

expertise. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals (CAHs), who advice Centers for Medicare & Medicaid Services (CMS) only regarding the level of supervision for hospital outpatient therapeutic services.

New appointments are made in a manner that ensures a balanced membership under the FACA guidelines.

The Panel presently consists of the following members and a Chair.

(**Note:** The asterisk [\*] indicates the Panel members whose terms end during CY 2016, along with the month that the term ends.)

- E. L. Hambrick, M.D., J.D., Chair, a CMS Medical Officer.
- Karen Borman, M.D., F.A.C.S.\*(January 2016)
- Dawn L. Francis, M.D., M.H.S.
- Ruth Lande
- Jim Nelson, M.B.A., C.P.A., F.H.F.M.A.\*(January 2016)
- Leah Osbahr, M.A., M.P.H.\*(January 2016)
- Jacqueline Phillips\*(February 2016)
- Johnathan Pregler, M.D.
- Traci Rabine\*(January 2016)
- Michael Rabovsky, M.D.
- Wendy Resnick, F.H.F.M.A.
- Michael K. Schroyer, R.N.
- Marianna V. Spanki-Varelas M.D., Ph.D., M.B.A.\*(February 2016)
- Norman Thomson, III, M.D.
- Gale Walker\*(January 2016)
- Kris Zimmer

## II. Provisions of the Notice

We published a notice in the **Federal Register** on August 28, 2015, entitled "Medicare Program; Solicitation of Nominations to the Advisory Panel on Hospital Outpatient Payment (80 FR 52294). The notice solicited nominations for up to seven new members to fill the vacancies on the Panel beginning in CY 2016. As a result of that notice, we are announcing seven new members to the Panel. The Panel consists of a Chair and 15 members. The seven new Panel member appointments are for 4-year terms beginning March 1, 2016 and will assure that we continue to have a Chair and 15 members available to attend our scheduled meeting.

### *New Appointments to the Panel*

New members of the Panel will have terms beginning on March 1, 2016 and continuing through February 28, 2020 as follows:

- Shelly Dunham, R.N.
- Kenneth Michael Flowe, M.D., M.B.A.
- Erika Hardy, R.H.I.A.

- Karen A. Lambert
- Scott Manaker, M.D., Ph.D.
- Agatha L. Nolen, Ph.D., D.Ph.
- Richard Nordahl, M.B.A.

## III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: *February 2, 2016.*

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2016-02798 Filed 2-10-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of the Assistant Secretary, Office of the Deputy Assistant Secretary for Early Childhood Development, Office of Head Start, Office of Child Care; Statement of Organization, Functions, and Delegations of Authority

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** Statement of organization, functions, and delegations of authority. The Administration for Children and Families (ACF) has reorganized the Office of the Deputy Assistant Secretary for Early Childhood Development (ODAS-ECD) within the Office of the Assistant Secretary (OAS), the Office of Head Start (OHS), and the Office of Child Care (OCC). This reorganization will transfer reporting authority of OCC and OHS in their entirety from OAS to the ODAS-ECD. This reorganization creates within ODAS-ECD the Division of Policy and Budget; the Division of Comprehensive Services and Training and Technical Assistance; the Division of Research, Analysis, and Communications; and the Division of Interagency and Special Initiatives. Additionally, this reorganization will realign and combine several functions currently separately managed within OHS, OCC, and ODAS-ECD.

The ODAS-ECD reviewed the programmatic and administrative similarities and differences between

OHS and OCC and is proposing a new organizational structure that will not only retain the autonomy of the Head Start and Child Care programs and retain the best parts of how they provide services, but will also demonstrate a clear message to the field about the alignment of the Head Start and Child Care program offices, the unified focus of ensuring children receive quality services regardless of their program option, and a common message about the quality and expectations for services to children and families.

Internally, the proposed reorganization will generate a more integrated alignment of standards through Head Start and Child Care programs, the development of a unified training and technical assistance system, consistent access to resources at the ACF level for both programs, and a shared use of research resources and agenda. Additionally, the proposed reorganization will result in greater collaborative efforts among both offices thereby leveraging best practices across both offices (monitoring, program outreach, content development, etc.). Moreover, both staffs will gain a broader understanding of the early childhood field and the inter-dependencies between programs.

Within OHS, this reorganization eliminates the Education and Comprehensive Services Division and moves some of the functions to the newly created Division of Comprehensive Services and Training and Technical Assistance and the Division of Research, Analysis, and Communications within ODAS-ECD. It eliminates the Policy and Planning Division in OHS and moves some of those functions to the newly created Division of Policy and Budget within ODAS-ECD and to a new OHS Division of Planning, Oversight, and Policy. It eliminates the State Initiatives Division in OHS and moves some of those functions to each of the newly created Division of Interagency and Special Initiatives and the Division of Comprehensive Services and Training and Technical Assistance within ODAS-ECD. It also deletes the Grants and Contracts Division in OHS and moves the functions to two newly created and separate Divisions within OHS—the Division of Contracts and the Division of Grants. It combines the previous OHS Quality Assurance Division and OHS Policy and Planning Division to create the OHS Division of Planning, Oversight, and Policy. The OHS Program Operations Division remains the OHS Division of Program Operations.

Within OCC, this reorganization eliminates the Division of Technical Assistance and moves most of its functions to the newly created Division of Comprehensive Services and Training and Technical Assistance within ODAS–ECD. It also eliminates the Division of Policy in OCC and moves some of those functions to the newly created Division of Policy and Budget within ODAS–ECD and to the new OCC Division of Planning, Data, and Policy. Within OCC, it creates a new Division—the Division of Oversight and Accountability. The OCC Division of Program Operations remains the Division of Program Operations.

The goal of this reorganization is to more closely align early childhood programs, policies, and support functions in order to improve collaboration between OHS, OCC, and other federal agencies as appropriate. This will leverage best practices, generating more integrated and aligned standards through Head Start and Child Care, and improving access to ACF resources for OHS and OCC grantees while fully supporting the fundamental responsibility of operating Head Start and the Child Care and Development Fund to ensure the authorized purposes of each program and its funding are fully realized.

This notice amends Part K of the Statement of Organization Functions, and Delegations of Authority of the Department of Health and Human Services, Administration for Children and Families: Chapter K, Administration for Children and Families, as last amended 77 FR 23250–23260, April 18, 2012; Chapter KA, Office of the Assistant Secretary, as last amended 80 FR 33269–33270, June 11, 2015, and 75 FR 60471–60473, September 30, 2010; Chapter KU, Office of Head Start (OHS), as last amended 75 FR 81280–81282, December 27, 2010; Chapter KV, Office of Child Care (OCC) as last amended 75 FR 60471–60473, September 30, 2010.

I. Amend Chapter K, Administration for Children and Families, as follows:

A. Delete Section K.10, Administration for Children and Families, 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 Deputy Assistant Secretary for Administration, the Deputy Assistant Secretary for Policy, the Deputy Assistant Secretary for External Affairs, the Deputy Assistant Secretary for Early Childhood Development, 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 Public Affairs (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)  
II. Delete KA.20 Functions, Office of the Deputy Assistant Secretary for Early Childhood Development, paragraph E, in its entirety and replace with the following:

KAH.00 Mission. The Office of the Deputy Assistant Secretary for Early Childhood Development (ODAS–ECD) advises the Secretary, through the Assistant Secretary for Children and Families, in the formulation of policy positions, budget, and implementation strategies on matters related to early childhood programs and services under the purview of ACF. Additionally, ECD serves as the representative on behalf of the Assistant Secretary to the Department and on behalf of the Department to other agencies across the government on matters involving early childhood development.

KAH.10 Organization. ODAS–ECD is headed by the Deputy Assistant Secretary who reports directly to the Assistant Secretary for Children and Families. ODAS–ECD is organized as follows:

Office of the Deputy Assistant Secretary for Early Childhood Development (KAH)  
Division of Policy and Budget (KAH1)  
Division of Comprehensive Services and Training and Technical Assistance (KAH2)  
Division of Research, Analysis, and Communications (KAH3)

Division of Interagency and Special Initiatives (KAH4)

KAH.20 Functions. A. Office of the Deputy Assistant Secretary (KAH): The Office of the Deputy Assistant Secretary is responsible for: (1) Providing leadership, coordination, planning, and oversight of early childhood systems across Head Start, child care, and other relevant child- and family-serving governmental and non-governmental organizations at all levels; (2) promoting high-quality and accountable early childhood programs for all children; (3) coordinating the development of policy, legislative, regulatory, and budgetary proposals across the Office of Child Care (OCC) and the Office of Head Start (OHS); and (4) conducting outreach and maintaining relationships with and responding to inquiries from governmental and non-governmental organizations.

The Associate Deputy Assistant Secretary for Early Childhood Development (ADAS) reports to and assists the Deputy Assistant Secretary in carrying out the responsibilities of ECD and serves as a liaison to the Directors of OCC and OHS. The ADAS performs the duties of the Deputy Assistant Secretary when absent. The ADAS also supervises all Division Directors (KAH1–KAH4).

B. Division of Policy and Budget (KAH1): The Division of Policy and Budget is responsible for: (1) Advising the Deputy Assistant Secretary and the Directors of OCC and OHS on matters relating to policy, regulation development, legislative issues, and budget formulation to better align early childhood programs; (2) coordination and oversight of policies, regulations, program instructions, information memoranda, and other policy documents governing early childhood programs; (3) coordination of strategic plans and long-term goals to more effectively and efficiently protect and promote early childhood development; (4) overall budget coordination, development, presentation, and activities consistent with ACF and HHS vision and goals; (5) development of cross-cutting policy and strategic problem solving in early childhood settings; (6) reviewing, analyzing, and providing recommendations on budgetary and policy impacts of congressional or administrative proposals.

C. Division of Comprehensive Services and Training and Technical Assistance (KAH2): The Division of Comprehensive Services and Training and Technical Assistance is responsible for: (1) Supporting local, state, territory, and tribal grantees, and Regional Offices

in providing or promoting the coordination of high-quality, comprehensive, early childhood programs that are responsive to and supportive of early childhood development; and promoting family engagement and facilitating linkages to health, nutrition, dental, and mental health services, as well as promoting strong program management and fiscal systems, to build a diversified system across all early childhood settings that promotes school readiness and school-age success; (2) providing technical assistance to local agencies (in particular Head Start and Early Head Start grantees), states, territories, tribes, and Regional Offices concerning the administration of early childhood programs and school-age care programs (in conformance with applicable requirements); (3) supporting the implementation of training and technical assistance strategies to build capacity for program leaders, teachers, and other staff to implement evidence-based practices designed to increase the knowledge, skills, and competencies of the early childhood workforce, as well as their professional recognition and compensation; (4) providing leadership, coordination, and oversight of technical assistance grants, cooperative agreements and contracts, and publications to identify and promote replication of effective practices with children and families; (5) working with local, state, territorial, and tribal agencies, and Regional Offices to assess technical assistance needs and forging partnerships with public and private organizations to develop tailored approaches to address needs; (6) providing content expertise and leadership to the field in all comprehensive service areas, including, but not limited to, early childhood education; disability services; dual language learners; school age services; family and community engagement; management and fiscal operations; and health, wellness, safety and licensing; (7) supporting all content areas with a focus on relevant and necessary professional development; and (8) coordinating with the other divisions in ECD, OHS, and OCC on content related to monitoring, interagency agreements, policy, the Web site, and departmental responses to departmental inquiries.

D. Division of Research, Analysis, and Communications (KAH3): The Division of Research, Analysis, and Communications is responsible for: (1) Identifying and developing areas for research, demonstration, or developmental activities designed to improve the quality and level of services

provided to and by early childhood in conjunction with the Offices of Child Care and Head Start and the Office of Planning, Research and Evaluation; (2) conducting analyses and special studies of early childhood reports and documentation, and identifying future implications; (3) developing, directing, and coordinating communication and engagement with internal and external stakeholders; and (4) coordinating efforts to plan, evaluate, and improve external and internal communication and messaging in response to or anticipation of programmatic, policy, or research developments with implications affecting the early childhood landscape.

