for a discussion of the substantial clinical improvement criteria on each of the FY 2009 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.*

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who would like to present must register and submit their agenda item(s) to the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Comments from participants will be heard after scheduled statements if time permits. Once the agenda is completed, it will be posted on the CMS IPPS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.*

For presenters or participants unable to attend the CMS for the meeting, an open toll-free phone line, (888) 970–4128, is available. Persons who call in will be asked for the conference code by the conference operator. The conference code is ''New Tech.''

In addition, written comments will also be accepted and presented at the meeting if they are received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting. If the comments are to be considered before the publication of the proposed rule, the comments must be received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for the Town Hall Meeting. While there is no registration fee, individuals must register to attend the Town Hall Meeting.

Registration may be completed on-line at the following Web address: *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.* Select the link at the bottom of the page ''New Technology Town Hall Meeting'' to complete the on-line registration. After completing the registration, on-line registrants should print the confirmation page and bring it with them to the meeting.

If you are unable to register on-line, you may register by sending an email to the contacts listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Please include your name, address, telephone number, email address and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business by the date listed in the **DATES** section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 1 p.m., e.s.t. so that you will be able to arrive promptly at the meeting by 1:30 p.m., e.s.t.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

Authority: Section 503 of Public Law 108–173.

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

Dated: December 6, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. E7–24267 Filed 12–27–07; 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. 72, No. 123, pp. 35246–35247, dated Wednesday, June 27, 2007) is amended to reflect the abolishment of the 10 Regional Offices and the establishment of the Consortium for Medicare Health Plans Operations, the Consortium for Financial Management and Fee for Service Operations, the Consortium for Medicaid and Children's Health Operations, and the Consortium for Quality Improvement and Survey and Certification Operations.

Part F is described below:

- Section F.10. (Organization) reads as follows:

1. Office of External Affairs (FAC)
2. Center for Beneficiary Choices (FAE)
3. Office of Legislation (FAF)
4. Center for Medicare Management (FAH)
5. Office of Equal Opportunity and Civil Rights (FAJ)
6. Office of Research, Development, and Information (FAK)
7. Office of Clinical Standards and Quality (FAM)
8. Office of the Actuary (FAN)
9. Center for Medicaid and State Operations (FAS)
10. Consortium for Medicare Health Plans Operations (FAU)
11. Consortium for Financial Management and Fee for Service Operations (FAV)
12. Consortium for Medicaid and Children's Health Operations (FAW)
13. Consortium for Quality Improvement and Survey and Certification Operations (FAX)
14. Office of Operations Management (FAY)

15. Office of Information Services (FBB)
16. Office of Financial Management (FBC)
17. Office of Strategic Operations and Regulatory Affairs (FGA)
18. Office of E-Health Standards and Services (FHA)
19. Office of Acquisition and Grants Management (FKA)
20. Office of Policy (FLA)
21. Office of Beneficiary Information Services (FMA)

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

10. Consortium for Medicare Health Plans Operations (FAU)

• Serves as the Field focal point for all interactions with managed health care organizations, Medicare Advantage (MA) plans, Medicare prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (Part D) plans for issues relating to Agency programs, policy and operations.

• Serves as the Field's focal point for all Agency interactions with employers, employees, retirees and others operating on their behalf pertaining to issues related to Agency policies and operations concerning employer-sponsored prescription drug coverage for their retirees.

• Serves as the Field focal point for all interactions with beneficiaries, their families, care givers, health care providers, and others operating on their behalf concerning improving beneficiaries' ability to make informed decisions about their health and about program benefits administered by the Agency. These activities include strategic and implementation planning, execution, assessment and communications.

• Implements national policy for Medicare Parts C and D beneficiary eligibility, enrollment, entitlement, premium billing and collection, coordination of benefits, rights and protections, and dispute resolution process, as well as policy for managed care enrollment and disenrollment to assure the effective administration of the Medicare program.

