

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Designation of a Class of Employees for Addition to the Special Exposure Cohort**

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Pacific Proving Grounds, Enewetak Atoll, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On June 26, 2006, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked at the Pacific Proving Grounds (PPG) from 1946 through 1962 for a number of work days aggregating at least 250 work days, either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC, and who were monitored or should have been monitored.

This designation will become effective on July 26, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV.

Dated: July 5, 2006.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. E6-11029 Filed 7-12-06; 8:45 am]

BILLING CODE 4160-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panels (SEP): Avian Influenza Cooperative Research Centers—Studies at the Human-Animal Interface, Request for Applications (RFA) #CI06-009; and Non-Pharmaceutical Interventions for Pandemic Influenza, RFA #CI06-010**

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: "Avian Influenza Cooperative Research Centers—Studies at the Human-Animal Interface," Request for Applications (RFA) #CI06-009; and "Non-pharmaceutical Interventions for Pandemic Influenza," RFA #CI06-010.

Times and Dates: 8 a.m.–8:30 a.m., August 17, 2006 (Open).

8:30 a.m.–4 p.m., August 17, 2006 (Closed).

8 a.m.–8:30 a.m., August 18, 2006 (Open).

8:30 a.m.–4 p.m., August 18, 2006 (Closed).

Place: Sheraton Gateway Atlanta Airport Hotel, 1900 Sullivan Road, Atlanta, GA 30337, Telephone Number 770.997.1100.

Status: 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 Public Law 92-463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA #CI06-009, "Avian Influenza Cooperative Research Centers—Studies at the Human-Animal Interface"; and RFA #CI06-010, "Non-pharmaceutical Interventions for Pandemic Influenza."

For Further Information Contact: Felix Rogers, PhD, M.P.H., Scientific Review Administrator, National Immunization Program, CDC, 1600 Clifton Road, NE., Mailstop E-05, Atlanta, GA 30333, Telephone Number 404.639.6101.

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: July 6, 2006.

Alvin Hall,

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

[FR Doc. E6-11018 Filed 7-12-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[CMS-4123-N]

Medicare Program; Solicitation for Proposals for Medical Savings Account Demonstration Project

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice is to inform interested parties of an opportunity to apply to participate in the Medicare Advantage (MA) Medical Savings Account (MSA) demonstration project. The MA MSA demonstration design waives certain MA MSA plan requirements under sections 1859(b)(3), 1853(e), and 1854(c) of the Social Security Act. This waiver will allow entities to offer products that more closely resemble high deductible health plans (HDHPs) that are offered with Health Savings Accounts to the non-Medicare population. This demonstration will be conducted in accordance with the Secretary's demonstration authority under section 402(a)(1)(A) of the Social Security Amendments of 1967, 42 U.S.C. 1395b-1(a)(1)(A).

DATES: Applications will be considered timely if we receive them by July 21, 2006.

FOR FURTHER INFORMATION CONTACT:

Yolanda Robinson at (410) 786-7627. Interested parties can obtain a complete solicitation, application, and supporting information on the following CMS Web site at <http://www.cms.hhs.gov/MedicareAdvantageApps/>.

ADDRESSES: Mail or deliver applications and NOIs to the following address: Centers for Medicare and Medicaid Services, Attn: Yolanda Robinson CBC/MAG/DQPM, Mail Stop C4-23-07, 7500 Security Blvd., Baltimore, MD 21244.

Because of staff and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail.

SUPPLEMENTARY INFORMATION:**I. Background**

Sections 1851(a)(2)(C) and 1859(b)(3) of the Social Security Act (the Act) authorize Medicare Advantage plans to offer Medical Savings Accounts (MSAs) to beneficiaries. However, the required benefit structure is not perceived by insurance organizations as easily marketable. Similar to Health Savings Accounts (HSAs) accounts currently

available in the commercial market, the MSA demonstration allows more flexible benefits that will allow beneficiaries the freedom to exercise control over their health care spending while providing important protection against catastrophic health care costs. CMS is providing flexibility with this MSA demonstration project to make the increasingly popular consumer-directed plans available to Medicare beneficiaries. The demonstration framework includes the flexibility we are allowed under our demo authority.

The goal of the demonstration is to test whether the consumer directed health plans in Medicare will help lower health care cost for enrollees without adversely affecting the quality of health care services. We expect that this demonstration will make "HSA like" MSAs available to Medicare beneficiaries beginning January 1, 2007.

We are establishing this demonstration under section 402(a)(1)(A) of the Social Security Amendments of 1967, 42 U.S.C. § 1395b-1(a)(1)(A), which authorizes the Secretary to conduct demonstrations designed to test whether changes in methods of payment under Medicare would have the effect of increasing the efficiency and economy of Medicare services without adversely affecting the quality of services.

II. Provisions of the Notice

The purpose of this notice is to inform Medicare Advantage organizations of an opportunity to apply to participate in the Medicare Advantage (MA) Medical Savings Account (MSA) demonstration project. To assist in the planning process, we have posted the MA MSA plan demonstration framework as well as the MA MSA application on our Web site at <http://www.cms.hhs.gov/MedicareAdvantageApps/>. The framework outlines specific parameters for design flexibilities. The MA MSA application must be completed and the benefit design must stay within the boundaries of the MA MSA plan demonstration framework. The applicant must provide an operational discussion of the following:

- Product offering;
- Deposit calculations;
- Recovery policy for the current-year deposit, and procedures for members who are disenrolled from the plan before the end of the contract year. (Note that disenrollment may occur only for the reasons such as death or moving out of the service area as specified in section 1851(e)(5)(B) of the Act);
- Items and services to be counted toward the member's deductible;

- Whether a Prescription Drug Plan will be offered by your organization and marketed to potential MSA enrollees;

- Policy and procedures on portability of the member's account;

- Use of networks and whether/how cost sharing and the member out-of-pocket maximum will vary in-network versus out-of-network;

- Service area for product offering and whether it is individual and/or employer group; and

- Any other aspects making the product offering different from the statutory requirements of an MSA plan and as allowed under the framework.

Medicare Advantage organizations interested in participating in 2007 must submit a complete MA MSA application, which is available on the CMS Web site at <http://www.cms.hhs.gov/MedicareAdvantageApps/>, no later than July 21, 2006. Your organization's bid and benefit submission is due no later than August 10, 2006. Organizations interested in participating for 2008 are requested to submit an NOI to CMS as soon as possible for us to understand the level of future interest in the product. Submitting an NOI does not require your organization to apply, nor is it required to apply. The NOI form is posted at the above Web site.

III. Collection of Information Requirements

This information collection requirement is subject to the Paperwork Reduction Act of 1995 (PRA); however, the collection is currently approved under OMB control number 0938-0935 entitled "Medicare Advantage Applications" with a current expiration date of July 31, 2006.

Authority: Section 402(a)(1)(A) of the Social Security Act, 42 U.S.C. 1395b-1.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 30, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06-6192 Filed 7-10-06; 4:07 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D-0315]

Guidance for Industry on Providing Regulatory Submissions to the Center for Biologics Evaluation and Research in Electronic Format—Lot Release Protocols; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Lot Release Protocols" dated July 2006. The guidance is intended to provide manufacturers of biological products regulated by CBER with recommendations for submitting lot release protocols in electronic format to CBER Product Release Branch. This guidance document finalizes the draft guidance entitled "Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research" dated May 1998.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Astrid Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.