

Newborn Screening: An Ethical Analysis by The President's Council on Bioethics (December 2008); and *Controversies in the Determination of Death: A White Paper by The President's Council on Bioethics* (December 2008). Reports are forthcoming on organ transplantation and health care reform.

DATES: The meeting will take place Thursday, March 12, 2009, from 9 a.m. to 5 p.m., ET; and Friday, March 13, 2009, from 9 a.m. to 10:45 a.m., ET.

ADDRESSES: Renaissance Washington, DC Hotel, 999 9th Street, NW., Washington, DC 20001. Phone 202-898-9000.

FOR FURTHER INFORMATION CONTACT: Ms. Diane M. Gianelli, Director of Communications, The President's Council on Bioethics, 1425 New York Avenue, NW., Suite C100, Washington, DC 20005. Telephone: 202/296-4669. E-mail: info@bioethics.gov. Web site: <http://www.bioethics.gov>.

SUPPLEMENTARY INFORMATION: The meeting agenda will be posted at <http://www.bioethics.gov>. The Council encourages public input, either in person or in writing. At this meeting, interested members of the public may address the Council, beginning at 10:30 a.m., on Friday, March 13. Comments are limited to no more than five minutes per speaker or organization. As a courtesy, please inform Ms. Diane M. Gianelli, Director of Communications, in advance of your intention to make a public statement, and give your name and affiliation. To submit a written statement, mail or e-mail it to Ms. Gianelli at one of her contact addresses given above.

Dated: February 5, 2009.

F. Daniel Davis,

Executive Director, The President's Council on Bioethics.

[FR Doc. E9-3843 Filed 2-23-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

Correction

In notice document E9-1009 beginning on page 4748 in the issue of Tuesday, January 27, 2009 make the following correction:

On page 4749, in the first column, under the **ADDRESSES** section, in the sixth line,

“doris.lefkowitz@ahrq.hhs.gov” should read “doris.lefkowitz@ahrq.hhs.gov”.

[FR Doc. Z9-1009 Filed 2-23-09; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Aging the authority vested in the Secretary of Health and Human Services under section 119(c) of the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275 pertaining to making grants to Aging and Disability Resource Centers under the Aging and Disability Resource Center grant program.

These delegations shall be exercised under the Department's policy on regulations and the existing delegation of authority to approve and issue regulations. This delegation excludes the authority to issue reports to Congress.

I hereby affirmed and ratified any actions taken by the Assistant Secretary for Aging or other Administration on Aging officials, which involved the exercise of these authorities prior to the effective date of this delegation.

This delegation was effective upon date of signature.

Dated: February 9, 2009.

Charles E. Johnson,

Acting Secretary.

[FR Doc. E9-3839 Filed 2-23-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Rapid Diagnostic Tests for HIV and HCV

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

ACTION: Opportunities for collaboration for evaluation of rapid diagnostic tests for HIV and hepatitis C virus (HCV). The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), has an opportunity for collaboration to evaluate diagnostic tests for HIV and HCV. These evaluations will include evaluation of

the sensitivity and specificity of the tests, and the predictive value of algorithms using two or more different rapid tests in combination.

Specific tests are sought to meet one or more of the following purposes: (1) Laboratory-based or rapid point-of-care tests designed to detect both HIV antigen and antibody; (2) laboratory-based or rapid point-of-care tests that can distinguish persons with acute HIV infection from persons who have longer-standing HIV infection; (3) laboratory-based or rapid point-of-care tests that can be used as supplemental confirmatory tests to help diagnose HIV-1 or HIV-2 infection, (4) rapid laboratory-based or rapid point-of-care tests designed to detect HCV antibody, antigen or both. Tests of interest include those that can detect HIV-1/2 and/or HCV antibody, antigen, RNA, or DNA when used on whole blood, serum, plasma, oral fluid or dried blood spots. Evaluations will include the sensitivity and specificity of the test when used in the intended application (e.g., for screening or confirmation).

SUMMARY: The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (DHHS) seeks one or more companies that have developed or are distributing rapid diagnostic tests for HIV or HCV and are interested in marketing the tests for use in the United States. The Division of HIV/AIDS Prevention and the Division of Viral Hepatitis are interested in evaluating such tests. The evaluation will include determination of sensitivity and specificity of the test, and may also evaluate the predictive value of two or more different tests used in combination in populations of low prevalence. This collaboration will have an expected duration of two (2) to three (3) years. The goals of the collaboration include the timely development of data to be used to determine whether the test could be used in screening and/or diagnosis for HIV or HCV in the United States, and to examine laboratory-based or rapid point-of-care tests. These tests require high sensitivity to detect persons with acute and longer-standing HIV infection; or high specificity to distinguish persons with acute infection from those with longer-standing infection; or high specificity for tests that can be used as to confirm HIV-1 or HIV-2 infection. Acute HIV infection is defined as the early infection period associated with a transient symptomatic illness, high viral load, and expansive immunologic response. For HCV testing,

rapid tests to be used in the screening setting require high sensitivity and confirmatory tests with high specificity.

Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies who have a product that is suitable for commercial distribution.

DATES: Formal proposals must be submitted no later than 30 calendar days after date of publication in the **Federal Register**.

ADDRESSES: Formal proposals should be submitted to Sal Butera, Associate Director for Laboratory Science, NCHHSTP, CDC, 1600 Clifton Road, NE., Mailstop E-07, Atlanta, GA 30333; Phone 404-639-6379; Fax 404-639-3125; e-mail: SButera@cdc.gov.

Scientific questions should be addressed to Bernard M. Branson, M.D., Division of HIV/AIDS Prevention, NCHSTP, CDC 1600 Clifton Road, NE., Mailstop D-21, Atlanta, GA 30333; Phone 404-639-6166, Fax 404-639-0897; e-mail BBranson@cdc.gov.

SUPPLEMENTARY INFORMATION:

Technology Sought

One goal of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) is to develop new approaches to increase the number of persons infected with HIV and/or HCV who know their status and have access to effective treatment. These approaches might include increasing the use of more sensitive screening assays (such as antigen or nucleic acid amplification tests) that can identify persons with acute HIV infection; rapid tests that can identify resolved or ongoing HCV infection; and more sensitive and specific confirmatory assays that can be used at point-of-care to obviate the need for clients to return for confirmed test results. NCHHSTP is seeking rapid diagnostic tests that are suitable for commercial distribution and that are simple: preferably, tests that use direct, unprocessed specimens (e.g., whole blood); can be performed in 30 minutes or less by persons with minimal training; include all necessary reagents in the test kit; can be stored at temperatures between 25 and 39°C; and have a minimum 1-year shelf life. Of particular interest are tests with high sensitivity for early stage HIV infection and tests that can distinguish persons

with acute or recent HIV infection from persons with longer standing infections. NCHHSTP also seeks new methods that could serve to expedite confirmatory testing for HIV-1, HIV-2, and HCV either at the point-of-care or in the laboratory.

NCHHSTP and Collaborator Responsibilities

The NCHHSTP role may include, but will not be limited to, the following:

- (1) Providing scientific and technical expertise needed for the evaluation project;
- (2) Planning and conducting evaluation studies of the diagnostic tests and interpreting results; and
- (3) Publishing evaluation results.

The NCHHSTP anticipates that the role of the successful collaborator(s) will include the following:

- (1) Providing NCHHSTP access to data necessary to identify candidate tests for further evaluation; and
- (2) Providing tests that can be used in the evaluation.

Selection Criteria

Proposals submitted for consideration will be evaluated according to selection criteria, and should address, as best as possible and to the extent relevant to the proposal, each of the following:

- (1) Information on the technology used for the test, including basic operating principals such as antigen or antibody components used for detection;
- (2) Data available on the performance characteristics of the tests in different populations;
- (3) Information on the time required to perform the test, whether the test is performed on oral fluid, whole blood, serum, plasma, or dried blood spots, and the steps involved in performing the test;
- (4) Information on the storage requirements and stability of the test;
- (5) Interest by the company to seek FDA approval and market the test in the United States;
- (6) Ability to provide to CDC approximately 8,000 tests and all related equipment to enable laboratory validation at CDC;
- (7) Documentation of production capacity to provide at least 500,000 tests annually.

Dated: February 13, 2009.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E9-3865 Filed 2-23-09; 8:45 am]

BILLING CODE 4163-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Low Income Home Energy Assistance Program LIHEAP Leveraging Report.

OMB No.: 0970-0121.

Description: The LIHEAP leveraging incentive program rewards LIHEAP grantees that have leveraged non-federal home energy resources for low-income households. The LIHEAP leveraging report is the application for leveraging incentive funds that these LIHEAP grantees submit to the Department of Health and Human Services for each fiscal year in which they leverage countable resources. Participation in the leveraging incentive program is voluntary and is described at 45 CFR 96.87. The LIHEAP leveraging report obtains information on the resources leveraged by LIHEAP grantees each fiscal year (as cash, discounts, waivers, and in-kind); the benefits provided to low-income households by these resources (for example, as fuel and payments for fuel, as home heating and cooling equipment, and as weatherization materials and installation); and the fair market value of these resources/benefits.

HHS needs this information in order to carry out statutory requirements for administering the LIHEAP leveraging incentive program, to determine accountability and valuation of grantees leveraged non-federal home energy resources, and to determine grantees shares of leveraging incentive funds. HHS proposes to request a three-year extension of OMB approval for the currently approved LIHEAP leveraging report information collection.

Respondents: State, Local or Tribal Governments.