

Stop: S3-02-01, Baltimore, MD 21244 or send via email to MEDCACnomination@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Maria Ellis, Executive Secretary for the MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via email at Maria.Ellis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary signed the initial charter for the Medicare Coverage Advisory Committee (MCAC) on November 24, 1998. A notice in the **Federal Register** (63 FR 68780) announcing establishment of the MCAC was published on December 14, 1998. The MCAC name was updated to more accurately reflect the purpose of the committee and on January 26, 2007, the Secretary published a notice in the **Federal Register** (72 FR 3853), announcing that the Committee's name changed to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The current Secretary's Charter for the MEDCAC is available on the CMS Web site at: <http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf>, or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

The MEDCAC is governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act as amended (42 U.S.C. 217A).

We are requesting nominations for candidates to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not solely as representatives of professional associations or societies. We wish to ensure adequate representation of the interests of both women and men, members of all ethnic groups, and physically challenged individuals. Therefore, we encourage nominations of qualified candidates who can represent these interests.

The MEDCAC consists of a pool of 100 appointed members including: 94 at-large standing members (6 of whom are patient advocates), and 6 representatives of industry interests. Members generally are recognized

authorities in clinical medicine including subspecialties, administrative medicine, public health, biological and physical sciences, epidemiology and biostatistics, clinical trial design, health care data management and analysis, patient advocacy, health care economics, medical ethics or other relevant professions.

The MEDCAC works from an agenda provided by the Designated Federal Official. The MEDCAC reviews and evaluates medical literature and technology assessments, and hears public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries. The MEDCAC may also advise the Centers for Medicare & Medicaid Services (CMS) as part of Medicare's "coverage with evidence development" initiative.

II. Provisions of the Notice

As of June 2016, there will be 35 membership terms expiring. Of the 35 memberships expiring, 1 is an industry representative, 4 are patient advocates, and the remaining 30 membership openings are for the at-large standing MEDCAC membership.

All nominations must be accompanied by curricula vitae. Nomination packages should be sent to Maria Ellis at the address listed in the **ADDRESSES** section of this notice. Nominees are selected based upon their individual qualifications. Nominees for membership must have expertise and experience in one or more of the following fields:

- Clinical medicine including subspecialties
- Administrative medicine
- Public health
- Biological and physical sciences
- Epidemiology and biostatistics
- Clinical trial design
- Health care data management and analysis
- Patient advocacy
- Health care economics
- Medical ethics
- Other relevant professions

We are looking particularly for experts in a number of fields. These include cancer screening, genetic testing, clinical epidemiology, psychopharmacology, screening and diagnostic testing analysis, and vascular surgery. We also need experts in biostatistics in clinical settings, dementia treatment, minority health, observational research design, stroke epidemiology, and women's health.

The nomination letter must include a statement that the nominee is willing to serve as a member of the MEDCAC and

appears to have no conflict of interest that would preclude membership. We are requesting that all curricula vitae include the following:

- Date of birth
- Place of birth
- Social security number
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- List of areas of expertise

In the nomination letter, we are requesting that nominees specify whether they are applying for a patient advocate position, for an at-large standing position, or as an industry representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of financial conflict of interest. Department policy prohibits multiple committee memberships. A federal advisory committee member may not serve on more than one committee within an agency at the same time.

Members are invited to serve for overlapping 2-year terms. A member may continue to serve after the expiration of the member's term until a successor is named. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted. Individuals interested in the representative positions must include a letter of support from the organization or interest group they would represent.

Dated: October 13, 2015.

Patrick Conway,

CMS Chief Medical Officer and Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice of reorganization.

SUMMARY: Statement of Organization, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) has reorganized. The reorganization adds

