

organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to Paras M. Patel. We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see **ADDRESSES**). We will mail, e-mail, or fax the schedule to each participant before the hearing. Participants are encouraged to arrive early to ensure the designated order of presentation.

If you need special accommodations due to a disability, please contact Paras M. Patel at least 14 days in advance.

#### **IV. Notice of Hearing Under 21 CFR Part 15**

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner, the Office of Orphan Products Development, as well as representatives from the committee established by section 740 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010.

Under paragraph § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)).

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR 10.203(a)). Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

The hearing will be transcribed as stipulated in paragraph § 15.30(b). Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 45 days after the hearing. A transcript will also be available in either hardcopy or on a CD-ROM after submission of a Freedom of Information request. Submit written requests to the Division of Freedom of Information (HFI-35), Office of Management

Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

#### **V. Request for Comments**

Interested persons may submit written or electronic comments for consideration to the Division of Dockets Management (see **ADDRESSES**). Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions identified by topic to which they refer. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: April 26, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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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 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 75 FR 14608, dated March 26, 2010) is amended to reflect the reorganization of the Center for Global Health, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows: Delete in their entirety the titles and functional statements for the Center for Global Health (CW), and insert the following:

Center for Global Health (CW). The Center for Global Health (CGH): (1) Leads the execution of the Center for

Disease Control and Prevention's (CDC) global health strategy; (2) works in partnership to assist Ministries of Health to plan, manage effectively, and evaluate health programs; (3) achieves U.S. Government program and international organization goals to improve health, including disease eradication and elimination targets; (4) expands CDC's global health programs that focus on the leading causes of mortality, morbidity and disability, especially chronic disease and injuries; (5) generates and applies new knowledge to achieve health goals; and (6) strengthens health systems and their impact.

Office of the Director (CWA). (1) Provides strategic direction and guidance on the execution of CDC's global health strategy including decision-making, policy development and program planning and evaluation; (2) ensures the impact and effectiveness of Congressionally-mandated programs; (3) improves implementation and coordination of CDC global programs; (4) harmonizes CDC global health priorities with host country priorities to improve essential public health functions and maximize positive health outcomes, country ownership and sustainability; (5) supervises all CDC country directors and provides leadership in the selection of additional countries to expand or establish collaboration; (6) measures the performance of CDC's global health programs in terms of public health impact and fiscal accountability; (7) facilitates the conduct and maintenance of ethical and high quality, evidence-based scientific investigations by implementing regulatory requirements, monitoring human subjects compliance, and clearing scientific products; (8) promotes cross-cutting agendas and harmonizes CDC's global laboratory science activities to improve diagnostic methodologies and respond to threats of emerging pathogens; (9) provides leadership to promote growth of CDC global health programs; (10) analyzes, measures, and evaluates the global burden and distribution of disease; (11) promotes scientific innovation and best technical practices in global health surveillance, epidemiology, outbreak investigation, monitoring and evaluation, and informatics; (12) provides leadership on issues management, budget formulation and performance integration, and country-specific issues through triaging to programs; (13) participates in defining, developing, shaping and implementing U.S. global health policy and actions; (14) manages inter-governmental and

external affairs and cultivates strategic partnerships; (15) plans and executes CDC's global health communications strategy and public affairs media response/outreach; (16) provides oversight, guidance, and accountability for all operations functions, human resources, workforce management, budget formulation and distribution, extramural reviews and processing, internal and domestic travel, and property management responsibilities of CGH; and (17) develops standardized management processes and solutions for CDC country offices.

Division of Public Health Systems and Workforce Development (CWF). The Division of Public Health Systems and Workforce Development (DPHSWD) contributes to improving the health of the people of the U.S. and other nations by partnering with relevant foreign government ministries, educational institutions, Federal agencies, and international organizations to strengthen capacity of countries around the world to improve public health. To carry out its mission, the division performs the following functions: (1) Works with partners to build strong, transparent, and sustained public health systems through training, consultation, capacity building, and technical assistance in applied epidemiology, public health surveillance, evaluation, operational and implementation research, and laboratory systems; and promotes organizational excellence in public health through strengthening leadership and management capacity; (2) assists in developing and implementing CGH policy on public health system strengthening and sustainability; (3) collaborates with other CDC organizations, Federal agencies, international agencies, partner countries, and non-governmental organizations assisting ministries of health to build public health capacity in other areas of public health; and (4) supports and performs primary research on health systems and health systems performance that are relevant to the improvement of the division's own programs as well as the programs with which it collaborates.