• Participates in the development of national policies and procedures related to the development, qualification, and compliance of health maintenance organizations, competitive medical plans and other health care delivery systems and purchasing arrangements (such as prospective pay, case management, differential payment, selective contracting, etc.) necessary to assure the effective administration of the Agency's programs, including the development of statutory proposals.

• In conjunction with the Center for Beneficiary Choices (CBC), handles all phases of contracts with managed health care organizations eligible to provide care to Medicare beneficiaries.

• Responds to inquiries regarding Parts C and D coverage and payment policies.

• Implements national policies and procedures to support and assure appropriate State implementation of the rules and processes governing group and individual health insurance markets and the sale of health insurance policies that supplement Medicare coverage.

• In conjunction with CBC, implements regulations, guidelines, and instructions required for the dissemination of appeals policies to Medicare beneficiaries, MA plans, PDPs, CMS Consortia, beneficiary advocacy groups and other interested parties.

• Assures, in coordination with other Consortium Administrators and Central Office Centers and Offices, that the activities of Medicare managed care plans, agents, and State Agencies meet the Agency's requirements on matters concerning beneficiaries and other consumers.

• In partnership with appropriate Central Office components, administers the contracts and grants related to beneficiary and customer service, including the State Health Insurance Assistance Program grants.

• Participates in the formulation of strategies to advance overall beneficiary communications goals and coordinates the Field implementation of all beneficiary-centered information, education, and service initiatives.

• Builds a range of partnerships with other national organizations for effective consumer outreach, awareness, and education efforts in support of Agency programs.

• Serves as the Consortium focal point for emergency preparedness for the Field.

• Provides oversight in the areas of human resource procurement and logistics.

• Ensures the effective management of the Agency's information technology and information systems and resources in the Field.

• Implements the privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

• Proactively establishes, manages, and fosters partnerships within the Consortium with State and Local governments, providers and provider associations, beneficiaries and their representatives, and the media that are focused on CMS' goals and objectives.

• Serves as the primary point of contact to appropriate members of Congress, Federal, State, and Local officials and Tribal governments on matters concerning the Medicare program.

• Oversees the coordination and integration of CMS' activities with other Federal, State, Local, and private health care agencies and organizations.

• Counsels, advises, and collaborates with top Agency officials on policy matters and major considerations in developing, implementing, and coordinating CMS' programs as they interrelate in addressing national and regional strategies.

• Advises the Office of the Administrator (OA) on special programs as they relate to national initiatives and as they impact major constituents or their key representatives.

• Promotes accountability, communication, coordination and facilitation of cooperative corporate decision-making among CMS' top senior staff on management, operational and programmatic issues cross-cutting organizational components with diverse functions and activities.

11. Consortium for Financial Management & Fee for Service Operations (FAV)

• Serves as the Field focal point for all interactions with the Office of Financial Management and assists in its overall responsibility for the fiscal integrity of all Agency programs.

• Implements all benefit integrity policies and operations in coordination with other Agency components in the Field. Assists in the management of the Medicare program integrity contractors.

• Performs the Field's activities regarding Medicare Secondary Payer.

• Implements all civil money penalty policies in all CMS' programs.

• Oversees and coordinates the Field's preparation of certification statements for the Federal Managers Financial Integrity Act and Government Performance and Results Act.

• Serves as the Field focal point for all Agency interactions between health care providers and fee-for-service (FFS) contractors for issues relating to Part A and Part B FFS policies and operations.

• Coordinates provider and physician-centered Part A and Part B FFS information, education, and service initiatives in the Field.

• Responds to inquiries regarding Part A and Part B coverage and payment policies.

• Provides the Center for Medicare Managementwith comments on FFS current/proposed legislation in order to determine impact on providers.

• Performs activities related to the Medicare Part A and Part B processes (42 CFR part 405, subparts G and H), Part C (42 CFR part 422, subpart M), Part D (42 CFR part 423, subpart M) and the Program for All-Inclusive Care for the Elderly (PACE) for claims-related hearings, appeals, grievances and other dispute resolution processes that are beneficiary-centered.

• Implements national policy for Medicare Parts A and B beneficiary eligibility, enrollment, entitlement; premium billing and collection; coordination of benefits; rights and protections; dispute resolution process to assure the effective administration of the Medicare program.

• Serves as the Consortium focal point for emergency preparedness for the Field.

• Provides oversight in the areas of human resource procurement and logistics.

• Ensures the effective management of the Agency's information technology and information systems and resources in the Field.

• Implements the privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

• Proactively establishes, manages, and fosters partnerships within the Consortium with State and Local governments, providers and provider associations, beneficiaries and their representatives, and the media that are focused on CMS' goals and objectives.

• Serves as the primary point of contact to appropriate members of Congress, Federal, State, and Local officials and Tribal governments on matters concerning the Medicare program.

• Oversees the coordination and integration of CMS' activities with other Federal, State, Local, and private health care agencies and organizations.

• Counsels, advises, and collaborates with top Agency officials on policy matters and major considerations in developing, implementing, and coordinating CMS' programs as they interrelate in addressing national and regional strategies.

• Advises OA on special problems as they relate to national initiatives and programs and as they impact major constituents or their key representatives.

• Promotes accountability, communication, coordination and facilitation of cooperative corporate decision-making among CMS top senior staff on management, operational and programmatic issues cross-cutting organizational components with diverse functions and activities.

12. Consortium for Medicaid & Children's Health Operations (FAW)

• Serves as the Field focal point for all CMS activities relating to Medicaid and the State Children's Health Insurance Program (SCHIP) with States and Local governments (including the Territories).

• Implements national Medicaid program and fiscal policies and procedures which support and assure effective State program administration and beneficiary protection. In partnership with States, evaluates the success of State Agencies in carrying out their responsibilities and, as necessary, assists States in correcting problems and improving the quality of their operations.

• Implements, interprets, and applies specific laws, regulations, and policies that directly govern the financial operation and management of the Medicaid program and the related interactions with States.

• Reviews, approves and conducts oversight of Medicaid managed care waiver programs. Provides assistance to States and external customers on all Medicaid managed care issues.

• Implements national policies and procedures on Medicaid automated claims/encounter processing and information retrieval systems such as the Medicaid Management Information System and integrated eligibility determination systems.

• Through administration of the home and community-based services program and policy collaboration with other Agency components and the States, promotes the appropriate choice and continuity of quality services available to frail elderly, disabled and chronically ill beneficiaries.

• Coordinates with and provides input into the Medicaid Integrity Program (MIP). Develops strategies to prevent and detect improper payments, including fraud and abuse by providers and others, from Medicaid and SCHIP. Offers support and assistance to the States to combat provider fraud, waste, and abuse. Provides guidance and direction to State Medicaid programs based on the insights gained through MIP's efforts.

• Serves as the Consortium focal point for emergency preparedness for the Field.

• Provides oversight in the areas of human resource procurement and logistics.

• Ensures the effective management of the Agency's information technology and information systems and resources in the Field.

• Implements the privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

• Proactively establishes, manages, and fosters partnerships within the Consortium with State and Local governments, providers and provider associations, beneficiaries and their representatives, and the media that are focused on CMS' goals and objectives.

• Serves as the primary point of contact to appropriate members of Congress, State Governors, Federal, State, and Local officials and Tribal governments on matters concerning the Medicaid program.

• Oversees the coordination and integration of CMS' activities with other Federal, State, Local, and private health care agencies and organizations.

• Counsels, advises, and collaborates with top Agency officials on policy matters and major considerations in developing, implementing, and coordinating CMS' programs as they interrelate in addressing national and regional strategies.

• Advises OA on special problems as they relate to national initiatives and programs and as they impact major constituents or their key representatives.

• Promotes accountability, communication, coordination and facilitation of cooperative corporate decision-making among CMS' top senior staff on management, operational and programmatic issues cross-cutting organizational components with diverse functions and activities.

13. Consortium for Quality Improvement & Survey & Certification Operations (FAX)

• Serves as the Field focal point for all quality, clinical and medical science issues and policies for the Agency's programs. Provides leadership and coordination for the development and implementation of a cohesive, Agency-wide approach to measuring and promoting quality and leads the Agency's priority-setting process for clinical quality improvement. Coordinates quality-related activities with outside organizations. Monitors quality of Medicare, Medicaid, and the Clinical Laboratory Improvement Amendments (CLIA). Evaluates the success of interventions.

• Identifies and develops best practices and techniques in quality improvement; implementation of these techniques will be overseen by appropriate components. Develops and collaborates on demonstration projects to test and promote quality measurement and improvement.

• Develops tests and evaluates, adopts and supports performance measurement systems (quality

indicators) to evaluate care provided to CMS' beneficiaries except for demonstration projects residing in other components.

• Assures that the Agency's quality-related activities (survey and certification, technical assistance, beneficiary information, payment policies and provider/plan incentives) are fully and effectively integrated in the Field. Carries out the Health Care Quality Improvement Program for the Medicare, Medicaid, and CLIA programs.

• Assists in the specification and operational refinement of an integrated CMS quality information system, which includes tools for measuring the coordination of care between health care settings; analyzes data supplied by that system to identify opportunities to improve care and assess success of improvement interventions.

• Enforces the requirements of participation for providers and plans in the Medicare, Medicaid, and CLIA programs. Recommends revisions of the requirements based on statutory change and input from other components.

• Operates the Medicare Quality Improvement Organization and End Stage Renal Disease Network program, providing policies and procedures, contract design, program coordination, and leadership in selected projects.

• Identifies, prioritizes and develops content for clinical and health related aspects of CMS' Consumer Information Strategy; and collaborates with other components to develop comparative provider and plan performance information for consumer choices.

• Assists in the preparation of the scientific, clinical and procedural basis for, and recommends to the Administrator decisions regarding, coverage of new and established technologies and services. Maintains liaison with other Departmental components regarding the safety and effectiveness of technologies and services; prepares the scientific and clinical basis for, and recommends approaches to, quality-related medical review activities of contractors and payment policies.

• Serves as the focal point for all CMS Field activities relating to CLIA and the survey and certification of health facilities with States and Local governments (including the Territories).

• Implements, evaluates and refines standardized provider performance measures used within provider certification programs. Supports States in their use of standardized measures for provider feedback and quality improvement activities. Implements and supports the data collection and analysis systems needed by States to administer the certification program.

• Serves as the Consortium focal point for emergency preparedness for the Field.

• Provides oversight in the areas of human resource procurement and logistics.

• Ensures the effective management of the Agency's information technology and information systems and resources in the Field.

• Implements the privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

• Proactively establishes, manages, and fosters partnerships within the Consortium with State and Local governments, providers and provider associations, beneficiaries and their representatives, and the media that are focused on CMS' goals and objectives.

• Serves as the primary point of contact to appropriate members of Congress, State Governors, Federal, State, and Local officials and Tribal governments on matters concerning the Medicare and Medicaid programs.

• Oversees the coordination and integration of CMS' activities with other Federal, State, Local, and private health care agencies and organizations.

• Counsels, advises, and collaborates with top Agency officials on policy matters and major considerations in developing, implementing, and coordinating CMS' programs as they interrelate in addressing national and regional strategies.

• Advises OA on special problems as they relate to national initiatives and programs and as they impact major constituents or their key representatives.

• Promotes accountability, communication, coordination and facilitation of cooperative corporate decision-making among CMS top senior staff on management, operational and programmatic issues cross-cutting organizational components with diverse functions and activities.

Dated: November 23, 2007.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. E7–25305 Filed 12–27–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held by teleconference on February 5, 2008, from 12 noon to approximately 3:15 p.m. Eastern Time.

Location: National Institutes of Health, Building 29B, Conference Room C, 9000 Rockville Pike, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the specified location. A speakerphone will be provided at the specified location for public participation in the meeting, on site. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm*. Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Because of the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Gail Dapolito or Danielle Cubbage, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot