

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Member Conflict Review, Program Announcement (PA) 07-318, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1:00 p.m.–2:00 p.m., June 20, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Member Conflict Review, PA 07-318.”

Contact Person for More Information: Joan Karr, Ph.D., Scientific Review Officer, 2400 Executive Parkway, Mailstop E20, Atlanta, Georgia 30345, Telephone: (404) 498-2506.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of

Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 19711, dated April 2, 2013) is amended to consolidate the Office of the Chief Financial Officer and the Financial Management Office, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows: Delete in its entirety the titles and functional statements for the Office of the Chief Financial Officer (CAJ1P) and the Financial Management Office (CAJE) insert the following:

Office of the Chief Financial Officer (CAJE). The Office of the Chief Financial Officer (OCFO) ensures that the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) accomplish their public health mission through agency-wide fiscal accountability and oversight.

Office of the Director (CAJE1). The OCFO Office of the Director provides leadership and coordination in the development and administration of the CDC's financial management policies, overseeing the Office of Finance and Accounting and the Office of Budget. Specifically, the OCFO: (1) Manages the financial risk of the agency, (2) provides leadership and advice on matters of budget formulation, budget and performance integration, and Congressional appropriations for CDC and ATSDR; (3) collaborates with the Agency's senior leadership in the development and implementation of long-range, strategic program and financial plans; (4) provides oversight of the agency's financial activities and accounting practices; (5) performs reviews and training in high risk areas for both the Agency and the Department where there appears to be fiscal vulnerabilities; (6) provides expertise in interpreting appropriations law issues and financial policy matters; (7) advises and assists the CDC Director, the Chief Operating Officer, and other key agency officials—both in program and business service offices—on all fiscal aspects of the agency; (8) participates in budget reviews and hearings; (9) manages CDC's system of internal budgetary planning and control of funds; (10) develops and implements CDC-wide budgetary, accounting, and fiscal systems and procedures and prepares financial reports; (11) conducts CDC-wide manpower management (including productivity measurement) activities;

(12) serves as the focal point for domestic and international travel policy, procedures and interpretation; (13) provides legislation reference services; (14) analyzes data and makes recommendations to assure effective safeguards are in place to prevent fraud, waste and abuse; (15) assists in identifying or conducting special financial management training programs; (16) maintains liaison with the Department of Health and Human Services (DHHS), Office of Management and Budget (OMB), Congress, and other government organizations on financial management matters; and (17) provides support for public health by ensuring that appropriated funds provided to the agency are utilized, in compliance with Congressional mandate, for the sole purpose of preventing and controlling infectious diseases domestically and globally.

Office of Management Services (CAJE13). (1) Collaborates and maintains liaison with CDC management officials to monitor and address priority issues of concern to CDC leadership; (2) manages the OCFO's operational budget processes, including planning, execution, and monitoring; (3) manages OCFO's acquisition processes; (4) analyzes and provides recommendations on workload efficiency and resource utilization; (5) provides direction, strategy, analysis, operational support, and recommendations in matters concerning organizational performance and management services within OCFO; (6) coordinates the development of, and maintains, strategic management and performance measurement tools within OCFO; (7) monitors OCFO organizational performance and provides recommendations on performance improvement; (8) provides management, oversight, and administrative support for OCFO service desk operations; (9) provides direction, strategy, analysis, and operational support in all aspects of OCFO's human resources operations; (10) provides leading practices in government financial management practices to OCFO; (11) develops, implements, and manages recruiting, hiring, retention, and succession strategies; (12) coordinates creation and implementation of operating standards/procedures and processes, and monitors compliance; (13) develops, implements, and manages the professional development strategy and plan for OCFO; (14) develops and implements OCFO's communication strategy and plan; (15) manages the development and communication of financial

management policies; (16) serves as OCFO's point of contact on all matters concerning facilities management and space utilization; and (17) serves as OCFO's coordinator of community of operations (COOP) activities.

