comprehensive studies yet performed. Moreover, this study recognizes the true population structure and utilizes it to analytical advantage.

The annual burden estimates are as follows:

Type and number of respondents	Responses per respondent	Total responses	Hours	Total hours
Clients—700	1	700	4.0	2800
Total Number of Respondents	.....	700	.....	.....
Total Number of Responses	.....	700	.....	.....
Total Hours	.....	2800	.....	.....

Request for Comments

Comments are invited on: (a) whether the proposed collection is necessary, including whether the information has practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Send written comments to Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research, NIAAA, NIH, Park Bldg. Room 451, 12420 Parklawn Drive MSC 8110, Rockville, Maryland 20852.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans, contact Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research, NIAAA, Park Bldg. Room 451, 12420 Parklawn Drive MSC 8110, Rockville, Maryland 20852, or call non-toll-free number (301) 443–5781.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before September 2, 1997.

Dated: June 23, 1997.

Martin K. Trusty,

Executive Officer, NIAAA.

[FR Doc. 97–17199 Filed 6–30–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Transmission and Linkage Analysis of Alcoholism in a Southwestern American Indian Tribe; Collection of EEG Phenotypes Associated With Alcoholism

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which provides for an opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.