Office of the Director (CWF1). (1) Provides leadership, overall direction, and evaluation for the division; (2) formulates and coordinates execution of CDC's strategy for developing global public health capacity in applied epidemiology, public health systems management and leadership; (3) provides leadership and guidance on policy, program planning, program management, and operations; (4) plans, allocates, and monitors resources; (5) formulates, executes, and monitors

CORE budgets; (6) monitors and assists in the formulation and execution of branch and county project's budgets; (7) provides support and assistance to the branches in management, administrative, and personnel services; (8) develops and manages cooperative agreements, grants and contracts; (9) develops and disseminates communication material; (10) provides leadership in assisting national ministries of health, international agencies, and nongovernmental organizations in the delivery of epidemiologic services and the development of international epidemiologic networks; (11) liaises with other CDC organizations, other Federal agencies, ministries of health, and international organizations; (12) provides consultations with partners and stakeholders including nongovernmental organizations and the private sector on program development and overall public health systems and sub-systems; (13) develops and produces communication materials documenting the division's public health programs, accomplishments, and impact (e.g., annual reports, newsletters, Web sites, training materials); (14) develops and maintains intranet and internet Web sites for the division and its programs; (15) provides consultation and technical assistance to programs and partners in scientific communication, health communication, and public health marketing programs; and (16) assesses scientific communication needs for partners, and develops and delivers public health materials and information, and training tailored to the specific needs of the partners.

Sustainable Management Development Program (CWF12). (1) Partners with ministries of health, educational institutions, and nongovernmental organizations to promote organizational excellence in public health through strengthening leadership and management capacity; (2) works with partners to build capacity for public health leadership and management development through a multi-phased approach including situational analysis, capacity development, technical assistance, and sustainability; (3) develops strategic institutional partnerships for public health leadership and management capacity-building efforts; (4) develops faculty to enhance in-country leadership and management training capacity through the Management for International Public Health course and in-country training-of-trainers; (5) provides support to training faculty in

partner institutions to conduct performance needs assessments; develops locally appropriate curricula; and designs in-country leadership and management workshops that provide participants with practical skills needed to manage public health teams, programs, and organizations; (6) works with partner institutions to ensure the long-term sustainability of global public health leadership and management development programs; and (7) supports and performs primary operational and implementation research in support of continuous improvement of its own and partners' leadership and management programs.

FELTP and Systems Development Branch (Africa) (CWFB). (1) With partners, designs and conducts evidence-based instruction in public health disciplines needed to strengthen their public health systems, including instructional design, epidemiology, surveillance, laboratory operations and management, communications, and economic evaluation; (2) assists ministries of health in the African region and elsewhere to develop sustainable field epidemiology and laboratory training programs for public health systems strengthening; (3) develops models for continuous tracking and improvement of critical outputs and outcomes from field epidemiology and laboratory training programs around the world; (4) working with DPHSWD technical program components, provides consultation to ministries of health in development of surveillance systems (e.g., communicable and non communicable disease surveillance, injury, chronic diseases, etc.); (5) coordinates CDC's support the World Health Organization's (WHO) Integrated Disease Surveillance and Response strategy; (6) creates and maintains division wide computer-based and distance-based learning methods, and develops the capacity of partners to create, evaluate, and share their own; (7) develops and evaluates competency based training materials for the FELTP and similar program for use of the division and its partners; (8) maintains a divisional training material library and website; and (9) collaborates within CDC and with national or international organizations in development of competency-based training materials, evaluation of training, and design of surveillance systems needed to accomplish the mission.

FELTP and Systems Development Branch (Asia and the Americas) (CWFC). (1) Assists partners in assessing their needs for health systems strengthening; (2) plans, directs,

supports, implements, and coordinates field epidemiology and laboratory training programs, Data for Decision Making Projects, operational and implementation research projects, and other partnerships with ministries of health; (3) provides leadership and management oversight in assisting ministries of health in capacity building by training epidemiologists and other health professionals through the development of competency based, residency-style, applied training programs; (4) provides leadership and expertise in assisting national ministries of health to utilize trained public health workers for developing health policy, and implementing and evaluating health programs; (5) assigns and manages expert consultants as long-term, in-country advisors to ministry of health programs; (6) collaborates within CDC, with other Federal agencies, and with national and international organizations in support of partner programs; (7) provides consultation to ministries of health in development of surveillance systems (e.g., communicable and non-communicable disease surveillance, injury, chronic diseases, etc.); (8) develops and evaluates competency-based training materials for the FETP and similar programs for use of the division and its partners; and (9) collaborates within CDC and with national or international organizations in development of competency-based training materials, evaluation of training, and design of surveillance systems needed to accomplish mission.