Appropriations, Legislation, and Formulation Office (CAJE14). (1) Provides leadership, consultation, guidance, and advice on matters of public health and financial policy; (2) leads all CDC/ATSDR Congressional appropriations activities; (3) develops CDC/ATSDR's annual financial and public health policy request in accordance with DHHS, OMB, and Congressional requirements, policies, procedures, and regulations; (4) maintains liaison with the Office of the Secretary, Office of Management and Budget (OMB), other government organizations, and Congress on appropriations and financial policy matters; (5) develops materials for, and participates in, public health policy and financial reviews and hearings before DHHS, OMB, and Congress; (6) collaborates with other parts of CDC, and outside stakeholders, in the development and implementation of agency-wide financial and public health program plans; and (7) provides guidance and advice on the consolidation of budget and performance information as part of CDC's annual budget request.

Working Capital Fund (CAJE15). (1) Oversees implementation and operation of the working capital fund (WCF) for CDC, supporting the WCF Board, customers and service providers; (2) provides for execution of WCF operations; (3) ensures full cost recovery of fund activities; (4) collects operational data from service providers; (5) distributes WCF bills to customers; (6) provides support to standing committees; (7) gathers analysis and documentation for customer disputes; (8) monitors and reports on the financial condition of the fund; (9) monitors and reports on the performance of service providers; and (10) facilitates robust internal controls processes.

Office of Finance and Accounting (CAJEU). The Office of Finance and Accounting (OFA) provides financial services and policy for agency-level accounting functions, oversees financial data analysis, and reporting and financial systems management and business decision-making support surrounding the Agency's mission and goals.

Office of the Director (CAJEU1). Under the direction of the Finance and Accounting Officer, the OFA Office of the Director (OD) provides oversight and management of financial services and

policy. Specifically, the OFA OD: (1) Provides agency-level accounting functions, financial data analysis, and reporting; (2) provides financial systems management and business decision-making support surrounding the agency's mission and goals; (3) provides commercial payment services to CDC customers and payment support to CDC offices; (4) provides debt management services to CDC customers; (5) provides travel, IPAC and international payment services and support to CDC customers and travelers; (6) supports agency-wide planning, analysis, and reporting for agency public health goals strategy; (7) reports on compliance with laws, regulations, and decisions to CDC's CFO, to include status of internal financial controls and annual audit of financial accounts.

Accounting Branch (CAJEUB). (1) Oversees and provides approach to accounting for the Agency; (2) manages accounting treatment for CDC on all business systems implementations and upgrades to current business systems; (3) manages all financial audit reviews for the OCFO and conducts risk assessment on internal controls; (4) prepares Standard Form (SF) 133 Report on Budget Execution for CDC Appropriation and Intra-Departmental Delegation of Authority (IDDAs), Federal Agencies' Centralized Trial-Balance System (FACTS) I and II Report and Year-End Closing Statement (2108 Report), and SF 224 or their equivalent and all other required financial reports as applicable; (5) prepares, analyzes fluctuations, and coordinates explanations for differences on all required financial statements and notes; (6) performs Government Performance and Results Act (GPRA) reporting analysis for compliance; (7) ensures compliance of federal and department reporting requirements; (8) coordinates accounting policy issues with the DHHS Office of Financial Policy and OCFO's Office of Management Services; (9) manages Fund Balance with Treasury, including authority, disbursements (payroll and non-payroll), collections, deposit funds and budget clearing accounts; (10) prepares manual and ADI journal vouchers for corrections to the general ledger; (11) performs monthly, quarterly, and year-end close out process of the general ledger; (12) serves as liaison with the Procurements and Grants Office, Buildings and Facilities Offices, Program Offices, and Budget Execution Services on capital asset procedures; (13) manages financial accounting for all assets for CDC, including real and personal property, equipment, land, leases, software,

personal property, and stockpiles; (14) conducts financial and inventory reconciliations for all applicable assets, including inventory such as Vaccine for Children and Strategic National Stockpile, real and personal property, equipment, leases, leasehold improvements, land, and others as needed; (15) leads and directs grants management activities within OCFO; (16) provides training and assistance to CDC project officers and grants management officials on various financial management aspects of grants; (17) serves as liaison with grantees and other operating divisions for financial questions/inquiries related to grants; (18) manages the process to perform grant processing for commitments, obligations, advances, disbursements, and accruals; (19) manages grants transactions, such as vendor set-up, establishing sub-accounts, Common Accounting Number (CAN) set-up within the Payment Management System (PMS), reconciling sync file to PMS, and posting files from PMS; (20) conducts grant reviews, monitors rates of expenditure for existing grant awards, and supports Program in grant execution; and (21) records undelivered order adjustments or obligations as needed.

