

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