

contingency fee basis and overpayments the MAO recoups as a result of the RAC activities would be retained by the MAO. In approaching this work, the RAC contractor would consider the use of complex and automated review of claims.

- Approaches to implementing the following special rules provisions of section 6411(b) of ACA:

++ We want to utilize RACs to ensure that each Part C and Part D plan has anti-fraud plans in place and to review the effectiveness of those anti-fraud plans. In accordance with section 1893(h) of the ACA, the RACs for the Part C and Part D programs would be paid on a contingency basis, as in the Medicare FFS program. We are interested in the industry's views on how to pay RACs on a contingency basis for reviewing anti-fraud plans in the Part C and Part D programs given there are no recoveries or overpayments resulting from a review of such plans. Should this contingency basis differ from how RACs are paid for reviewing Medicare FFS claims? If so, how?

++ The statute requires that we use RACs to examine claims for reinsurance payments to determine whether Part D plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under the statute. Under the Part D statute, Part D plans legitimately incur costs in excess of allowable reinsurance costs during the catastrophic phase of the benefit. In the catastrophic phase of the defined standard benefit, 80 percent of the negotiated price is paid by Federal reinsurance, 15 percent is the responsibility of the sponsor (and is incorporated into their bid for the direct subsidy) and 5 percent is the responsibility of the beneficiary. Prospective reinsurance payments to plans are based on plans' estimates of reinsurance costs and, as required by statute, we reconcile these prospective reinsurance payments for sponsors with actual reinsurance costs. Given this annual reconciliation process, requiring RACs to review the accuracy of the prospective reinsurance payments is less likely to result in recovery of overpayments.

However, we are considering having RACs examine the accuracy and completeness of sponsors' reporting of Direct and Indirect Remuneration (DIR). The DIR information reported by plans includes rebates paid by pharmaceutical manufacturers, as well as other remuneration received by the plan that has the effect of reducing their drug costs, and is used as a factor in our payment calculations to Part D plans. Under-reporting of DIR by plans would

overstate plans' drug costs, including in the catastrophic phase of the benefit, and would result in an overpayment to the plan. We are interested in receiving comments on how RACs could be used to review the accuracy and completeness of DIR information provided to us by plans.

++ The statute also requires that we use RACs to review estimates submitted by Part D plans with respect to enrollment of high cost beneficiaries. A Part D sponsor's estimates for the enrollment of high cost beneficiaries may impact the reinsurance estimates in their Part D bids and thus, the prospective reinsurance subsidy payments they receive from us. However, given the structure of the Part D program that requires us to reconcile reinsurance subsidy payments against a Part D sponsor's actual costs, requiring RACs to undertake this activity is less likely to result in recovery of any reinsurance overpayments. However, as noted previously, we are interested in receiving comments on how RACs might be used to identify overpayments and underpayments associated with DIR reporting.

++ We are interested in learning about successful overpayment recoupment models in managed care that may already exist in the commercial sector and to what extent these models are applicable to Part C. Successfully integrating RACs into Part C presents a particular challenge because of how Part C payments are paid. Under the statutory payment formula, plans are paid on a capitated basis. Therefore, the plan, not the government, is at direct risk for any overpayments and underpayments made to its providers. We are interested in learning whether and how other purchasers have identified overpayments and underpayments made by capitated plans and to what extent savings were shared between the plan and the purchaser.

- Any additional information concerning the development of a RAC program in Medicare Part C and Part D and how we can establish the required program elements to protect the Medicare Parts C and D programs from fraud, waste, and abuse.

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

Dated: December 8, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Head Start; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) has reorganized the Office of Head Start (OHS). This reorganization creates the Grants and Contracts Division and the State Initiatives Division. It renames the Educational Development and Partnership Division, titling it the Education and Comprehensive Services Division. It also renames the Immediate Office of Head Start, the Office of the Director. Additionally, it renames the Policy and Budget Division, the Policy and Planning Division.

FOR FURTHER INFORMATION CONTACT: Yvette Sanchez-Fuentes, Office of the Director, Office of Head Start, 1250 Maryland Avenue, SW., Washington, DC 20024, 202-205-8573.