E. Division of Interagency and Special Initiatives (KAH4): The Division of Interagency and Special Initiatives is responsible for: (1) Fostering coordination at the federal, regional, state, and local levels to develop a continuum of comprehensive early childhood services, promoting family engagement and facilitating linkages to health, nutrition, dental, and mental health services from birth to age 8, and promoting connections and transitions with services for expectant families and school-age care programs serving children up to age 13; (2) formulating strategic plans and long-term goals to encourage development of this continuum of services and innovative programming; (3) ensuring coordination of policy and budget activities between federal agencies and within ACF as appropriate; (4) designing, developing, and planning with internal and external organizations regarding early childhood programs; (5) serving as the focal point to provide direction, coordination, and oversight of special initiatives; (6) developing and managing projects, and tracking internal and external agency initiatives; (7) serving as the liaison with other government agencies for policy and procedure development, coordination, and execution of jointly administered programs and initiatives involving early childhood, afterschool, and summer programs.

III. Delete Chapter KU, Office of Head Start, in its entirety and replace with the following:

KU.00 Mission. The Office of Head Start (OHS) has primary responsibility for the overall direction, policy and budget development and management, and oversight of Head Start operations authorized under the Head Start Act. OHS advises the Deputy Assistant Secretary for Early Childhood Development on issues regarding the Head Start program (including Early Head Start). OHS identifies legislative and budgetary requirements; identifies

areas for research, demonstration, and developmental activities; presents operational planning objectives and initiatives relating to Head Start and Early Head Start to the Deputy Assistant Secretary for Early Childhood Development; and oversees the progress of approved activities. OHS provides leadership and coordination for the activities of the Head Start program in the ACF Central Office, including the Head Start Regional Program Units. OHS represents Head Start in inter-agency activities with other federal and non-federal organizations.

KU.10 Organization. OHS is headed by a Director who reports directly to the Deputy Assistant Secretary for Early Childhood Development. OHS is organized as follows:

Office of the Director (KUA)  
 Division of Program Operations (KUB)  
 Head Start Regional Program Units (KUBDI–XII)  
 Division of Planning, Oversight, and Policy (KUE)  
 Division of Grants (KUF)  
 Division of Contracts (KUG)  
 Division of Budget Execution (KUH)

KU.20 Functions. A. Office of the Director (KUA): The Office of the Director (OD) serves as the principal advisor to the Deputy Assistant Secretary for Early Childhood Development on the administration of discretionary grant programs providing Head Start and Early Head Start services. The OD has overall responsibility for policy and budget development specific to Head Start, as well as for the management and oversight of the Head Start program and supervision of OHS Division Directors. The OD is responsible for: (1) Providing public information services by responding to inquiries from the public and private sectors; (2) serving as the central point for operational and long-range planning needs for OHS; (3) conducting outreach and maintaining relationships with Department officials; other federal departments; state, tribal, and local officials; and private organizations and individuals; (4) coordinating and planning Head Start and Early Head Start activities to maximize program effectiveness; and (5) managing large-scale or high-profile activities involving multiple OHS areas of responsibility. The Deputy Director reports to and assists the Director in carrying out the responsibilities of OHS and performs the duties of the Director when absent.

The Administration Team is responsible for providing administrative and human resource support to OHS in: (1) Planning and coordinating the

provision of new employee orientation, staff development, and training; (2) personnel administration, including position descriptions, job analysis, recruitment and selection, employee and labor relations, work force analysis, and PMAP coordination; (3) timekeeping, oversight of travel, transhare, and credit card accounts/profiles; (4) managing controlled space, facilities, and equipment; and (5) liaison for work/life balance, staff wellness, and employee recognition.

B. Division of Program Operations (KUB): The Division of Program Operations is responsible for: (1) Advising the Director on all strategic and operational activities related to the design and implementation of Head Start and Early Head Start programs in the 12 regions; (2) providing oversight, direction, and guidance to the Head Start Regional Program Units; (3) providing ongoing management of national Head Start program operations inclusive of grantee-level Designation Renewal System determinations, funding, ongoing oversight and monitoring, and training and technical assistance; (4) managing Head Start program-level data systems; and (5) serving as OHS liaison to the Offices of Grants Management and Information Systems.

