

a. The agency or any component thereof, or
 b. Any employee of the agency in his or her official capacity, or
 c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To assist a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, 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 program.

7. To assist 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 Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by 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 such PHI that are otherwise 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, 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 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:

All records are stored on the magnetic disk sub-system of the Sun Solaris 10 Server. Furthermore, these records are saved to magnetic tape backup on a nightly basis.

RETRIEVABILITY:

The records are retrieved by health insurance claims number or other individually identifying numbers.

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 may apply 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. OMB 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:

CMS will retain identifiable HPMS data for at least 10 years or as long as needed for program research.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Plan Data, Plan Oversight and Accountability Group, Center for Beneficiary Choices, Center for Medicare & Medicaid Services, 7500 Security Boulevard, C4-14-21, Baltimore, Maryland 21244-1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. 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 specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the records 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).

RECORDS SOURCE CATEGORIES:

The identifying information contained in these records is obtained from the health plan and Part D organizations (which obtained the data from the individual concerned) or the individuals themselves. Also, these data will be linked with CMS administrative data, such as claims and enrollment.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Head Start; Request for Nominations for the Secretary's Advisory Committee on Re-Designation of Head Start Grantees

AGENCY: Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the establishment of and invites nominations for members to the Secretary's Advisory Committee on Re-Designation of Head Start Grantees. The Secretary is required by section 641 of Public Law (Pub. L.) 110-134 to convene an expert panel to provide advice and recommendations on the development of a transparent, reliable and valid system for designation renewal of Head Start grantees. The panel is required to be convened by March 12, 2008.

Nominations: We will consider nominations if they are received no later than fifteen (15) days from the date of publication of this notice. Submissions will only be taken electronically, although individuals for whom this procedure introduces a barrier may make alternative arrangements through the contact information below. Nominations in the format described below should be submitted to colleen.rathgeb@acf.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Colleen Rathgeb, Office of Head Start, e-mail colleen.rathgeb@acf.hhs.gov or (202) 205-7378.

SUPPLEMENTARY INFORMATION:**I. Background**

The Secretary is required by section 641 of Public Law 110-134 to convene an expert panel to provide advice and recommendations on the development of a transparent, reliable and valid system for designation renewal to determine if a Head Start agency is delivering a high-quality and comprehensive Head Start program that meets the educational, health, nutritional, and social needs of the children and families it serves, and meets program and financial management requirements and the program performance standards.

The Charter requires that the panel meet up to three times. The panel shall consist of a non-voting chair and seven expert panel members who have expertise in the areas outlined below. Members of the panel serve terms up to two years based on the needs of the panel.

The Department will give close attention to equitable geographic distribution and to minority and female representation so long as the effectiveness of the Committee is not diminished.

II. Criteria for Nominees

All members must have technical expertise to enable them to participate fully in the work of the panel. The panel

will consist of a non-voting chair and seven members, one member within each of the following demonstrated competency areas, as evidenced by training, expertise and experience:

- Early childhood program accreditation,
- research on early childhood development,
- governance and finance of nonprofit organizations,
- delivery of services to populations with special needs and their families,
- assessment and evaluation of programs serving young children,
- an employee of the Office of Head Start, and
- an executive director of a Head Start agency.

Any interested person or organization may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of nomination, including which specific expertise above the person is being nominated to fill,
- curriculum vitae of the nominee, and
- statement from the nominee that the nominee is willing to serve on the panel.

III. Copies of the Charter

To obtain a copy of the panel's Charter, submit a written request to the above contact.

Dated: January 8, 2008.

Daniel C. Schneider,

Acting Assistant Secretary, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Food and Drug Administration's Transition to the Federal Dockets Management System**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that effective January 15, 2008, the public will no longer be able to submit electronic comments to its Dockets through FDA's Web site. Electronic comments to FDA's Dockets may continue to be submitted through the Federal eRulemaking Portal. In recent months, FDA has alerted the public through our published **Federal**

Register documents that after the transition date, electronic submissions will only be accepted by FDA through Federal Dockets Management System (FDMS). Please note that the process for submitting written comments to FDA's Dockets will remain the same.

FOR FURTHER INFORMATION CONTACT: The Division of Dockets Management Public Room (HFA-305), Food and Drug Administration, 5630 Fishers Lane, 1061, Rockville, MD 20852, 301-827-6860, or FAX: 301-827-6870.

SUPPLEMENTARY INFORMATION:**I. Background:**

FDMS is a major component of the President's e-Rulemaking Initiative, which provides easy access to the public dockets maintained by Federal agencies, while streamlining and increasing the efficiency of the internal, regulatory procedures for agencies. FDMS is designed so that the public has a single point of access to the public dockets across the Federal government and agencies have a standard, online procedure to manage and process dockets, documents, and public comments/submissions. The Initiative reduces costs by eliminating duplicative information systems and technical infrastructures.

A. What is FDMS?

FDMS is a full-featured electronic docket management system that gives Federal personnel and docket managers the ability to better manage their rulemakings, adjudications, and other docketed program activities. FDMS also provides the public with a one-stop site to search, view and download documents, as well as post comments/submissions to federal agencies.

FDMS makes it easier for all segments of the public with access to a computer and the Internet—whether at home, at work, or at a local library—to submit comments to agency dockets. FDMS is accessible on the Internet at <http://www.Regulations.gov>.

B. How Can I Access and Use FDMS?

FDMS is accessible on the Internet at <http://www.Regulations.gov>. The public may use FDMS to access available public docket materials online, as well as submit electronic comments to a particular docket available in FDMS.

C. How Can I Search FDMS?

FDMS provides two basic methods of searching to retrieve dockets and docket materials that are available in the system: (1) Quick Search to search using a full-text search engine and Browsing options or (2) Advance Search which displays various indexed fields such as