

Dated: May 12, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-04-52]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498-1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Dale Verell, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

CDC Model Performance Evaluation Program, OMB No. 0920-0274—Revision—Public Health Practice Program Office (PHPPPO), Centers for Disease Control and Prevention (CDC).

In 1986, the Centers for Disease Control and Prevention (CDC) implemented the Model Performance Evaluation Program (MPEP) to evaluate the performance of laboratories conducting testing to detect human immunodeficiency virus type 1 (HIV-1) antibody (Ab), and to support CDC's mission of improving public health and preventing disease through continuously improving laboratory practices.

High-quality HIV-1 antibody testing is essential to meeting the public health objectives for the prevention and control of this retrovirus infection. High-quality CD4+ T-cell determinations and HIV-1 viral RNA (viral load) determinations are essential to HIV-infected patient care and management, and the mission of reducing retrovirus-associated morbidity and mortality. Prevention programs, diagnostic clinics, and seroprevalence studies rely not only on accurate antibody testing results to document HIV infection but also accurate CD4+ T-cell determinations and HIV-1 viral RNA determinations. The impetus for developing this

program came from the recognized need to assess the quality of retroviral and AIDS-related laboratory testing and to ensure that the quality of testing was adequate to meet medical and public health needs. The objectives of the MPEP are to: (1) Develop appropriate methods for evaluating quality in laboratory testing systems (including test selection, sample collection, and reporting and interpreting test results); (2) develop strategies for identifying and correcting testing quality failures; and (3) evaluate the effect of testing quality on public health.

This external quality assessment program will be made available at *no cost* (for receipt of sample panels) to sites conducting testing to detect human immunodeficiency virus type 1 (HIV-1) antibody (Ab), CD4+ T-cell determinations, and HIV-1 viral RNA determinations. This program will offer laboratories/testing sites an opportunity for:

- Assuring accurate tests are being provided by the laboratory/testing site through external quality assessment;
- Improving testing quality through self-evaluation in a non-regulatory environment;
- Testing well characterized samples from a source outside the test kit manufacturer;
- Discovering potential testing problems so that procedures can be adjusted to eliminate them;
- Comparison of testing results with others at a national and international level; and
- Ability to consult with CDC staff to discuss testing issues.

There are no costs to respondents.

Form name	Number of respondents	Numbers of response per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Enrollments (new)	100	1	3/60	5
HIV Testing Survey	1,000	1	1	333*
CD4+ T-cell determinations Survey	325	1	30/60	54*
HIV-1 Ab PE Results Form	900	2	10/60	300
HIV-1 RNA PE Results Form	210	2	10/60	70
CD4+ T-cell determinations PE Results Form	300	2	10/60	100
Totals				862

* Both the HIV and the CD4+ T-cell determinations surveys are performed every other year; therefore, the total hour burden for these two surveys was divided by three to determine annualized hourly burden for the three-year approval period.

Dated: May 13, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): The Great Lakes Human Health Effects Research Program, Program Announcement Number 04023

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): The Great Lakes Human Health Effects Research Program, Program Announcement Number 04023.

Times and Dates: 1 p.m.-1:30 p.m., June 23, 2004 (Open); 1:30 p.m.-4:30 p.m., June 23, 2004 (Closed).

Place: National Center for Environmental Health/Agency for Toxic Substance Disease Registry, 1825 Century Boulevard, Atlanta, Georgia 30345, Teleconference Number 404.498.0632.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92-463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04023.

For Further Information Contact: J. Felix Rogers, Ph.D., M.P.H., CDC, National Center for Environmental Health/Agency for Toxic Substance Disease Registry, Office of Science, 1825 Century Boulevard, Atlanta, GA 30345, 404.498.0624.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 12, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10113]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. This is necessary to ensure compliance with provisions of Section 641 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We cannot reasonably comply with the normal clearance procedures because of an unanticipated event and possible public harm.

Section 641 of the MMA provides for the implementation of a demonstration under which Medicare would pay under Part B for drugs and biologicals that would not otherwise be covered until Part D is implemented in 2006. Drugs covered under this demonstration must be replacements for existing covered Medicare drugs and biologicals that are

provided incident to a physicians service or are replacements for oral cancer drugs that are otherwise covered under Medicare Part B. Cost sharing under the demonstration is to be in the same manner as Medicare Part D. The statute also required that the demonstration begin 90 days after passage of the legislation, which was March 8, 2004. Due to the complexities of implementing this demonstration, we were unable to meet that deadline. However, because of the importance of this demonstration to beneficiaries with serious illnesses and the already delayed time frame, it is urgent that there not be further delay.

CMS is requesting OMB review and approval of this collection by May 28, 2004, with a 180-day approval period. Written comments and recommendation will be accepted from the public if received by the individuals designated below by May 25, 2004.

Type of Information Collection Request: New collection; *Title of Information Collection:* Application for Participation in Medicare Replacement Drug Demonstration; *Use:* Section 641 of the MMA mandated a demonstration that would pay for drugs/biologicals prescribed as replacements for existing covered Medicare drugs. A report to Congress evaluating the impact of this demonstration was also mandated. In order to enroll in this demonstration, a beneficiary will be required to submit the application forms. Beneficiaries who wish to be considered for a low income subsidy must also provide the information on the "Application for Financial Assistance"; *Form Number:* CMS-10113 (OMB#: 0938-NEW); *Frequency:* Other: once per beneficiary; *Affected Public:* Individuals or Households; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 20,417.

We have submitted a copy of this notice to OMB for its review of these information collections.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be