Financial Systems Branch (CAJEUC). (1) Provides management and coordination necessary for OCFO to have access to systems, data, and reporting capability; (2) develops, implements, and manages long-term systems strategy for OCFO; (3) provides systems analysis, design, programming, implementation, enhancement and documentation of OCFO related systems; (4) provides technical support and assistance for data error analysis and resolution, coordination of system initiatives, management of information technology resources, and the access and interpretation of financial system data; (5) serves as a liaison to the Unified Financial Management System (UFMS) Operations and Maintenance and other internal and external groups as needed; (6) manages all aspects of OCFO's systems security and administration; (7) performs certification and accreditation of OCFO systems; (8) performs CAN realignment coordination; and (9) manages OCFO hardware and equipment, and serves as the custodial officer.

Commercial Payment Branch (CAJEUD). (1) Manages all activities, policies, quality control, and audit support for accounts payable and disbursement functions for commercial payments; (2) serves as the CDC subject matter expert on all financial matters dealing with commercial payments; (3)

ensures all commercial payments are made in accordance with applicable Federal laws and standards, such as appropriations law; (4) serves as liaison with the Department of Treasury, the Centers/Institute/Offices (CIOs), as well as outside customers, to provide financial information and reconcile commercial payment issues; (5) provides training and advice on commercial payment and disbursement issues; (6) manages transactions related to commercial accounts payable and disbursements; (7) completes all reconciliations of sub-ledgers to general ledger related to commercial payments; (8) compiles and submits a variety of cash management and commercial reports required by Treasury and various outside agencies; (9) responds to commercial inquiries for invoices and certifies payments; (10) performs quality control and quality assurance reviews and participates in internal reviews; and (11) assists with undelivered order adjustments or obligations as needed.

Debt Management Branch (CAJEUE). (1) Oversees and provides approach to invoicing, billing, collections, reconciliations and reporting for the Agency; (2) serves as the central point of contact for the Agency on all debt management issues, including training and issue resolution; (3) develops strategy and analysis for reimbursable agreements in accordance with the center, division, and/or office; (4) manages all aspects of accounts receivable transactions in UFMS, prepares invoices, and processes billing; (5) works with programs, the Chief Financial Officer, and OCFO to resolve all posting errors, such as the resolution for over-obligated and unsigned agreements, indirect cost (IDC) calculations, and uncollectible debt; (6) analyzes the intra-and inter-governmental eliminations process for compliance with financial statements; (7) prepares and submits Agency-level financial reports to HHS/OS; and (8) prepares and submits the year end certification and verification of the Treasury Report on receivables.

Travel, IPAC, and International Payment Branch (CAJEUG). (1) Manages all activities, policies, quality control, and audit support for accounts payable and disbursement functions for travel, IPAC, and international payments; (2) serves as the CDC subject matter expert on all financial matters dealing with all travel, IPAC, and international payments; (3) ensures all travel, IPAC, and international payments are made in accordance with applicable Federal and international laws and standards, such as appropriations law; (4) serves as liaison with the Department of Treasury,

the Centers/Institute/Offices (CIOs), as well as outside customers, to provide financial information and reconcile travel, IPAC, and international payment issues; (5) compiles and submits a variety of cash management and travel reports required by Treasury and various other outside agencies; (6) provides training and advice on payment, travel and disbursement issues; (7) manages transactions related to accounts payable, such as processing cables, reimbursements, IPAC disbursements, and payments for foreign nationals and visiting fellows; (8) completes all reconciliations of sub-ledgers to general ledger related to travel, IPAC, and international payments; (9) responds to traveler inquiries for vouchers and certifies payments; (10) manages change of station payment processing; (11) performs quality control and quality assurance reviews; (12) provides expertise, guidance, oversight, and interpretation of policies, laws, rules and regulations for all aspects of travel procedures and policies at CDC, including the use of the automated travel system, local travel, domestic and foreign temporary duty travel, and change of station travel for civil service employees, foreign service employees, commissioned officers, CDC fellows, etc.; (13) communicates and implements Departmental travel policies; (14) manages the administrative aspects of travel for the agency, including enforcement of travel card policy, delegations of authority, distribution of cash purchase memos, and approval of first-class memos; (15) serves as liaison with travel provider for travel contract matters; (16) provides travel support to the Emergency Operations Center; and (17) develops CDC conference travel planning and reporting for DHHS and Congress.

Office of Budget (CAJEV). Under the direction of the Budget Officer, the office provides oversight of agency-level budget execution functions, financial data analysis, and reporting; and oversees planning for agency-wide budget execution.

Office of the Director (CAJEV1). Under the direction of the Budget Officer, the office: (1) Provides agency-level budget execution functions, financial data analysis, and reporting; (2) provides budgetary information for business decision-making support surrounding the agency's mission and goals; (3) develops high-level plans to execute Agency-level budget; (4) ensures changes and plans are in compliance with decisions and Agency direction; (5) reports compliance of laws, regulations, and decisions to CDC's Budget Officer and CFO; (6)

provides agency-wide budget planning, analysis, and reporting for agency budget execution and public health goals strategy; (7) provides Agency spend plan validation, remediation, and analysis; (8) provides funds control management for the Agency-level budget; (9) assists in the review of Congressional bill language to identify and properly account for earmarks and other directed programs; (10) provides Departmental and OMB reporting; and (11) provides budget execution for Centralized Mandatory Services.

Business Operations Unit (CAJEV12). (1) Provides agency-level budget execution functions, financial data analysis, and reporting; (2) assists the Office of Budget in researching budgetary information for business decision making support surrounding public health; (3) assists in developing plans to execute Agency-level budget; (4) ensures changes and plans are in compliance with decisions and Agency direction; (5) reports compliance of laws, regulations, and decisions to the budget officer; (6) assists in agency-wide budget planning, analysis, and reporting for Agency budget execution and public health goals strategy; (7) assists the budget officer in providing agency spending plan validation, remediation, and analysis; (8) provides information to the budget officer surrounding funds control management for the Agency's budget; (9) assists in the review of Congressional bill language to identify and properly account for earmarks and other directed programs; (10) assists in preparing Departmental and OMB reporting requirements; and (11) provides budget execution for Centralized Mandatory Services.

Budget Execution Services Branch 1 (CAJEVB). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports program in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise programs on future spending decisions; (7) assists program officials in developing sub-allocation of

Center, and/or Division ceilings; (8) communicates and shares knowledge with programs, OCFO Central, and CDC's OCFO budget analyst community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 2 (CAJEVC). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports programs in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with programs, OCFO Central, and CDC's OCFO budget analyst community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 3 (CAJEVD). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports programs in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with program, OCFO Central, and CDC's

OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 4 (CAJEVE). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports Program in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with program, OCFO Central, and CDC's OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Budget Execution Services Branch 5 (CAJEVG). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports programs in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise Program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with program, OCFO Central, and CDC's OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes

recommendations for future-year budget.

Budget Execution Services Branch 6 (CAJEVH). This branch supports one or more Centers and/or Offices by performing the following: (1) Provides the legal and regulatory expertise and support to execute CDC's budget within the framework of DHHS, OMB, and Congressional regulations, and policies of CDC OD; (2) manages to the expectations agreed upon in the Budget Execution Services Service Level Agreement; (3) promotes structured, ongoing partnerships with the Centers, Divisions, and Offices; (4) manages and supports program in all aspects of funds management; (5) provides the leadership and guidance for spend plan creation and administration, in compliance with all Federal guidelines and policies, such as the Anti-Deficiency Act; (6) provides the overall analysis and reconciliation of spend plans to advise Program on future spending decisions; (7) assists program officials in developing sub-allocation of Center, and/or Division ceilings; (8) communicates and shares knowledge with programs, OCFO Central, and CDC's OCFO Budget Analyst Community; and (9) performs cost-benefit analysis to review financial requests and makes recommendations for future-year budget.

Dated: April 18, 2013.

Sherri A. Berge,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0380]

Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of