the Chief of Staff, the Deputy Assistant Secretary for External Affairs, and the Associate Deputy Assistant Secretary for Early Childhood Development positions to the Office of the Assistant Secretary. It also renames the Inter-Departmental Liaison for Early Childhood Development position to the Deputy Assistant Secretary for Early Childhood Development. It eliminates the Office of the Deputy Assistant Secretary for Policy and External Affairs. The reorganization removes the Office of Human Services Emergency Preparedness and Response from within the Office of the Assistant Secretary and creates the Office of Human Services Emergency Preparedness and Response as a direct report to the Assistant Secretary. It renames the Office of Public Affairs to the Office of Communications. Lastly, it changes the reporting relationship of the Office of Regional Operations and the Office of Communications from the Assistant Secretary to a direct report to the Deputy Assistant Secretary for External Affairs. This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter K, Administration for Children and Families (ACF), as last amended in 77 FR 23250–23260, April 18, 2012; Chapter KA, Office of the Assistant Secretary, as last amended in 80 FR 33269–33270, June 11, 2015; Chapter KJ, Office of Regional Operations, as last amended in 71 FR 59117–59123, October 6, 2006; and Chapter KN, Office of Public Affairs, as last amended in 77 FR 61002–61003, October 5, 2012.

I. Under Chapter K, Administration for Children and Families, delete K.00 Mission in its entirety and replace with the following:

K.00 Mission. The Administration for Children and Families (ACF) provides national leadership and direction to plan, manage, and coordinate the nationwide administration of comprehensive and supportive programs for vulnerable children and families. The Administration oversees and finances a broad range of programs for children and families, including Native Americans, persons with developmental disabilities, refugees, and legalized aliens, to help them develop and grow toward a more independent, self-reliant life. These programs, carried out by state, county, city, and tribal governments, and public and private local agencies, are designed to promote stability, economic security, responsibility, and self-sufficiency.

The Administration coordinates development and implementation of family-centered strategies, policies, and linkages

among its programs, and with other federal and state programs serving children and families. The Administration's programs assist families in financial crisis, emphasizing short-term financial assistance, and education, training and employment for the long term. Its programs for children and youth focus on those children and youth with special problems, including children of low-income families, abused and neglected children, those in institutions or requiring adoption or foster family services, runaway youth, children with disabilities, migrant children, and Native American children. The Administration promotes the development of comprehensive and integrated community and home-based modes of service delivery where possible. The Administration provides national leadership to develop and coordinate public and private programs and serves as a focal point for states in the provision of financial assistance and intervention programs that promote and support permanence for children and family stability. The Administration advises the Secretary on issues pertaining to children and families, including Native Americans, refugees, and legalized aliens.

II. Under Chapter K, Administration for Children and Families, delete K.10 Organization in its entirety and replace with the following:

K.10 Organization. The Administration for Children and Families (ACF) is a principal operating division of the Department of Health and Human Services (HHS). The Administration is headed by the Assistant Secretary for Children and Families, who reports directly to the Secretary. The Assistant Secretary also serves as the Director of Child Support Enforcement. In addition to the Assistant Secretary, the Administration consists of the Principal Deputy Assistant Secretary, the Chief of Staff, the Deputy Assistant Secretary for Administration, the Deputy Assistant Secretary for Policy, the Deputy Assistant Secretary for Early Childhood Development, the Deputy Assistant Secretary for External Affairs, and Staff and Program Offices. ACF is organized as follows:

Office of the Assistant Secretary for Children and Families (KA)
Administration on Children, Youth and Families (KB)
Administration for Native Americans (KE)
Office of Child Support Enforcement (KF)
Office of Community Services (KG)
Office of Family Assistance (KH)
Office of Regional Operations (KJ)
Office of Planning, Research and Evaluation (KM)
Office of Communications (KN)
Office of the Deputy Assistant Secretary for Administration (KP)
Office of Refugee Resettlement (KR)
Office of Legislative Affairs and Budget (KT)
Office of Head Start (KU)
Office of Child Care (KV)
Office of Human Services Emergency Preparedness and Response (KW)

III. Under Chapter KA, Office of the Assistant Secretary for Children and Families, delete KA.20 Functions,

Paragraph A in its entirety and replace with the following:

KA.20 Functions. A. Office of the Assistant Secretary for Children and Families: The Office of the Assistant Secretary for Children and Families is responsible to the Secretary for carrying out ACF's mission and provides executive supervision of the major components of ACF. These responsibilities include providing executive leadership and direction to plan and coordinate ACF program activities to ensure their effectiveness; approving instructions, policies, publications, and grant awards issued by ACF; and representing ACF in relationships with governmental and non-governmental organizations. The Principal Deputy Assistant Secretary serves as an alter ego to the Assistant Secretary for Children and Families on program matters and acts in the absence of the Assistant Secretary for Children and Families. The Chief of Staff advises the Assistant Secretary for Children and Families and provides executive leadership and direction to the operations of ACF. The Deputy Assistant Secretary for External Affairs provides executive leadership and direction to the Offices of Regional Operations and Communications. The Deputy Assistant Secretary for Early Childhood Development serves as a key liaison and representative to the Department for early childhood development on behalf of the Assistant Secretary, ACF, and to other agencies across the government on behalf of the Department. The Deputy Assistant Secretary for Policy has responsibility for cross-program coordination of ACF initiatives, including efforts to promote interoperability and program integration.

IV. Under Chapter KJ, Office of Regional Operations, delete KJ in its entirety and replace with the following:

KJ.00 Mission. The Office of Regional Operations (ORO) advises the Assistant Secretary for Children and Families through the Deputy Assistant Secretary for External Affairs on all strategic and operational activities related to implementation of agency goals and priorities at the regional level. ORO oversees the performance of the Offices of the Regional Administrators (ORA) on coordination of cross-cutting and special emphasis programs and initiatives, emergency preparedness, tribal government relations, state, and local ACF-related affairs, and administrative functions in Regions I–X, Offices of the Regional Administrators (ORA).

The ORAs are located in the ten HHS Regional Offices: Region I (Boston), Region II (New York), Region III (Philadelphia), Region IV (Atlanta), Region V (Chicago), Region VI (Dallas), Region VII (Kansas City), Region VIII (Denver), Region IX (San Francisco), and Region X (Seattle). Each ORA, through the Director, ORO, and in coordination with ACF Program Directors, represents ACF to states, counties, cities, or towns, territories, and tribal governments, grantees, and public and private local organizations. The ORA coordinates issues that may have significant regional or national impact. The ORA develops plans in conjunction with the

Program Directors to meet ACF goals and objectives and initiatives and participates in regional activities to inform the public about ACF programs at the regional level in coordination with the ACF Office of Communications. The ORA contributes to the development of ACF national policy based on knowledge of services in the region.

KJ.10 Organization. The Office of Regional Operations (ORO) is headed by a Director who reports to the Assistant Secretary through the Deputy Assistant Secretary for External Affairs. The ORO is organized as follows:

Office of the Director (KJA)

Regional Operations Staff (KJB)

Office of the Regional Administrators (KJDI–X)

KJ.20 Functions. A. Office of the Director (KJA): The Office of the Director (OD) provides executive leadership and assistance on all strategic and operational activities related to implementation of the agency's national goals and priorities at the regional level. The Director is the principal advisor to the Assistant Secretary for Children and Families through the Deputy Assistant Secretary for External Affairs on regional matters involving special emphasis programs and initiatives, emergency preparedness, tribal government relations, state and local ACF partnership activities, and regional administrative functions. The Director represents the Assistant Secretary for Children and Families within HHS and with other federal agencies and task forces on regional activities.

The OD: (1) Oversees the Regional Administrators in administering regional activities and implementing cross-cutting program initiatives; (2) serves as a focal point for operational and long-range planning; and (3) coordinates with the ACF Central Office components to ensure that the Regional Administrators can help coordinate certain national priorities and initiatives, state and local partnership activities, special programs, and emergency preparedness and response operations.

B. Regional Operations Staff (KJB): The Regional Operations Staff: (1) Develops and manages liaison processes between ACF Regional Offices and the Assistant Secretary for Children and Families; (2) supports the Offices of the Regional Administrators (ORA) of each region by implementing and overseeing the management systems and procedures for communication and workload that emanate from ACF national priorities and initiatives, special emphasis programs, emergency preparedness, tribal government relations, and state and local ACF partnership activities; (3) monitors and evaluates ORA operations and makes plans for the utilization of regional resources to accomplish approved objectives; and (4) manages administrative and human resources functions, and salaries and expenses for the ORA.

