or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

10. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers, or that has the authority to investigate potential fraud or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs.

B. Additional Circumstances Affecting Routine Use Disclosures. This system contains Protected Health Information as defined by the Department of Health and Human Services (HHS) regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, 65 Fed. Reg. 82462 (12–28–00), Subparts A and E. Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of data not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer diskette and on magnetic storage media.

RETRIEVABILITY:

Information can be retrieved by name and health insurance claim number of the beneficiary.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. Office of Management and Budget Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 6 years and 3 months. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Medicare Advantage Appeals and Payment Systems, Information Services Modernization Group, Office of Information Services, CMS, Room N3–16–24, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the systems manager who will require the system name, SSN, address, date of birth, sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5 (a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Data for this system is collected from MAs and MAPDs (which obtained the data from the individuals concerned), Social Security Administration, and the Medicare Beneficiary Database system of records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–20909 Filed 10–17–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation; Notice of Secretary's Advisory Committee Meeting

AGENCY: OPRE, ACF, HHS.

ACTION: Notice of Meeting—Advisory Committee on Head Start Accountability and Educational Performance Measures.

SUMMARY: The Secretary of Health and Human Services, by authority of 42 U.S.C. 9836A, Section 641A(b) of the Head Start Act, as amended (5 U.S.C. Appendix 2), has formed the Advisory Committee on Head Start Accountability and Educational Performance Measures (the Committee). The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2).

The function of the Committee is to help assess the progress of HHS in developing and implementing

educational measures in the Head Start Program. This includes the Head Start National Reporting System (NRS). The Committee is to provide recommendations for integrating NRS with other ongoing assessments of the effectiveness of the program. The Committee will make recommendations as to how NRS and other assessment data can be included in the broader Head Start measurement efforts found in the Family and Child Experiences Survey (FACES), the national Head Start Impact Study, Head Start's Performance Based Outcome System and the ongoing evaluation of the Early Head Start program.

Date: November 1, 2005, 8:30 a.m.–5:30 p.m. (Dinner Recess). November 2, 2005, 8:30 a.m.–4:30 p.m.

Place: The Beacon Hotel, 1615 Rhode Island Ave, NW., Washington, DC 20036.

Agenda: The Committee will hear presentations related to existing Head Start evaluations and NRS implementation and will continue the discussions begun at the first meeting in June 2005.

SUPPLEMENTARY INFORMATION: This, the second meeting of the Committee, is open to the public. Persons wishing to bring written statements or papers focused on relevant, existing research with Head Start populations or on measures appropriate for low-income four- and five-year-old children are welcome to do so. Individuals may e-mail such documents to *Secretaryadvisory-hs@esi-dc.com* or mail to: ESI, ATTN: Xzavier Wright, Head Start Bureau—Secretary's Advisory Committee, 7735 Old Georgetown Road, Suite 600, Bethesda, Maryland 20814.

Documents received shall be presented to the Committee.

The Committee meeting records shall be kept at the Aerospace Center located at 901 D Street, SW., Washington, DC 20447. The Head Start Bureau will also make material related to this meeting available on the Head Start Web site *http://www2.acf.dhhs.gov/programs/hsb/*.

An interpreter for the deaf and hard of hearing will be available upon advance request by contacting *xzavier@esi-dc.com*.

Naomi Goldstein,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 05–20758 Filed 10–17–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0410]

Prescription Drug User Fee Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the Prescription Drug User Fee Act (PDUFA). The legislative authority for PDUFA expires in September 2007. Without further legislation, we will no longer be able to collect user fees for the prescription drug program and resources critical to running the program would become unavailable to us. We invite public comment on the PDUFA program and suggestions regarding what features we should propose for the next PDUFA program.

DATES: The public meeting will be held on November 14, 2005, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by October 31, 2005. You may register electronically at *CBERTraningSuggestions@cber.fda.gov*. Walk-in registration at the meeting site will also be accepted. Submit written comments by December 14, 2005.

ADDRESSES: The meeting will be held at the Natcher Conference Center, National Institutes of Health, Bldg. 45, Center Dr., 9000 Rockville Pike, Bethesda, MD 20815. Parking is limited, and there may be delays entering the NIH campus due to increased security. All visitors' vehicles will be inspected, and visitors must show one form of identification (ID) (such as a government-issued photo ID, driver's license, passport, etc.) We recommend arriving by subway (Metrorail) if possible. NIH is accessible from the Metrorail's ''Red Line'' at the Medical Center/NIH station.

Submit written comments 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:

For information regarding this notice: Patricia A. Stewart, Office of Policy and Planning (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2647, FAX: 301–594–6777, e-mail: *Patricia.Stewart@oc.fda.gov*.

For information regarding registration: Melanie Whelan or Kathy Eberhart, Office of Communication, Training and Manufacturers Assistance (HFM–49), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–2000, FAX: 301–827–3079.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing its intention to hold a public meeting on PDUFA. The authority for PDUFA expires in September 2007. Without further legislation, FDA would no longer be able to collect user fees for the prescription drug program. Resources critical to running the program would become unavailable to FDA. We are now considering what features we should propose for the next PDUFA program. We are convening a public meeting to hear stakeholder views on this subject. We are offering the following two general questions for consideration, and we are interested in responses to these questions and any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the PDUFA program thus far?

2. What aspects of PDUFA should be retained, or what should be changed to further strengthen and improve the program?

We provide the following background on the PDUFA program so potential participants can better understand the history and evolution of the PDFUA program and its current status.

II. What is PDUFA? What Does It Do?

PDUFA, in broad terms, is a series of laws that have authorized us to collect fees from companies that produce certain human drug and biological products. The original PDUFA (PDUFA I) was enacted in 1992 (as the Prescription Drug User Fee Act, Public Law 102–571) and had a 5-year life. In 1997, as PDUFA I expired, Congress passed the FDA Modernization Act (FDAMA, Public Law 105–115). FDAMA included, among other things, an extension of PDUFA (PDUFA II) for an additional 5 years. In 2002, Congress extended PDUFA again for 5 years (PDUFA III) through the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107–188).

PDUFA's original intent was to provide additional revenues to us so that we could hire more staff to improve the process for the review of human