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 KU, Office of Head Start (OHS), as last amended 71 FR 59117-59123, October 6, 2006.

I. Under Chapter, KU, Office of Head Start, delete KU in its entirety and replace with the following:

KU.00 MISSION. The Office of Head Start (OHS) advises the Assistant Secretary for Children and Families on issues regarding the Head Start program (including Early Head Start). OHS develops legislative and budgetary proposals; identifies areas for research, demonstration and developmental activities; presents operational planning objectives and initiatives relating to Head Start and Early Head Start to the Assistant Secretary; and oversees the progress of approved activities. It 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 Assistant Secretary for Children and Families. OHS is organized as follows:

Office of the Director (KUA)

Program Operations Division (KUB)

Head Start Regional Program Units (KUBDI–XII)

Education and Comprehensive Services Division (KUC)

Quality Assurance Division (KUE)

Policy and Planning Division (KUF)

Grants and Contracts Division (KUG)

State Initiatives Division (KUH)

KU.20 FUNCTIONS. A. Office of the Director (KUA): The Office of the Director (OD) serves as the principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other officials of the Department on the administration of discretionary grant programs providing Head Start Services. The Director provides the direction for OHS based on ACF's and HHS' goals and objectives.

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 Deputy Director supervises all six Division Directors in addition to the Budget, Administrative, and Information Systems Teams. The divisions are as follows: Program Operations Division, Education and Comprehensive Services Division, Quality Assurance Division, Policy and Planning Division, Grants and Contracts Division, and State Initiatives Division.

The Administrative Team provides support to OHS, including: (a) Serving as the focal point for operational and long-range planning; (b) functioning as Executive Secretariat for OHS, including managing correspondence, correspondence systems, and electronic mail requests; (c) providing management and administrative services and advice, by coordinating human resources activities, and (d) as appropriate, developing policy and procedures relating to these activities.

The Budget Team (a) Provides leadership in the development of the budget while ensuring consistency with ACF's and the Department's vision and goals, (b) is responsible for budget development and execution, and (c) serves as the primary contact for ACF on all budget development and execution activities related to Head Start. The Information Systems Team (IST) provides support to OHS in providing centralized information systems policy, procedures, standards, and guidelines. IST also provides support through: (a) The oversight of information resources management (IRM) systems, including the Early Childhood Learning and

Knowledge Center and Head Start Enterprise System; (b) directing and coordinating OHS' Privacy Act responsibilities; (c) directing and maintaining OHS electronic records and forms management programs; (d) developing long-range IRM plans; (e) developing policies, procurement plans, and budgets for OHS information systems; and (f) serving as the information services liaison to ACF and other agencies to coordinate e-government strategies and policies.

B. Program Operations Division (KUB): The Program Operations Division (POD) advises the OHS Director on all strategic and operational activities related to implementation of the agency's programs in the 12 regions. POD is responsible for the Head Start regional programs administered by the Head Start Regional Program Units which include Region XI, the American Indian and Alaska Native Head Start, and Region XII, the Migrant and Seasonal Head Start.

—Head Start Regional Program Units (KUBDI–XII): The Head Start Regional Program Units are each headed by a Regional Program Manager (RPM) who reports to the Director of the Program Operations Division. The RPM, through subordinate regional staff, in collaboration with program components, is responsible for: (1) Providing program and technical administration of ACF discretionary programs related OHS; (2) collaborating with OHS States Collaboration Projects on all significant policy matters; (3) providing technical assistance to entities responsible for administering OHS programs to resolve identified problems; (4) ensuring that appropriate procedures and practices are adopted; (5) working with appropriate State, local, and tribal officials to develop and implement outcome-based performance measures; 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. The Head Start Regional Program Unit serves agencies that provide services to the children and families throughout the United States. The Regional Program Unit (a) guides the day-to-day management of Head Start programs in its jurisdictions; (b) provides technical assistance, resources, and information to the various entities responsible for administering these programs; (c) designates and provides oversight for interim grantees; and (d) represents Head Start to state, county, city, and Tribal governments; grantees; and public and private organizations.

Regions I through X are located in the ACF geographical regions. Region XI, American Indian and Alaskan Native Head Start, serves agencies that provide services to the children and families of American Indian and Alaskan Natives. Migrant and Seasonal Head Start is represented by Region XII and serves agencies that provide services to the children and families of migrant and seasonal workers. Regions XI and XII are located in the OHS central office.

C. Education and Comprehensive Services Division (KUC): The Education and Comprehensive Services Division (ECSD) develops and coordinates the content and direction of Head Start program components and provides leadership to improve classroom practice, family engagement and involvement, health and disabilities services and cultural and linguistic responsiveness. The ECSD (1) recommends and establishes policy in the content areas; (2) recommends strategies for achieving quality services; (3) develops regulation, guidance, and other policy materials aimed at improving grantee performance in the content areas; (4) develops areas for research and demonstration activities to improve the quality and levels of services provided to Head Start children; (5) manages discretionary projects; and (6) develops training and technical assistance strategies to improve Head Start programs' performance in specific component areas which include integrated content; health, nutrition, dental, and mental health; parent, family, and community engagement; and quality teaching and learning.

D. Quality Assurance Division (KUE): The Quality Assurance Division (QAD) (1) oversees all major planning and implementation activities to determine Head Start and Early Head Start programs' compliance with all applicable requirements and regulations; (2) conducts data analyses on monitoring outcomes to inform training and technical assistance efforts and policy and guidance development; (3) serves as the liaison to the Office of Inspector General (OIG) for targeted OIG's audits; (4) oversees special agency initiatives such as the erroneous payment study; and (5) manages the OHS Complaint Line.

E. Policy and Planning Division (KUF): The Policy and Planning Division (PPD) provides support and guidance in all matters related to defining and setting policy for the OHS that will affect local Head Start programs and the early childhood community at-large. The Division will strengthen guidance and vision to the

early childhood community, formulate the OHS strategic plans and long-term goals, provide guidance and support with budget planning, oversee development of regulations and other policy issuances, and serve as liaison with ACF and HHS legislative offices on all Congressional matters relating to Head Start.

F. Grants and Contracts Division (KUG): The Grants and Contracts Division (GCD) (1) Oversees matters related to competitive funding opportunities; (2) manages competition, paneling, and selection of national contracts and Head Start and Early Head Start replacement grantees; (3) provides ongoing fiscal oversight of national contracts; (4) serves as the lead for the OHS Program Management and Fiscal Operations Center; and (5) serves as the liaison to the Office of Administration, Divisions of Grants Management and Division of Grants Policy.

G. State Initiatives Division (KUH): The State Initiatives Division (SID) leads and consolidates collaboration efforts to new and expanding Head Start programs. The Division will promote collaborations with state pre-k programs, local child care providers and other national and state early childhood efforts to ensure the sustainability of strong collaborations. The Division serves as the locus for ensuring that mandates in the Head Start Act regarding collaboration are implemented as well as coordination with the U.S. Department of Education and state early childhood entities. The Division will focus on State Advisory Councils, Centers of Excellence, State Collaboration Offices, and the Training and Technical Assistance System.

II. *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.

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

IV. *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: December 16, 2010.

David A. Hansell,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Circulatory System Devices Panel of the Medical Devices 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). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices 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 on January 25 and 26, 2011, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Main Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. 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

line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 25, 2011, the committee will discuss and make recommendations regarding regulatory classification of Automated External Defibrillators to either reconfirm to class III (subject to premarket approval application (PMA)) or reclassify to class II (subject to premarket notification (510(k))), as directed by section 515(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360e(i)).

On January 26, 2011, the committee will discuss, make recommendations and vote on information related to the PMA supplement for the RX Acculink Carotid Stent System, sponsored by Abbott Vascular. The RX Acculink is indicated for treatment of patients at high and standard risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined as follows:

1. Patients with neurological symptoms and >50 percent stenosis of the common or internal carotid artery or patients without neurological symptoms and >80 percent (high risk) or >70 percent (standard risk) stenosis of the common or internal carotid artery and

2. Patients must have a reference vessel diameter within the range of 4.0 and 9.0 mm at the target lesion.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 18, 2011. Oral presentations from the public will be scheduled for 1 hour at approximately 1 p.m., immediately following lunch on both days. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on