C. Offices of the Regional Administrators (KJDI–X): Each of the ORAs is headed by a Regional Administrator who reports to the Deputy Assistant Secretary for External Affairs through the Director, ORO. Each Office: (1) Helps support ACF's key national goals and priorities; (2) communicates ACF's

regional interests, concerns, and relationships within HHS and among other federal agencies and focuses on state agency culture change, more effective partnerships, and improved customer service; (3) manages special and sensitive projects; (4) serves as a focal point for public affairs and contacts with the media, public awareness activities, information dissemination, and education campaigns in coordination with the ACF Office of Communications and in conjunction with the HHS Regional Director; (5) assists the ACF Regional Administrator in the management of cross-cutting initiatives and activities among the regional components; and (6) as appropriate, and in coordination with the ACF Central Office components, assists with activities relating to developmental disabilities, refugee resettlement, economic and community development, tribal and special initiative activities.

The Regional Administrators: (1) Oversee the management of ACF regional staff in the ORA; (2) coordinate activities across regional programs; (3) ensure that goals and objectives are carried out; and (4) alert the Assistant Secretary for Children and Families through the Director, ORO, the DAS of External Affairs, and/or Central Office ACF Program Directors to problems and issues that may have significant regional or national impact.

As requested by the Director of Regional Operations or Central Office ACF Program Directors, the ORA represents ACF at the regional level in executive communications within ACF, with the HHS Regional Director, other HHS Operating Divisions, other federal agencies, and public or private local organizations.

Within the ORA, an administrative staff: (1) develops regional work plans, in coordination with Central Office Program Directors, related to the overall ACF strategic plans, and tracks, monitors, and reports on regional progress in the attainment of ACF national goals and objectives; (2) coordinates routine budget, administrative, and human resource functions as required, including Executive Secretariat, ACF-controlled space, computer and computer peripheral equipment, and health and safety for the ORA; (3) coordinates ACF programs during emergencies in the regions, including natural disasters, pandemic flu, or other disasters; (4) serve as ACF's focal point for Continuity of Operations Program planning, implementation, and coordination; (5) coordinates regional ACF deployments of human services assessments and action teams during state and/or federally declared emergencies and disasters; and (6) coordinates resources for regional special emphasis activities with the HHS Regional Director's office.

V. Under Chapter KN, Office of Public Affairs, delete KN in its entirety and replace with the following:

KN.00 Mission. The Office of Communications (OC) develops, directs, and coordinates public affairs and communication services for ACF. It provides leadership, direction and oversight in promoting ACF's public affairs policies, programs, and initiatives. OC oversees

Freedom of Information Act requests, digital communications, and also provides printing and distribution services for ACF.

KN.10 Organization. OC is headed by a Director who reports to the Assistant Secretary through the Deputy Assistant Secretary for External Affairs. The Office is organized as follows:

Office of the Director (KNA)

Division of News and Media (KNB)

Division of Digital Information (KNC)

Division of Freedom of Information Act (KND)

KN.20 Functions. A. The Office of Director provides leadership and direction to the Office of Communications in administering its responsibilities. The Office provides direction and leadership in the areas of public relations policy and internal and external communications services. It serves as advisor to the Assistant Secretary for Children and Families through the Deputy Assistant Secretary for External Affairs in the areas of public affairs; provides advice on strategies and approaches to be used to improve public understanding of and access to ACF programs and policies; and coordinates and serves as ACF liaison with the Assistant Secretary for Public Affairs. The Office serves as Regional Liaison on public affairs issues.

B. Division of News and Media develops and implements public affairs strategies to achieve ACF program objectives in coordination with other ACF components. It coordinates news media relations strategy; responds to all media inquiries concerning ACF programs and related issues; develops fact sheets, news releases, feature articles for magazines and other publications on ACF programs and initiatives; and manages preparation and clearance of speeches and official statements on ACF programs. It coordinates regional public affairs policies and public affairs activities pertaining to ACF programs and initiatives.

C. Division of Digital Information manages the ACF Web site, social media accounts, audio-visual, publications, and printing management systems for ACF. It manages preparation and clearance of all ACF audio-visual product, publications, and graphic designs, including planning, budget oversight, and technical support. It provides centralized graphics design services to ACF. It reviews requests for proposals for contracts and grants that involve publications, audio-visual materials and/or public information, and education activity. It manages all ACF Web site content, 508 compliance, and other federal laws and regulations governing digital media.

D. Division of Freedom of Information Act (FOIA) implements elements of ACF's Open Government Initiative. The FOIA division receives requests under the FOIA statute, elicits the requested records from program offices, reviews the records and redacts accordingly, and provides responses to the requestor.

VI. Under Chapter KW, Create the Office of Human Services Emergency Preparedness and Response:

KW.00 Mission. The Office of Human Services Emergency Preparedness and

Response (OHSEPR) promotes resilience of vulnerable individuals, children, families, and communities impacted by disasters and public health emergencies and provides expertise in human services preparedness, response, and recovery through policy, planning, operations, and partnerships.

OHSEPR coordinates ACF's work in emergency preparedness, response, and recovery planning, policy, and operations, working in close partnership with ACF Program Offices and the Immediate Offices of the Regional Administrators. OHSEPR supports fulfillment of disaster human services within the integrated response and recovery operations of the Department of Health and Human Services (HHS). OHSEPR administers the Human Services Immediate Disaster Case Management Program, which is the FEMA HHS alternate of the Disaster Case Management Program.

KW.10 Organization. OHSEPR is headed by a Director, who reports to the Assistant Secretary, and consists of: Office of the Director (KW1) Division of Disaster Case Management (KW2) Division of Emergency Planning, Policy and Operations (KW3)

KW.20 Functions. A. The OD is responsible for the administrative oversight and strategic direction of all OHSEPR programs, projects, and activities. The Office of the Director implements the strategic vision of the Director, manages budgetary and legal matters affecting OHSEPR, administers human resources and program evaluation functions, and assures alignment of activities by all OHSEPR divisions with the Director's strategy and applicable laws, policies, doctrines, and frameworks related to the provision of HHS ACF disaster human services.

The Administrative Team provides administrative and budget support to OHSEPR. These responsibilities include, but are not limited to: (1) serving as the Executive Secretariat for OHSEPR, including managing correspondence, correspondence systems, and public requests; (2) coordinating human resources activities; and (3) as appropriate, development of internal policies and procedures relating to these activities.

B. Division of Disaster Case Management is responsible for administration of the Human Services Disaster Case Management Program to assist states, tribes, and territories in establishing the capacity to coordinate and provide case management services in the event of a presidentially declared disaster for which Individual Assistance is approved. This Division develops and maintains the capability to deploy Immediate Disaster Case Management (IDCM) teams upon activation by the Federal Emergency Management Agency (FEMA). The Division manages contracts for IDCM staffing assets and infrastructure, and for electronic case record to support provision of IDCM services to survivors in states and tribes as tasked by FEMA.

C. Division of Emergency Planning, Policy and Operations is responsible for administration of ACF human services preparedness, response, and recovery for disasters and public health emergencies, as

well as "steady state" capabilities necessary to maintain readiness for response or recovery operations to future events. The Division manages deployable and non-deployable capabilities for operations, including ACF's Watch Desk and threat analysis, situational awareness reporting, deployment of requested emergency response and recovery staffing assets, coordination of ACF support for federal emergency missions, and liaison with federal interagency and other partners in response and recovery. This Division is responsible for administration of OHSEPR's activities to promote emergency preparedness of ACF programs, community resilience to the human services impacts of disasters and public health emergencies, and participation in HHS-wide and government-wide emergency planning and policymaking. The Division manages preparedness activities and messaging. The Division coordinates fulfillment of ACF participation in Departmental and federal policy workgroups related to disasters, tools and guidance intended to promote preparedness of ACF programs and community resilience for ACF served populations, and training and exercise programs to continually improve ACF's capacity to support disaster human services for affected populations.

VII. Continuation of Policy

Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within the Administration for Children and Families, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

VIII. Delegation of Authority

All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

IX. Funds, Personnel, and Equipment

Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Dated: September 21, 2015.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Organ Transplantation (ACOT).

Date and Time: November 17, 2015, from 12:00 p.m. to 4:00 p.m. Eastern Time.

Place: The meeting will be via audio conference call and Adobe Connect Pro.

Status: The meeting will be open to the public.

Purpose: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, thereby increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members including the Chair. Members serve as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine, and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

Agenda: The Committee will hear presentations including those on the following topics: Donor Management Research; the HOPE Act; and Program Updates. Agenda items are subject to change as priorities indicate.

After Committee discussions, members of the public will have an opportunity to comment. Because of the Committee's full agenda and timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be posted on Department's organ donation Web site at <http://www.organdonor.gov/legislation/advisory.html#meetings>.