C. Division of Planning, Oversight, and Policy (KUE): The Division of Planning, Oversight, and Policy is responsible for: (1) Overseeing the development and issuance of policy, regulations, program instructions, information memoranda, and other policy documents governing Head Start and Early Head Start; and legislative issues and budget formulation in coordination with ODAS-ECD and consistent with ACF early childhood priorities; (2) overseeing all major planning and implementation activities to determine Head Start and Early Head Start programs' compliance, quality, and performance with all applicable requirements and regulations; (3) conducting data analyses on monitoring outcomes to inform training and technical assistance efforts, and policy guidance and development; (4) serving as the liaison to the Office of Inspector General (OIG) for targeted OIG audits; (5) managing the OHS Complaint Line; and (6) assisting in the preparation of Congressional reports and briefing materials for hearings and testimony.

D. Division of Grants (KUF): The Division of Grants is responsible for: (1) Overseeing matters related to competitive discretionary and cooperative agreement funding opportunities; (2) managing discretionary grant competition,

including Designation Renewal, paneling, and awarding; (3) serving as the liaison to the Office of Administration, Divisions of Grants Management, and Division of Grants Policy for all matters related to competitive funding; and (4) oversight and management of interim grantees.

E. Division of Contracts (KUG): The Division of Contracts is responsible for: (1) Providing ongoing oversight of national Head Start and Early Head Start contracts; (2) providing expert technical assistance and guidance to OHS contract officer representatives on all matters related to procurement and acquisition; (3) providing ongoing monitoring of all OHS contracts ensuring internal controls are adequate; and (4) serving as liaison to the Contracts Offices.

F. Division of Budget Execution (KUH): The Division of Budget Execution is responsible for: (1) Identifying budgetary needs and working with divisions within ECD to ensure adequate funding; (2) providing oversight, execution, and ongoing management of all federal Head Start program and administrative funds; (3) providing guidance and advice on the execution of the Head Start and Early Head Start budgets; (4) establishing and implementing procedures for all phases of budget execution; (5) completing detailed reviews and analyses of grantees financial operating plans ensuring budgetary resources are used in a manner consistent with the OHS mission and are not over spent or obligated beyond appropriate limits; (6) apportioning funds appropriated by Congress; (7) preparing all required financial reports necessary and entry of all past-year data requirements; and (8) preparation of historical budget-related data, congressional inquiries, and data for budget formulation and hearings.

G. Head Start Regional Program Units (KUBDI-XII): The Head Start Regional Program Units are each headed by a Regional Program Manager (RPM) who report to the Director of the Division of Program Operations. Head Start Regional Program Units are responsible for: (1) Administering funding, ongoing oversight and monitoring, and training and technical assistance to the grantee agencies that provide services to Head Start and Early Head Start children and families; (2) providing ongoing management of Regional Head Start program operations, including State Collaboration grants; (3) serving as OHS Liaison within the Region to the Regional Office of Child Care and the Office of Grants Management; and (4) advising the Director on Regional issues impacting the Head Start program.

Regions I through X are located in the ACF geographical regions. Region XI, American Indian/Alaska Native Head Start, located at the OHS central office, administers grants for Indian Head Start grantees. Region XII, Migrant and Seasonal Head Start, located at the OHS central office, administers grants for agencies that serve the children and families of migrant and seasonal farm workers.

IV. Delete Chapter KV, Office of Child Care, in its entirety and replace with the following:

KV.00 Mission. The Office of Child Care (OCC) advises the Deputy Assistant Secretary for Early Childhood Development on matters relating to services provided in child care centers, homes, and school-age care programs, focusing on the twin goals of supporting family success and child development by improving access to high-quality child care to promote healthy development, school readiness, and school success for children. OCC identifies legislative and budgetary requirements; identifies areas for research, demonstration, and developmental activities; presents operational planning objectives and initiatives relating to child care to the Deputy Assistant Secretary for Early Childhood Development; and oversees the progress of approved activities. OCC has primary responsibility for the overall direction, policy and budget development and management, and oversight of Child Care program operations authorized under the Child Care and Development Block Grant (CCDBG) and section 418 of the Social Security Act. OCC supports state, tribal, and territorial grantees' efforts to provide financial assistance to low-income families so children can have access to high-quality child care so parents can engage in work, education, and other activities to support their families and be successful. OCC develops comprehensive, cross-sector systems of quality improvement so Child Care programs can achieve higher levels of quality training and education for the child care work force and programs. OCC provides leadership and coordination for child care issues within ACF, HHS, and with relevant federal, state, local, and tribal governmental and non-governmental organizations.

KV.10 Organization. OCC is headed by a Director who reports to the Deputy Assistant Secretary for Early Childhood Development. OCC is organized as follows:

Office of the Director (KVA)  
Division of Program Operations (KVA2)  
Division of Oversight and  
Accountability (KVA3)

Division of Planning, Data, and Policy (KVA4)

Child Care Regional Program Units (KVADI-X)

KV.20 Functions. A. Office of the Director (KVA): The Office of the Director (OD) serves as the principal advisor to the Deputy Assistant Secretary for Early Childhood Development on the administration of Child Care programs. The OD is responsible for the overall management, oversight, and policy and budget development specific to the Child Care program, and for supervision of the OCC Division Directors. The OD is also responsible for: (1) Providing public information services by responding to inquiries from the public and private sectors; (2) serving as the central point for operational and long-range planning needs for OCC; (3) conducting outreach and maintaining relationships with Department officials; other federal departments; state, tribal, and local officials; and private organizations and individuals; (4) coordinating and planning Child Care activities to maximize program effectiveness; and (5) managing large-scale or high-profile activities involving multiple OCC areas of responsibility. The Deputy Director assists the Director in carrying out the duties of the Office of the Director (OD) and performs the duties of the Director when absent.

Within the Office of the Director, Management Operation Staff is responsible for: (1) Managing the execution of the budgets for OCC-operated programs and for federal administration of the OCC program; (2) serving as the central control point for operational and long-range planning of the needs of OCC; (3) planning for and coordinating the provision of staff development and training; (4) providing support for OCC's personnel administration, including staffing, employee and labor relations, performance management, and employee recognition; (5) managing procurement planning and providing technical assistance regarding procurement; (6) managing OCC-controlled space, facilities, and equipment, including providing for health and safety; (7) planning for, acquiring, distributing, and controlling OCC supplies; (8) functioning as Executive Secretariat for OCC, including managing correspondence, correspondence systems, electronic mail requests, and mail and messenger services; (9) overseeing processes related to approval and payment of travel; and (10) maintaining fax,

computer, and computer peripheral equipment.

B. Division of Program Operations (KVA2): The Division of Program Operations is responsible for: (1) Developing and managing the process to solicit, collect, and document Child Care Development Fund (CCDF) plans of states, territories, and tribes to comply with federal CCDBG law and regulation on a triennial basis; (2) regional liaison activities, including communicating on a regular basis with regional Program Unit staff; oversight of the review and approval process for the Triennial CCDF Plans of state, territories, and tribes; and responding to questions on policy and other issues by consulting or referring to other staff; (3) collecting and maintaining information related to grantee program plans and benchmarks for achieving full implementation and compliance with federal law and regulation; (4) anticipating, identifying, and providing technical assistance for grantees to support the CCDF Program; (5) analyzing and describing grantee CCDF Plans, trends, policy and program challenges, and opportunities of major significance to inform the Director, other ACF and HHS officials, grantees, and the general public; (6) tracking and supporting special initiatives; (7) establishing partnerships with public and private entities to improve access to quality child care; (8) coordinating program activities with other government and non-governmental agencies; and (9) managing and overseeing cooperative ventures with other entities.

C. Division of Oversight and Accountability (KVA3): The Division of Oversight and Accountability is responsible for: (1) Monitoring grantees for compliance in the implementation of CCDF plans, and for programmatic and fiscal compliance with policies, regulations, and other guidance authorized under the CCDBG and section 418 of the Social Security Act; (2) planning, directing, and coordinating a comprehensive fiscal monitoring program encompassing budget planning and execution, automated financial systems, fiscal accounting, internal and external audit reporting requirements, improper payment reporting methodology, and corrective actions; (3) coordinating and targeting on-site visits to grantees to provide performance oversight and promote continuous program improvement; (4) overseeing and processing grantee reports to ensure grantee accountability; (5) serving as the liaison to the Office of Inspector General for OIG audits and Government Accountability Office (GAO) studies;

and (6) identifying and developing ongoing quality improvement strategies to address challenges grantees have in the successful implementation of their programs, which includes coordinating with the Regional Program Units and the Division of Training and Technical Assistance within ODAS-ECD.

D. Division of Planning, Data, and Policy (KVA4): The Division of Planning, Data, and Policy is responsible for: (1) Advising the Office of the Director and overseeing development and issuance of policies, regulations, program instructions, information memoranda, and other policy documents; legislative issues; and budget formulation governing the CCDF program in coordination with ODAS-ECD and consistent with ACF early childhood priorities; (2) analyzing and describing grantee data trends to inform policy guidance and development, the Director, other ACF and HHS officials, grantees, and the general public; (3) overseeing procedures for and collection of state, territory, and tribal grantee administrative and expenditure data and reports as required by the CCDBG; (4) reviewing data to determine accuracy in reporting and to work with grantees to identify challenges to accurate and timely data reporting; (5) developing and tracking performance measures to ensure the program meets established goals; (6) conducting data analysis to inform training and technical assistance efforts and policy guidance and development; and (7) assisting in the preparation of Congressional reports and briefing materials for hearings and testimony.

E. Child Care Regional Program Units (KVADI-X): The OCC Regional Program Units are headed by an OCC Regional Program Manager who reports to the Deputy Director, OCC. The Regional Program Manager, through subordinate regional staff and in collaboration with program components, is responsible for: (1) Providing program and technical administration of OCC block and discretionary programs; (2) collaborating with the OCC Central Office, states, and other grantees on all significant policy matters; (3) providing technical assistance to entities responsible for administering OCC programs to resolve identified problems; (4) ensuring that appropriate procedures and practices are adopted; (5) working with appropriate state, tribal, and local officials to develop and implement outcome-based performance goals that further the OCC mission of supporting children and families by increasing access to affordable, high-quality child care; and (6) monitoring the programs to

ensure their efficiency and effectiveness, and ensuring that these entities conform to federal laws, regulations, policies, and procedures governing the programs.

V. *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 ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

VI. *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.

VII. *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.

**FOR FURTHER INFORMATION CONTACT:** Linda K. Smith, Office of the Deputy Assistant Secretary for Early Childhood Development, 901 D Street SW., Washington, DC 20447, (202) 401-9200. This reorganization will be effective upon date of signature.

Dated: February 5, 2016.

**Sylvia M. Burwell,**  
Secretary.

[FR Doc. 2016-02784 Filed 2-10-16; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Pharmacy Compounding Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pharmacy Compounding Advisory Committee (PCAC).

*General Function of the Committee:* To provide advice on scientific, technical, and medical issues concerning drug compounding under

sections 503A and 503B (21 U.S.C. 353A and 353B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

*Date and Time:* The meeting will be held on March 8, 2016, from 8:30 a.m. to 4:30 p.m., and on March 9, 2016, from 8:30 a.m. to 1 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [PCAC@fda.hhs.gov](mailto:PCAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Background:* Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)); (2) section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

The Drug Quality and Security Act adds a new section, 503B, to the FD&C Act that creates a new category of "outsourcing facilities." Outsourcing facilities, as defined in section 503B of

the FD&C Act, are facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), concerning the labeling of drugs with adequate directions for use; (2) section 505, concerning the approval of human drug products under NDAs or ANDAs; and (3) section 582, concerning the track and trace requirements in the Drug Supply Chain Security Act (Pub. L. 113-53). Outsourcing facilities are not exempt from CGMP requirements in section 501(a)(2)(B) of the FD&C Act.

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list (the "section 503A bulk drug substances list") developed by the Secretary through regulations issued by the Secretary (see section 503A(b)(1)(A)(i) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (see section 503A(b)(3)(A) of the FD&C Act).

A condition that must be satisfied to qualify for the exemptions in section 503B of the FD&C Act is that the compounded drug is not identified (directly or as part of a category of drugs) on a list published by the Secretary, by regulation after consulting with the Pharmacy Compounding Advisory Committee, of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely