

## 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 25743-25746, dated May 2, 2013) is amended to reflect the reorganization of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Revise the functional statement for the Office of the Associate Director for Science (CVJ12), as follows:

Office of the Associate Director for Science (CVJ12). (1) Ensures process consistency for science across the CIOs; (2) facilitates cross-center decision-making regarding science; (3) facilitates communication regarding scientific and programmatic services across the Office of Infectious Diseases (OID); (4) conducts necessary regulatory and ethical reviews for activities involving human participants, including determining whether an activity includes research, includes human subjects, is exempt or requires Institutional Review Board approval, and whether an exception is needed to the Public Health Service HIV policy; (5) reviews funded activities for application of human research regulations; (6) reviews, approves, and tracks research protocols, clinical investigations, and the Food and Drug Administration regulated response activities intended for submission to CDC Human Research Protections Office; (7) coordinates and tracks Office of Management and Budget clearance under the Paperwork Reduction Act; (8) serves as the focal point for the OID for implementing policies and guidelines for the conduct of the peer review of infectious disease extramural research grant proposals and subsequent grant administration; (9) coordinates and conducts in-depth external peer review, objective review including special emphasis panel (SEP) process, and secondary program relevance review of extramural research applications by use of consultant expert panels; (10) makes recommendations to the appropriate

infectious disease center director on award selections and staff members serve as the program officials in conjunction with CDC grants management and policy officials to implement and monitor the scientific, technical, and administrative aspects of awards; (11) facilitates scientific collaborations between external and internal investigators; and (12) disseminates and evaluates extramural research progress, findings, and impact.

Delete in its entirety the title and functional statement for the Extramural Research Program Office (CVJ14).

Revise the functional statement for the Office of Management and Program Support (CVJ15), as follows:

Office of Management and Program Support (CVJ15). (1) Helps implement and enforce management and operations policies and guidelines developed by federal agencies, DHHS, and Staff Service Offices (SSO); (2) plans, develops, implements, and provides oversight and quality control for center-wide policies, procedures, and practices for administrative management and acquisition and assistance mechanisms, including contracts, memoranda of agreement, and cooperative agreements; (3) provides management and coordination of NCHHSTP-occupied space and facilities; (4) supplies technical guidance and expertise regarding occupancy and facilities management to emergency situations; (5) provides oversight and management of the distribution, accountability, and maintenance of CDC property and equipment; (6) provides oversight, quality control, and management of NCHHSTP records; (7) serves as lead and primary contact and liaison with relevant SSO on all matters pertaining to the center's procurement needs, policies, and activities; (8) develops, reviews, and implements policies, methods and procedures for NCHHSTP non-research extramural assistance programs; (9) interprets general policy directives, proposed legislation, and appropriation language for implications on management and execution of center's programs; (10) provides consultation and technical assistance to NCHHSTP program officials in the planning, implementation, and administration of assistance programs; (11) develops, coordinates and implements objective review processes, including the SEP process for funding of CDC infectious disease non-research grants and cooperative agreements. (12) oversees the formulation of the NCHHSTP budget and responds to inquiries related to the budget; (13) provides technical information services to facilitate dissemination of relevant

public health information and facilitates collaboration with national health activities, CDC components, other agencies and organizations, and foreign governments on international health activities; (14) provides oversight for the programmatic coordination of HIV, STD, viral hepatitis, and TB activities between NCHHSTP and other CIOs; develops recommendations to the CDC Director as the lead CIO for these programs for the distribution of HIV, STD, viral hepatitis, and TB funds CDC-wide; (15) provides guidance and coordination to divisions on cross-divisional negotiated agreements; (16) facilitates state and local cross-divisional issues identification and solutions; (17) in coordination with the Office of Program Planning and Policy Coordination, responds to Congress as needed; (18) serves as NCHHSTP liaison to relevant SSOs for all matters related to financial management; (19) serves as focal point for emergency operations and deployment; (20) manages and coordinates workforce development and succession planning activities within NCHHSTP in collaboration with internal and external partners, and coordinates the recruitment, assignment, technical supervision, and career development of staff with emphasis on developing and supporting diversity initiatives and equal opportunity goals; (21) facilitates the assignment of field staff in accordance with CDC and NCHHSTP priorities and objectives and reassesses the role of NCHHSTP field staff assignees to state and local health jurisdictions; and (22) provides center-wide training to supervisors, managers and team leaders.

Dated: May 15, 2013.

**Sherri A. Berger,**

*Chief Operating Officer, 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 27398-27399,

dated May 10, 2013) is amended to reorganize the Procurement and Grants Office, Office of the Chief Operating Officer, Office of the Director, 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 Procurement and Grants Office (CAJH) insert the following:

Procurement and Grants Office (CAJH). (1) Advises the Director, Centers for Disease Control and Prevention (CDC), the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), and their staff, and provides leadership and direction for CDC acquisition and assistance activities to improve the public's health; (2) plans and develops CDC-wide policies, procedures, and practices in acquisition and assistance areas to support public health science and programs; (3) obtains research and development, services, equipment, supplies, and construction in support of CDC's public health mission through acquisition processes; (4) awards, administers, and terminates contracts, purchase orders, grants, and cooperative agreements essential to improve public health; (5) maintains a continuing program of reviews, evaluations, inquiries, and oversight activities of CDC-wide acquisitions and assistance to ensure adherence to laws, policies, procedures, regulations, and alignment to CDC's public health goals; and (6) maintains liaison with the Department of Health and Human Services (DHHS), General Services Administration (GSA), Government Accountability Office (GAO), and other federal agencies on acquisition and assistance policies, procedures, and operating matters.

Office of the Director (CAJH1). (1) Provides overall leadership, guidance and coordination in all areas of acquisitions and grants activities on behalf of the CDC; (2) provides overall leadership, guidance and coordination in all areas of the Procurement and Grants Office (PGO) activities in order to support CDC's public health mission; (3) provides leadership, supervision, and management of staff necessary to fully manage the performance of PGO; (4) ensures PGO's policies, processes, requests for information and procedures adhere to all rules and regulations and are in alignment with CDC's public health goals; (5) develops and implements organizational strategic planning goals and objectives that support CDC's public health goals; (6) provides overall budgetary and human resource management, and administrative support; (7) directs and

coordinates activities in support of the department's Equal Employment Opportunity Program and employee development; (8) develops, implements, and manages professional development strategy and plan for PGO; (9) develops, implements, and manages recruiting, hiring, retention, and succession strategies; (10) coordinates creation and implementation of operating standards/procedures and processes, and monitors compliance; (11) provides and oversees the delivery of PGO-wide administrative management and support services in the areas of fiscal management, personnel, travel, records management, internal controls, and other administrative services; (12) develops and implements administrative policies, procedures, and operations, as appropriate, for PGO, and prepares special reports and studies, as required, in the administrative management areas; (13) serves as PGO's point of contact on all matters concerning facilities management and space utilization; (14) serves as PGO's coordinator of continuity of operations activities; (15) prepares annual budget formulation and budget justifications; (16) manages PGO's internal acquisition processes; (17) maintains liaison with DIMS, GSA, GAO, and other federal agencies on acquisition and assistance compliance activities; (18) maintains a continuing program of evaluation of PGO-wide internal procedures to ensure adherence to laws, policies, procedures, and regulations and make recommendations for ongoing improvement; (19) coordinates Inspector General and General Accounting Office audit activities; (20) coordinates financial audits and reviews and prioritizes resolution using risk-based approaches; (21) provides professional advice on accounting and cost principles in resolving audit exceptions as they relate to the acquisition and assistance processes; (22) develops an Annual Quality Assurance Plan; (23) provides technical and managerial direction for the development, implementation, and maintenance of grants and contracts systems; (24) manages HHS grants and administrative systems; (25) manages activities related to information security; and (26) ensures implementation of data standards across PGO.

Office of Policy, Performance, and Communications (CAJH13). (1) Provides technical and managerial direction for the development of PGO and CDC-wide policies in the acquisition and assistance areas to support CDC's public health science and programs; (2) participates with senior management in program planning, policy

determinations, evaluations, and decisions concerning escalation points for acquisition and assistance; (3) provides leadership, coordination, and collaboration on issues management and triaging, and ensures the process of ongoing issues identification, management, and resolution; (4) conducts policy analysis (including regulatory, legal, economic) and identifies and tracks legislation; (5) provides policy review and clearance of materials; (6) manages and responds to Congressional inquiries (e.g., prepare briefings and hearings, facilitate reports to Congress); (7) identifies and assesses policy best practices and helps diffuse and replicate those practices; (8) identifies emerging or cross-cutting policy issues and serves as a catalyst in advancing action; (9) serves as the focal point for the policy analysis, technical review and final clearance of executive correspondence and policy documents that require approval from the CDC Director, CDC Leadership Team, or officials within DHHS; (10) maintains relations with key organizations and individuals working on grants and contract policies or related legislation; (11) coordinates and manages PGO annual planning activities with the Office of Acquisition Services and the Office of Grants Services; (12) conducts continuing studies and analysis of division activities and provides recommendations on workload efficiency and resource utilization; (13) manages and analyzes complex data, develops queries, reports, and analytic tools; (14) develops and implements PGO organizational performance and provides recommendations on performance improvement; (15) conducts ongoing environmental scans of data systems to evaluate PGO performance; (16) designs studies and conducts analysis to streamline grant and contract business processes and improve data consistency, availability, and accuracy; (17) creates PGO data standards; (18) manages activities and reporting for the CDC Director's Quarterly Performance Review initiative; (19) provides communications support to PGO Director and Deputy Director (e.g., presentations, emails, All Hands meetings); (20) manages the flow of any decision documents and correspondence for signature by PGO and CDC Directors; (21) ensures accurate and consistent information dissemination, including Freedom Of Information Act requests and Executive Secretariat controlled correspondence; (22) ensures consistent application of CDC correspondence standards and

styles; (23) designs, plans, organizes, develops, and implements employee communications activities; (24) provides centralized access to all tools and information held on the Intranet and provides leadership in the development and branding of PGO's Intranet and Internet sites and Web pages; (25) manages and responds to media requests for access to subject matter experts, reports, and publications; and (26) provides leadership, technical assistance, and consultation to PGO in establishing best practices in internal and external business communication and implements external communication strategies to promote and protect the agency's brand.

**Office of Acquisition Services (CAJHK).** The Office of Acquisition Services (OAS) provides leadership for operations and policies relating to agency-level acquisition functions, directs OAS staff development, and oversees acquisition activity analysis and business decision-making processes in support of the agency's public health mission.

**Office of the Director (CAJHK1).** (1) Provides overall leadership, guidance and coordination in all areas related to acquisitions; (2) provides leadership, supervision, and management of acquisitions staff; (3) ensures policies, processes, and procedures adhere to all rules and regulations and are in alignment with CDC's public health goals; (4) develops and implements organizational strategic planning goals and objectives; (5) provides budgetary and human resource management and administrative support; (6) develops procedures and guidance to implement CDC or office policies, HHS policies, and rules and regulations; (7) leads the development of contracts policy agendas with federal agencies and organizations; (8) provides cost advisory support to acquisitions activities with responsibility for initiating requests for audits and evaluations and providing recommendations to contracting officer, as required; (9) conducts continuing studies and analysis of acquisition activities; (10) provides technical and managerial direction for the development, implementation, and maintenance of acquisition systems; (11) maintains a continuing program of reviews, evaluations, inquiries and oversight activities of CDC-wide acquisitions to ensure adherence to laws, policies, procedures and regulations and alignment with CDC's public health goals; (12) provides technical and managerial direction for functions related to interagency agreement management and VISA

purchase card management; (13) operates CDC's Small and Disadvantaged Business Program, and provides direction and support to various other socioeconomic programs encompassing acquisition and assistance activities; (14) develops formal training in procurement for awardees and CDC staff; (15) develops, implements and manages professional development related to required certifications; and (16) plans and directs all activities related to contract closeout.

**Acquisition Branch 1 (CAJHKB).** This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts the acquisition of services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and noncompetitive) to support CDC's national and international public health operations, utilizing a wide variety of contract types and pricing arrangements; (2) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (3) participates with top program management in program planning, policy determination, evaluation, and direction concerning acquisition strategies and execution; (4) provides leadership and guidance to CDC project officers and public health program officials; (5) maintains a close working relationship with CDC program office components in carrying out their public health missions; (6) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (7) reviews statements of work from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contracts; (8) directs and controls acquisition planning activities to assure total program needs are addressed and procurements are conducted in a logical, appropriate, and timely sequence; (9) provides continuing surveillance of financial and administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) provides technical assistance, where indicated, to improve the management of acquisition-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (11)

performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (12) assures that contractor performance is in accordance with contractual commitments; (13) maintains branch's official contract files; (14) identifies and mitigates risks associated with contracts and purchase orders; and (15) provides innovative problem-solving methods in the coordination of international procurement for a wide range plan with public health partners in virtually all major domestic and international health agencies dealing with health priorities/issues, to include resolution of matters with the Department of State.

**Acquisition Branch 2 (CAJHKB).** This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts the acquisition of services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and noncompetitive) to support CDC's national and international public health operations, utilizing a wide variety of contract types and pricing arrangements; (2) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (3) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (4) provides leadership and guidance to CDC project officers and public health program officials; (5) maintains a close working relationship with CDC program office components in carrying out their public health missions; (6) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (7) reviews statements of work from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals and negotiates and issues contracts; (8) directs and controls acquisition planning activities to assure total program needs are addressed and procurements are conducted in a logical, appropriate, and timely sequence; (9) provides continuing surveillance of financial and administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public

health activities; (10) gives technical assistance, where indicated, to improve the management of acquisition-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (11) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (12) assures that contractor performance is in accordance with contractual commitments; (13) maintains branch's official contract files; and (14) identifies and mitigates risks associated with contracts and purchase orders.

Acquisition Branch 3 (CAJHKD). This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts the acquisition of services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and noncompetitive) to support CDC's national and international public health operations, utilizing a wide variety of contract types and pricing arrangements; (2) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (3) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (4) provides leadership and guidance to CDC project officers and public health program officials; (5) maintains a close working relationship with CDC program office components in carrying out their public health missions; (6) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (7) reviews statements of work from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contracts; (8) directs and controls acquisition planning activities to assure total program needs are addressed and procurements are conducted in a logical, appropriate, and timely sequence; (9) provides continuing surveillance of financial and administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public

health activities; (10) gives technical assistance, where indicated, to improve the management of acquisition-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (11) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (12) assures that contractor performance is in accordance with contractual commitments; (13) maintains branch's official contract files; (14) identifies and mitigates risks associated with contracts and purchase orders; and (15) plans, directs, and conducts the acquisition of services, institutional support services, architect-engineering services, construction of new buildings, alterations, renovations, commodities, and equipment in support of CDC/ATSDR facilities, utilizing a wide variety of contract types and pricing arrangements.

Acquisition Branch 4 (CAJHKE). This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts the acquisition of services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive) to support CDC's national and international public health operations, utilizing a wide variety of contract types and pricing arrangements; (2) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (3) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (4) provides leadership and guidance to CDC project officers and public health program officials; (5) maintains a close working relationship with CDC program office components in carrying out their public health missions; (6) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (7) reviews statements of work from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contracts; (8) directs and controls acquisition planning activities to assure total program needs are addressed and

procurements are conducted in a logical, appropriate, and timely sequence; (9) provides continuing surveillance of financial and administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) gives technical assistance, where indicated, to improve the management of acquisition-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (11) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (12) assures that contractor performance is in accordance with contractual commitments; (13) maintains branch's official contract files; (14) identifies and mitigates risks associated with contracts and purchase orders; (15) assures the acquisition functions in support of the center are accomplished with field office locations; and (16) plans and directs all activities related to interagency agreements.

Office of Grants Services (CAJHL). The Office of Grants Services (OGS) provides leadership for operations and policies relating to agency-level grants functions, directs OGS staff development, and oversees grants activity analysis and business decision-making processes in support of the agency's public health mission.

Office of the Director (CAJHL1). (1) Provides overall leadership, guidance and coordination in all areas related to grants; (2) provides leadership, supervision, and management of grants staff; (3) ensures policies, processes, and procedures adhere to all rules and regulations and are in alignment with CDC's public health goals; (4) develops and implements organizational strategic planning goals and objectives; (5) provides budgetary, human resource management and administrative support; (6) develops procedures and guidance to implement CDC, HHS and office policies and rules and regulations; (7) leads the development of grants policy agendas with federal agencies and organizations; (8) provides cost advisory support to assistance activities with responsibility for initiating requests for audits and evaluations, and providing recommendations to grants management officer, as required; (9) conducts continuing studies and analysis of grant activities; (10) provides

technical and managerial direction for the development, implementation, and maintenance of grants systems; (11) provides measures of effectiveness and termination of grants and cooperative agreements; (12) maintains a continuing program of reviews, evaluations, inquiries, and oversight activities of CDC-wide assistance to ensure adherence to laws, policies, procedures, and regulations and alignment with CDC's public health goals; (13) provides technical and managerial direction for functions related to objective review and grants close out; (14) serves as a central CDC receipt and referral point for all applications for assistance funds, including interfacing with the automated grants systems and relevant DHHS line of business agencies and distributing draft public health program announcements for review; (15) develops formal training in grants management for awardees and CDC staff; and (16) develops, implements, and manages professional development related to required certifications.

Infectious Disease Services Branch (CAJHLB). This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (2) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards; (3) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (4) provides leadership, direction, and approaches in developing grants announcements; (5) participates with leadership in program planning, policy determination, evaluation, and directions concerning assistance strategies and execution; (6) provides leadership and guidance to CDC project officers and public health program officials related to grants activities; (7) maintains a close working relationship with CDC program office components in carrying out their public health missions; (8) reviews assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and issues grants and cooperative agreements; (9) provides continuing surveillance of financial and administrative aspects of assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) gives technical

assistance, where indicated, to improve the management of assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC office and the public; (11) assures that grantee performance is in accordance with assistance requirements; (12) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; and (13) maintains branch's official assistance files.

Chronic Disease and Birth Defects Services Branch (CAJHLC). This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (2) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards; (3) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (4) provides leadership, direction, and approaches in developing grants announcements; (5) participates with leadership in program planning, policy determination, evaluation, and directions concerning assistance strategies and execution; (6) provides leadership and guidance to CDC project officers and public health program officials related to grants activities; (7) maintains a close working relationship with CDC program office components in carrying out their public health missions; (8) reviews assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and issues grants and cooperative agreements; (9) provides continuing surveillance of financial and administrative aspects of assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) gives technical assistance, where indicated, to improve the management of assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC office and the public; (11) assures that grantee performance is in accordance with assistance requirements; (12) provides for the collection and reporting of business management and public health

programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; and (13) maintains branch's official assistance files.

OD, Environmental, Occupational Health and Injury Prevention Services Branch (CAJHLD). This branch supports one or more centers, and/or offices by performing the following: (1) Plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (2) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards; (3) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (4) provides leadership, direction, and approaches in developing grants announcements; (5) participates with leadership in program planning, policy determination, evaluation, and directions concerning assistance strategies and execution; (6) provides leadership and guidance to CDC project officers and public health program officials related to grants activities; (7) maintains a close working relationship with CDC program office components in carrying out their public health missions; (8) reviews assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and issues grants and cooperative agreements; (9) provides continuing surveillance of financial and administrative aspects of assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) gives technical assistance, where indicated, to improve the management of assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC office and the public; (11) assures that grantee performance is in accordance with assistance requirements; (12) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (13) maintains branch's official assistance files; and (14) assures public health assistance functions are accomplished with field office locations.

Global Health Services Branch (CAJHLE). This branch supports one or more centers, and/or offices by

performing the following: (1) Plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (2) plans, directs, coordinates, and conducts the grants managements functions and processes in support of public health assistance awards; (3) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; (4) provides leadership, direction, and approaches in developing grants announcements; (5) participates with leadership in program planning, policy determination, evaluation, and directions concerning assistance strategies and execution; (6) provides leadership and guidance to CDC project officers and public health program officials related to grants activities; (7) maintains a close working relationship with CDC program office components in carrying out their public health missions; (8) reviews assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and issues grants and cooperative agreements; (9) provides continuing surveillance of financial and administrative aspects of assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (10) gives technical assistance, where indicated, to improve the management of assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC office and the public; (11) assures that grantee performance is in accordance with assistance requirements; (12) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (13) maintains branch's official assistance files; and (14) provides innovative problem-solving methods in the coordination of international grants for a wide range plan with public health partners in virtually all major domestic and international health agencies dealing with health priorities/issues, to include resolution of matters with the Department of State.

Dated: May 10, 2013.

**Sherri A. Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

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**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0514]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

**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 information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for Clinical Laboratory Improvement Amendments of 1998 (CLIA) categorization of in vitro diagnostic (IVD) tests when a premarket review is not needed.

**DATES:** Submit either electronic or written comments on the collection of information by July 22, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Requests for CLIA Categorization—42 CFR 493.17 (OMB Control Number 0910-0607)—Extension

A guidance document entitled "Guidance for Administrative Procedures for CLIA Categorization" was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The guidance recommends that in the