Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–05–06, Baltimore, MD 21244–1850 or contact Ms. Johnson via e-mail at *Lynne.Johnson@cms.hhs.gov*.

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Lynne Johnson at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–0090, by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll-free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/FACA/04_APME.asp*) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is ''in the public interest in connection with the performance of duties imposed * * * by law.'' Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for ''activities * * * to broadly disseminate information to [M]edicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.''

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1311(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 and approved the renewal of the charter on November 14, 2006. The establishment of the charter and the renewal of the charter were announced in the February 17, 1999 **Federal Register** (64 FR 7899), and the March 23, 2007 **Federal Register** (72 FR 13796), respectively. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. The Secretary delegates authority to the Administrator.

The goals of the Panel are as follows:

- To provide recommendations on the development and implementation of a national Medicare education program that describes the options for selecting a health plan and prescription drug plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To provide recommendations on how to expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Gwendolyn T. Bronson, SHINE/SHIP Counselor, Massachusetts SHINE Program; Dr. Yanira Cruz, President and Chief Executive Officer, National Hispanic Council on Aging; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Nan Kirsten-Forte, Executive Vice President, Consumer Services, WebMD; Dr. Jessie C. Gruman, President and Chief Executive Officer, Center for the Advancement of Health; Dr. Frank B. McArdle, Manager, Hewitt Research Office, Hewitt Associates; Rebecca Snead, Executive Vice President and Chief Executive Officer, National Alliance of State Pharmacy Associations. Thirteen new members will be appointed to the panel and announced at the meeting.

The agenda for the October 22, 2008, meeting will include the following:

- Recap of the previous (June 26, 2008) meeting.
- Introduction of New Members.
- Medicare Outreach and Education Strategies.
- Public Comment.
- Listening Session with CMS Leadership.
- Next Steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 10, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–21910 Filed 9–25–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register**, Vol. 73, No. 127, pp. 37463–37464, dated Tuesday, July 1, 2008) is amended to reflect an update to the functions for the Center for Medicare Management.

Part F. is described below:

- Section F. 20. (Functions) reads as follows:

Center for Medicare Management (FAH)

- Serves as the focal point for all Agency interactions with health care providers, intermediaries, carriers, and Medicare Administrative Contractors (MACs) for issues relating to Agency fee-for-service (FFS) policies and operations.
- Responsible for policies related to scope of benefits and other statutory, regulatory and contractual provisions.
- Based on program data, develops payment mechanisms, administrative mechanisms, and regulations to ensure that CMS is purchasing medically necessary items and services under Medicare FFS.

• Develops, evaluates and maintains policies, regulations, and instructions that define the scope of benefits and payment amounts for:

1. Hospitals for inpatient services under the inpatient prospective payment system and the long-term care hospital prospective payment system;
2. Inpatient services in hospitals and units excluded from the prospective payment systems;
3. Physicians and non-physician practitioners;
4. Hospital outpatient departments, comprehensive outpatient rehabilitation facilities and ambulatory surgical centers;
5. Clinical laboratory services;
6. Ambulance services;
7. Prescription drugs and blood, blood products and hemophilia clotting factor; and
8. Telemedicine services, rural health clinics, and federally-qualified health centers.

• Formulates CMS policy for development, analysis, and maintenance of new and revised medical codes and medical classification systems (including ICD–9–CM, Healthcare Common Procedure Coding System, Diagnosis Related Groups, and Ambulatory Payment Classifications) and develops common medical coding standards and policy.

• Participates in the development and evaluation of proposed legislation pertaining to assigned subject areas.

• Coordinates with the Office of Clinical Standards and Quality on coverage issues in assigned areas.

• Develops, evaluates, and reviews regulations, manuals, program guidelines, and instructions required for the dissemination of program policies to program contractors and the health care field.

• Identifies, studies and makes recommendations for modifying Medicare policies to reflect changes in beneficiary health care needs, program objectives, and the health care delivery system.

• Develops, evaluates and maintains policies, regulations, and instructions that define the scope of benefits and payment amounts for skilled nursing facilities, home health agencies, hospice, durable medical equipment, orthotics, prosthetics and supplies.

• Develops and evaluates national Medicare policies and principles for applying limitations to the costs of skilled nursing facilities and home health agencies. Develops criteria for exceptions to the cost limitations for skilled nursing facilities. Reviews and makes decisions on requests for such exceptions.

• Analyzes payment data, develops, maintains and updates payments rates for End Stage Renal Disease services and Program of All-Inclusive Care for the Elderly sites.

• Manages designation process for Medicare organ transplant centers, organ procurement organizations and for hospitals seeking out-of-service-area waivers.

• Develops, issues and administers the specifications, requirements, methods, standards, policies, procedures and budget guidelines for Medicare claims processing related activities, including detailed definitions of the relative responsibilities of providers, contractors, CMS, other third-party payers and the beneficiaries of the Medicare program.

• Develops and releases the coding and pricing databases and software for physician, laboratory, Skilled Nursing Facility, Home Health, Inpatient, Outpatient and supplier services in the Medicare claims processing standard systems.

• Develops policies related to the integration of health care services, including policies on ownership and referral arrangements, business relationships and conflict of interest.

• Serves as the CMS lead for management, oversight, budget and performance issues relating to Medicare carriers, fiscal intermediaries, and MACs.

• Functions as CMS liaison for all Medicare carrier, fiscal intermediary, and MAC program issues and, in close collaboration with the regional offices and other CMS components, coordinates Agency-wide contractor activities.

• Manages contractor instructions, workload, and change management process.

• Manages and oversees Medicare contractor provider inquiry, outreach, and education activities including specifying Budget Performance Requirements, allocating and managing budget dollars across contractors, evaluating supplemental budget requests, issuing program instructions and participating in contractor performance evaluation activities.

• In conjunction with the CMS program area experts, develops training programs and materials, and training tools to educate providers, physicians, suppliers and Medicare contractor provider education staff on new initiatives and changes to the Medicare program.

• Develops national provider/supplier education products and training tools for Medicare contractors as well as for provider education provided directly by CMS.

• Supports communication between CMS and the provider/supplier community through facilitation of ''open door'' and Participating Physician Advisory Committee meetings, other listening sessions and promotes awareness of Agency initiatives by sponsoring exhibit programs at industry conferences.

• Develops system requirements and computer software for select portions of Medicare FFS claims processing systems.

• Develops and implements Medicare FFS program requirements for provider billing and for claims processing systems.

• Implements the Medicare Health Support Program.

Dated: September 18, 2008.

James W. Weber,

Acting Director, Office of Operations Management, Centers for Medicare & Medicaid Services.

[FR Doc. E8–22690 Filed 9–25–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0514]

Draft Guidance for Industry on End-of-Phase 2A Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''End-of-Phase 2A Meetings.'' This draft guidance provides information on end-of-phase 2A (EOP2A) meetings for sponsors of investigational new drug applications (INDs) who seek guidance on employing clinical trial simulation and quantitative modeling of prior knowledge (e.g., drug, disease, placebo) to design trials for better dose response estimation, dose selection, and other appropriate issues. This draft guidance is intended to further FDA initiatives directed at identifying opportunities to facilitate the development of innovative medical products and to improve the quality of drug applications through early meetings with sponsors.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit