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.

SUPPLEMENTARY INFORMATION:

I. Background

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. 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 (63 FR 29742, June 1, 1998). The guidance announced in this notice was revised based on public comments submitted to the Division of Dockets Management on the draft guidance. The guidance is intended to provide manufacturers of biological products regulated by CBER with recommendations for submitting to CBER Product Release Branch lot release protocols in electronic format.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 610.2(a) have been approved under OMB control number 0910–0206.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11040 Filed 7–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), 42 U.S.C. 300aa–1 *et seq.*, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: The agency must receive nominations on or before August 14, 2006.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl A. Lee, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, HSB, HRSA at (301) 443–2124 or e-mail: *clee@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, and the Federal Advisory Committee Act of October 6, 1972, 5 U.S.C. App., HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying Federal, State, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows: Three health professionals, who are not employees of the United States Government and have expertise in the healthcare of children; and the epidemiology, etiology, and prevention of childhood diseases; and the adverse reactions associated with vaccines, at least two of whom shall be pediatricians; three members from the general public, at least two of whom shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A health professional who has expertise in the healthcare of children and the epidemiology, etiology, and prevention of childhood diseases; (2) an attorney whose specialty includes representation of a vaccine manufacturer; and (3) a member of the general public. Nominees will be invited to serve a 3-year term beginning January 1, 2007, and ending December 31, 2009.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to