**Division of Global HIV/AIDS (CWG)**  
The Division of Global HIV/AIDS (DGHA) provides technical assistance to host governments, working through its strong partnerships with Ministries of Health and local and international partners to implement integrated HIV/AIDS clinical and preventive services and systems; develop and strengthen laboratory services; and provide epidemiologic science, informatics, and research support to develop sustainable public health systems in resource-constrained countries. DGHA: (1) Provides leadership, management, and services to DGHA country offices; (2) implements integrated evidence-based prevention, care, and treatment programs and services; (3) evaluates program cost effectiveness and impact to assist with prioritization, inform program planning, and determine appropriate rates of program expansion, and supports transition of responsibility for implementation of HIV programs to indigenous partners and Ministries of Health; (4) builds sustainable public health capacity in laboratory services

and systems; (5) ensures epidemiologic and scientific excellence in HIV/AIDS programs; (6) contributes to the broader scientific body of knowledge in global public health by systematically evaluating the scope and quality of global HIV/AIDS programs; (7) implements operations and effectiveness research to inform the design of current and future programs as well as optimize allocation of human and financial resources; (8) strengthens in-country capacity to design and implement HIV/AIDS surveillance systems and surveys; (9) builds host government public health management capacity and trains in-country public health workforce with the goal of long term program sustainability; (10) supports host government capacity to monitor and evaluate the process, outcome, and impact of HIV prevention, care, and treatment programs, and (11) helps countries respond to public health emergencies, assisting in response planning and implementation with Ministries of Health and other international partners.

**Office of the Director (CWG1).** (1) Provides strategic leadership, guidance, management and oversight to all DGHA programs and ensures coordination and communication across its branches and with other CDC programs including CDC/Washington; U.S. Government (USG) agencies, including the Department of Health and Human Services (HHS), the United States Agency for International Development (USAID), and Department of State (DoS); and other international organizations; (2) plans, implements, and oversees all field programs along with other USG agencies; (3) manages all DGHA country directors and provides leadership and guidance to country offices in all matters of daily operation, including management of global workforce staff; (4) provides leadership and guidance on policy development and interpretation, budget formulation, program planning, issues management, management and operations, and evaluation; (5) helps to build capacity and strengthen the public health response by sharing best practices through communication materials and coordinating dissemination of resources to the media, partners, and other audiences; (6) identifies opportunities for leveraging and enhancing partnerships for public health protection and synergies with other Agency programs and partners; (7) provides DGHA management and operations services in coordination with appropriate CDC staff offices, including processing travel and assisting with accountability and management of HHS/

CDC property, facilities, and equipment; (8) ensures timely and sufficient DGHA domestic staff placement through recruitment, hiring, and orienting of qualified staff; (9) ensures retention of qualified staff by providing workforce management and career development services for DGHA domestic staff; (10) ensures scientific excellence for all DGHA scientific, programmatic, and informational documents/materials which includes providing scientific review and clearance of manuscripts for publication, abstracts for presentation, and protocols for institutional review boards and human subjects review; (11) provides coordination and support for, as well as contributes to, global public health evaluation and operational research to maximize the effectiveness and quality of global HIV/AIDS interventions to guide DGHA programs and policies; (12) establishes and implements standards for organizational excellence; (13) provides direct technical assistance and maintains relationships with host country partners and responds to other health needs as required; (14) assures accountability of program funds and reports on progress; and (15) collaborates with other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

**International Laboratory Branch (CWGB).** (1) Serves as a reference laboratory that provides guidance on quality assurance and certification for international sites; (2) provides technical assistance to country programs in the areas of laboratory information systems and laboratory systems; (3) provides training packages, training, guidance, and support to host nations, other USG agencies and international and national partners on HIV, Sexually Transmitted Infection (STI), and opportunistic infection (OI) diagnostics and monitoring techniques; HIV incidence testing; hematology; chemistry; CD4; TB/OI testing; antiretroviral treatment (ART) resistance testing; dried blood spot polymerase chain reaction for early infant diagnosis; viral load monitoring; and ensuring the quality of laboratories and testing activities; (4) serves as a training center of excellence for HIV/STI/OI diagnostics for international sites; (5) provides laboratory assistance to international surveillance activities to monitor trends of HIV prevalence and incidence; (6) assists in the surveillance of HIV subtypes in the overall context of supporting sero-surveillance programs; (7) assists in the surveillance and evaluation of HIV drug resistance as part of antiretroviral care and treatment

programs and serves as a reference laboratory for the World Health Organization (WHO)—CDC HIV drug resistance network; (8) develops strategies and methodologies to meet the clinical and diagnostic needs of HIV/AIDS programs; (9) assists in the evaluation and validation of serologic and nucleic acid assays for measurement of HIV incidence to enable evaluation of effectiveness of prevention programs; (10) develops comprehensive testing algorithms for HIV diagnosis; (11) contributes to operational research to maximize the effectiveness and quality of global HIV/AIDS interventions to guide DGHA programs and policies; (12) conducts laboratory capacity assessments and assists in development of infrastructure for effective implementation of programs in countries where DGHA operates; (13) provides laboratory guidance and support on national strategic planning and quality management of tiered laboratory systems in host nations and consults on all technical aspects of laboratory procurement, standardization, quality control and quality assurance; (14) works with international accrediting organizations to establish guidance, training, and tools for accreditation of laboratory systems in resource-poor settings; (15) supports ongoing collaboration with international laboratory experts and national and regional laboratory personnel to resolve technical issues and develops international tools, guidelines, curriculum and other resources to improve laboratory capacity in host nations; (16) develops and implements strategies to expand the laboratory health workforce and increase human capacity of host government public health programs to strengthen and ensure a sustainable public health response to HIV/AIDS; (17) promotes a transition toward greater sustainability of laboratory systems through the support of country-driven efforts; (18) establishes strategic Public Private Partnerships for strengthening laboratory systems, training, development of referral systems for transporting samples, and quality management schemes; (19) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHA Office of the Director (OD) Science Office; (20) contributes to the greater body of scientific knowledge through the presentation of laboratory operational research findings at conferences and through publications in peer reviewed journals; and (21) collaborates with other DGHA branches; other CDC and

HHS programs and offices; other USG agencies; and other national and international organizations.

HIV Prevention Branch (CWGC). (1) Provides technical assistance and builds capacity to implement, improve, expand, sustain, and maximize effectiveness of HIV prevention programs; (2) provides technical assistance for scale-up of prevention and biomedical interventions and linkage with other HIV clinical services; (3) assists DGHA country programs in the recruitment of safe blood (products) donors, quality testing, blood bank management, appropriate use of blood and blood products, and prevention of severe anemia; (4) fosters the improvement of HIV prevention and counseling services through blood donor education, mobilization, and retention of safe blood donors; (5) supports development of safe injection practices, improved sharps waste management, safer blood transfusions, and avoidance of unnecessary medical injections; (6) assists in the development, implementation, and evaluation of model behavior change interventions and programs to reduce risk-behaviors and enhance health-seeking behaviors; (7) helps strengthen, expand, and make accessible programs to prevent, diagnose, and treat STIs in high risk populations and to prevent HIV infection among persons seeking treatment for STIs; (8) assists in tailoring HIV prevention programs to meet the special needs of youth and drug-using populations; (9) helps to develop, expand, and evaluate voluntary HIV counseling and testing programs in both clinical and community settings; (10) assists in the provision of technical support to DGHA programs in developing laboratory, clinical, and administrative capacities to prevent HIV/AIDS; (11) assists in implementing, and monitoring the quality and impact of, prevention programs for persons living with HIV/AIDS and their families and integrating HIV prevention programs within health services for HIV care and treatment; (12) assists in safe and effective implementation of biomedical interventions, including the scale-up of male circumcision; (13) assists in monitoring the training of health care workers to prevent HIV; (14) contributes to operational research to maximize the effectiveness and quality of global HIV/AIDS interventions to guide DGHA programs and policies; (15) establishes strategic Public Private Partnerships to build capacity for and maximize effectiveness of HIV prevention programs in host countries; (16) ensures scientific excellence for all

branch manuscripts, protocols, and programs in collaboration with the DGHA OD Science Office; and (17) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

HIV Care and Treatment Branch (CWGD). (1) Provides technical assistance and builds capacity in developing and implementing sustainable comprehensive care and treatment programs for persons with HIV/AIDS. This includes prevention, diagnosis, and treatment services for HIV/AIDS, tuberculosis, other opportunistic infections, and opportunistic cancers; (2) provides technical expertise and support to country programs, partners, and Ministries of Health in planning, implementing, and evaluating effective strategies for care and treatment of persons with HIV; (3) provides HIV care and treatment expertise to country programs, partners, and Ministries of Health on management, standard operating procedures, human resources, physical infrastructure, training, drug and health commodities management, laboratory services, monitoring and evaluation, community services, linkage between HIV and other programs, promotion of prevention, and sustainability; (4) provides support for continuous quality improvement of HIV care and treatment programs; (5) promotes appropriate integration of services, including HIV prevention interventions into clinical care and treatment settings and HIV services into general medical services; (6) conducts operational research in collaboration with country programs to identify best practices, address barriers, and respond to emerging scientific issues related to HIV care and treatment service delivery; (7) collaborates with international partners to synthesize the scientific body of knowledge on HIV care and treatment, including TB/HIV co-infection; (8) collaborates with international partners to develop and disseminate tools (e.g., protocols and training curricula), guidelines and policies; (9) supports analysis of program costs and cost effectiveness to assist with prioritization, inform program planning, and determine appropriate rates of program expansion; (10) supports capacity building of host countries to transition responsibility for implementation of HIV care and treatment services to indigenous partners and Ministries of Health, with result of increasing ownership, sustainability and service delivery cost

efficiencies; (11) establishes strategic Public Private Partnerships aimed at augmenting capacity for developing and implementing sustainable comprehensive care and treatment programs, including prevention, diagnosis, and treatment services for HIV/AIDS, tuberculosis, other opportunistic infections, and opportunistic cancers; (12) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHA OD Science Office; (13) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Maternal and Child Health Branch (CWGE). (1) Supports the international scale up of comprehensive, quality prevention of mother-to-child HIV transmission (PMTCT) and pediatric (Peds) programs by developing adaptable training tools, utilizing operational research to identify and implement models of service delivery adapted to district, regional, sub-national and national contexts; (2) provides technical expertise and support to countries in planning, implementing, and evaluating effective strategies for scaling up of sustainable programs for the prevention, diagnosis, and treatment of HIV/AIDS, tuberculosis, and other opportunistic infections in women, infants, and children, including linking PMTCT/Peds HIV programs with HIV clinical and preventive services and other maternal and child health settings/contexts; (3) builds national capacity for and provides guidance on development of policy for formulations for and access to appropriate long-term combination ART for HIV-infected children; (4) conducts operational research in collaboration with country programs to promote best practices, address barriers, and respond to emerging scientific issues for PMTCT/Peds HIV service delivery; (5) collaborates with international partners to contribute to the scientific body of knowledge on global PMTCT/Peds and broader maternal and child health issues and to develop and disseminate tools, guidelines, and policies to translate research for improved program implementation in resource-constrained countries; (6) provides support for continuous quality improvement of PMTCT and Peds HIV care and treatment programs, including those within broader maternal and child health programs; (7) supports analysis of program costs and cost-effectiveness to assist with prioritization, inform

program planning, and determine appropriate rates of program expansion; (8) acts as a key part of a broader CDC strategic response to address health needs and gender-related issues of maternal and child health worldwide, supporting a comprehensive, multidisciplinary approach to building maternal and child health services and systems capacity in host countries; (9) establishes strategic Public Private Partnerships for HIV maternal and child health services and systems capacity in host countries; (10) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHA OD Science Office; and (11) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Epidemiology and Strategic Information Branch (CWGG). (1) Assists countries in developing and/or enhancing HIV-related surveillance systems and in using the results of surveillance surveys for impact monitoring, program planning, and HIV/AIDS policy making; (2) assists and provides training on analyzing, disseminating, and using HIV/AIDS data; (3) assists and provides training to CDC programs and host country governments to assess and ensure the quality of the data collected in HIV-related surveillance systems and HIV/AIDS program monitoring systems; (4) strengthens host government capacity to monitor and evaluate the process, outcome, and impact of HIV/AIDS prevention, care, and treatment programs, other related global health programs, and health systems through the development of guidelines, curricula, and other tools; (5) implements and evaluates novel approaches for conducting surveillance and surveys, and conducting program monitoring and evaluation; (6) performs epidemiologic investigations of HIV/AIDS as well as provides statistical and epidemiologic technical assistance for in-country investigations; (7) supports surveys and monitoring and evaluation systems that measure HIV prevalence, changes in HIV-related behavior, and health status among individuals and at the population level; (8) strengthens country monitoring systems that track program service delivery and ensure effective, evidence based programming; (9) provides support to the DoS Office of the US Global AIDS Coordinator (OGAC) and to interagency USG in-country teams to monitor and evaluate the outputs, outcomes, and impact of global HIV/AIDS activities and advises

interagency in-country teams on planning of strategic information activities; (10) improves the collection and analysis of data through development of guidelines on HIV surveillance and assists countries to develop procedures to standardize HIV surveillance systems, write protocols for HIV surveillance, train for data collection, and assist with data cleaning and data analysis; (11) provides a wide range of statistical and epidemiologic support and technical expertise to agencies and staff engaged in global HIV/AIDS activities, including consultation and direct assistance at all stages of a public health study; specifically, development of study design, sample size and power estimation, questionnaire design, data monitoring, statistical analysis and report writing; (12) provides comprehensive data management support to staff and countries engaged in global HIV/AIDS activities, including development of data organization plan and standards for coding of data elements, quality assurance, maintenance of databases, report generation, and implementation of policies on electronic record retention and data security; (13) coordinates, oversees, or assists in the formulation of epidemiology and strategic information funding/budgets and in the execution of a variety of acquisition and assistance awards; (14) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHA OD Science Office; and (15) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Health Economics, Systems, and Integration Branch (CWGH). (1) Identifies priority information needs for program planning, resource allocation, efficiency and program integration, and develops economic analysis and operational research activities; (2) implements economic studies, including costing and cost-effectiveness studies, and applies advanced modeling techniques to inform and optimize global health planning, policy and programs, and provide a broader understanding of the effects of health programs on improving economic and other non-health outcomes; (3) supports USG efforts in projecting financing needs to efficiently meet program targets in areas of prevention, care and treatment, and human resources for health (HRH); (4) guides development and implementation of monitoring systems to routinely capture program

expenditure data to support planning, accountability and efficient programming; (5) trains and mentors partner country personnel in the methods and application of economic analysis of global health programs and policy; (6) provides technical input, guidance, review and implementation support to operational research on and evaluation of global HIV/AIDS activities; (7) supports the development of partner country health finance systems and capacity to develop sustainable and accountable programs, and assists in the implementation of national AIDS spending assessment activities; (8) assists countries in the collection, transmission, classification, storage, and analysis of strategic information, and helps countries to design, implement, maintain, and evaluate a wide range of information systems to both support implementation of global HIV/AIDS services, and to monitor and evaluate the results to inform policy and program decisions; (9) supports the integration of HIV data into broader, more comprehensive health information systems, supports development of comprehensive health information systems, and works to ensure that systems are not duplicative; (10) works with in-country counterparts to provide technical assistance on strengthening health information systems in-country, including systems needs assessments, identifying and resolving DGHAs, describing data exchanges needed across these systems, and developing standards for data and for system interoperability; (11) in conjunction with WHO/Joint United Nations Program on HIV/AIDS develops: standardized definitions for data that support ART, HIV/TB, maternal child health, PMTCT, and other clinical care; open source tools for the implementation of electronic patient record and other systems; security and confidentiality guidance for HIV/AIDS data; guidance on unique identification and matching of patient records across disparate information systems; (12) participates in USG interagency technical working groups and provides technical leadership to address global health information systems, Health Systems Strengthening (HSS), and HRH issues and initiatives; (13) provides technical support for the routine monitoring of health related governance including financial accountability, programmatic transparency, policy development and enforcement, and engagement and regulation of the private health sector, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria; (14)

develops the HSS operational research agenda for DGHA and implements public health evaluations related to health systems; (15) provides broad HSS technical assistance and support to USG in-country teams and host countries to improve the delivery of HIV and other health services and work toward transition to country ownership of program; (16) supports branches in strengthening health systems, developing metrics to assess DGHA's contribution to HSS and implementing monitoring systems to routinely collect DGHA's health system impact, especially in the areas of laboratory systems, maternal child health services, HIV care and treatment service delivery, blood safety programs, and prevention services; (17) helps define CDC's role and identify priority needs for strengthening HRH to support sustainability of HIV programs; (18) provides HRH technical assistance and other support to meet priority HRH needs, including pre-service and in-service training, task-shifting, capacity-building of accreditation and credentialing bodies, HRH planning and management, workplace performance and safety, and the development of human resource information systems and their use in health decision-making; (19) conducts monitoring and evaluation of US-supported HRH activities, to help inform U.S. resource and program decision-making; (20) ensures that public health epidemiologists, laboratorians, and administrators are represented in the goal of training and retaining 140,000 new health professionals; (21) supports operational research activities and public health evaluations that address current HRH questions and monitoring needs; (22) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHA OD Science Office; and (23) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Country Operations Branch (CWGJ). (1) Provides operations support to facilitate effective delivery of global HIV/AIDS activities in DGHA country programs in the areas of fiscal management, procurement, personnel, extramural (grants, cooperative agreements and contracts) programs, and other administrative services; (2) serves as the key linkage between DGHA headquarters and DGHA country offices coordinating calls and liaising with the CDC Financial Management Office (FMO) and Procurement and Grants

Office (PGO), Atlanta Human Resources Center, and OGAC; (3) serves as the CDC representative on the OGAC core team/country support team; (4) develops strategies to improve the technical skills and problem-solving abilities of country program managers and locally employed staff who work in the administrative, management and operational area; (5) provides short- and long-term consultation, technical assistance, and backstopping for management and operations issues and staff to DGHA country offices; (6) provides long-term management and operations support for smaller countries; (7) ensures timely and sufficient CDC international staff placement through recruitment, hiring, orienting, deploying, and assisting with relocation of qualified staff; (8) ensures retention of qualified staff by providing workforce management and career development services for CDC international staff; and (9) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Program Budget and Extramural Management Branch (CWGK). (1) Coordinates all DGHA procurement and extramural activities in creating spend plans in compliance with federal appropriations law, congressional intent, and global HIV/AIDS policies; (2) facilitates and manages the development, clearance, and award of all new and ongoing DGHA headquarters and field grants, cooperative agreements, and contracts; (3) provides technical assistance and guidance to the countries and branches on budget and extramural issues including assisting programs in determining the appropriate funding mechanism to support global HIV/AIDS activities; (4) provides training and tools to DGHA country programs to improve budget and cooperative agreement management; (5) manages DGHA headquarters budget and tracks overall DGHA budget, which includes conducting budget planning exercises and managing the annual close-out process; (6) provides funding and budgetary data for regular reports including the Headquarters Operational Plan, GAO and IG audits, country Annual Program Results to OGAC, and other requests for data; (8) reviews and provides input on budgetary and procurement policy-related documents; (9) liaises and collaborates, as appropriate, with the DGHA Associate Director for Science, other financial and procurement-related units and offices including FMO and PGO, as well as other CDC and HHS offices, OGAC, and

other USG agencies; (10) collaborates with other DGHA branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations. Division of Parasitic Diseases and Malaria (CWH). The Division of Parasitic Diseases and Malaria (DPDM) prevents and controls parasitic diseases in the U.S. and throughout the world by providing diagnostic, consultative, epidemiologic services, and training. In carrying out its mission, DPDM: (1) Conducts surveillance, investigations, and studies of parasitic diseases to define disease etiology, mode of transmission, and populations at risk, and to develop effective methods for diagnosis, prevention, control, and elimination; (2) conducts or participates in clinical, field, and laboratory research to develop, evaluate, and improve laboratory methodologies, materials and therapeutic practices used for rapid and accurate diagnosis and treatment of parasitic diseases; (3) provides epidemic aid, epidemiologic consultation, and reference diagnostic services to state and local health departments, other federal agencies, and national and international health organizations; (4) conducts a program of laboratory and field research in the biology, ecology, and host-parasitic relationships to develop better methods for diagnosis, prevention, and control of parasitic diseases; (5) provides scientific and technical assistance to other components within CDC when the work requires unique expertise or specialized equipment not available in other CDC components; (6) serves as WHO Collaborating Centers for Cysticercosis, Research Training and Eradication of Dracunculiasis, Control and Elimination of Lymphatic Filariasis, Evaluating and Testing New Insecticides, Insecticide Resistance, Insect Vectors; Malaria Control in Africa, Human African Trypanosomiasis, Production and Distribution of Malaria Sporozoite ELISAs; (7) maintains field-based research and program activities in numerous developing countries; and (8) provides marketing communications support for responsive, evidence-based information targeted to the public, local and state health officials, international partners, and private organizations to inform health decisions, to prevent, and control parasitic diseases in the U.S. and abroad. Office of the Director (CWH1). (1) Works with CGH OD to ensure spending plans and budget are in line with the overall infectious disease strategies and priorities; (2) ensures that the CGH strategy is executed by the divisions and aligned with overall CDC

goals; (3) co-develops execution strategies for the division with the branch chiefs; (4) provides program and science quality oversight; (5) builds leadership at the division and branch levels; (6) evaluates the strategies, focus, and prioritization of the division research, program, and budget activities; (7) identifies and coordinates synergies between the division and relevant partners; (8) ensures that policy development is consistent and appropriate; (9) facilitates research and program activities by providing leadership support; (10) proposes resource priorities throughout the budget cycle; (11) ensures scientific quality, ethics, and regulatory compliance; (12) fosters an integrated approach to research, program, and policy activities; and (13) liaises with HHS and partners as defined in the partnership management plan.

Malaria Branch (CWHB). (1) Conducts malaria surveillance, prevention, and control in U.S. residents and visitors by monitoring the frequency and distribution of malaria cases that occur in U.S. residents and visitors and the efficacy and safety of antimalarial drugs for chemoprophylaxis and chemotherapy; (2) provides clinical advice and epidemiologic assistance on the treatment, control, and prevention of malaria in the U.S. and in malaria endemic countries; (3) provides information to the U.S. public and to appropriate agencies and groups on appropriate measures to prevent and control malaria; (4) provides consultation, technical assistance, and training to malaria-endemic countries and to international and U.S. agencies and organizations on issues of malaria prevention and control; (5) conducts epidemiologic, laboratory, and field-based research projects, including laboratory and field studies on parasitic diseases to define biology, ecology, transmission dynamics, parasite species differences, host-parasite relationships, diagnostics, host immune responses, populations at risk, and determinants of morbidity and mortality; (6) conducts laboratory studies of malaria parasites utilizing animal models and in vitro systems for parasitic relationships, chemotherapy, and vaccine evaluation studies; (7) conducts field studies of malaria prevention and control tools and strategies; and (8) conducts assessments of malaria monitoring and evaluation methods and program use of these methods.

Parasitic Diseases Branch (CWHC). (1) Investigates outbreaks and unusual occurrences of parasitic diseases in concert with states, ministries of health, WHO, and other agencies and

organizations; (2) conducts surveillance of foodborne disease outbreaks and other parasitic diseases in the U.S.; (3) provides reference and laboratory diagnostic services to physicians and laboratories; (4) transfers technologies and expertise in laboratory diagnosis of parasitic infections to public health laboratories; (5) provides consultation on the prevention, treatment, and management of parasitic diseases to clinicians, laboratorians, departments of health, and other agencies; and provides otherwise unavailable anti-parasitic drugs to healthcare providers and ensures compliance with FDA's regulations; (6) supports the agency's overall emergency response mandate; (7) conducts field and laboratory investigations and research on the etiology, biology, epidemiology, ecology, pathogenesis, immunology, genetics, host-parasite relationships, chemotherapy and other aspects of parasitic diseases to develop new tools for identifying and controlling parasitic diseases; (8) develops and tests new laboratory methods and tools for improved diagnosis, control, and prevention of parasitic diseases, and conducts laboratory training courses for public health laboratories; (9) carries out and evaluates operational research to evaluate current strategies and develops new strategies to support programmatic activities for the control and elimination of parasitic diseases, and provides technical assistance to ministries of health, WHO, and other agencies and organizations for these programs; (10) provides training to Epidemic Intelligence Service officers, Emerging Infectious Disease fellows, American Society of Microbiology/Postdoctoral Fellows, Preventive Medicine Residents, public health prevention specialists, and other fellows and students; and (11) prepares and disseminates health communication materials on the prevention and treatment of parasitic diseases.

Entomology Branch (CWHB). (1) Conducts surveillance, field investigations, and laboratory studies on the vectors of parasitic diseases of humans, with a focus on malaria, Chagas' disease, lymphatic filariasis, onchocerciasis, and leishmaniasis, with a particular emphasis on the anopheline vectors of malaria; (2) serves as WHO Collaborating Centers for pesticides resistance, anopheline vector identification, antimalarial drug evaluation, and vector control; (3) develops methods supporting the use of pesticides for control of vector-borne diseases, the management of insecticide resistance, and the monitoring of anti-



parasitic drugs; (4) serves as an international reference reagent and anopheline vector repository, providing materials, training, and information related to malaria vectors; and (5) provides entomological consultation, epidemic aid, and training to local, state, federal and foreign agencies and international health organizations on surveillance and control of vectors and vector-borne diseases.

Division of Global Disease Detection and Emergency Response (CWJ). The Division of Disease Detection and Emergency Response (DGDDBER) supports CDC global efforts to strengthen public health systems abroad and build essential infrastructure in host countries. By providing leadership and coordinating with global partners, the Division increases preparedness and response to prevent and control naturally occurring and man-made threats to health. To carry out its mission, the Division performs the following functions: (1) Supports the requirements of the revised International Health Regulations by fostering collaborations, partnerships, integration, and resource leveraging to increase CDCs impact and achieve public health goals; (2) works with partners to build strong, transparent, and sustained global public health systems through training, consultation, capacity building, and technical assistance in applied epidemiology, public health surveillance, evaluation, and laboratory systems; (3) coordinates management and oversight of critical global health preparedness and emergency response activities across CDC, including situational awareness and partnership management at the global and regional level; (4) coordinates with and responds to requests from a wide array of internal CDC and external partners and stakeholders; and (5) provides stewardship and leadership support to global health preparedness programs housed in the Division.

Office of the Director (CWJ1). (1) Provides leadership, oversight, evaluation and overall direction and management for the activities of the Division; (2) develops Division overall strategy, policies on planning, evaluation, management, and operations; (3) plans, allocates, and monitors resources; (4) provides liaison with other CDC organizations, other Federal agencies, national ministries of health, international organizations, non governmental organizations, private sector, and others that CDC cooperates with in global health programs and activities; and (5) promotes high standards in science and ethics among CDC's international activities.

Global Disease Detection Branch (CWJB). The Global Disease Detection (GDD) Branch: (1) Provides leadership and works with partners around the globe to increase preparedness for and mitigate the consequences of a catastrophic public-health event, whether by an intentional act of terrorism, or the natural emergence of a deadly infectious disease; (2) provides program support, resources and technical assistance to the seven Global Disease Detection (GDD) Centers around the world; (3) supports emerging infectious disease detection and response, pandemic influenza preparedness, health communications, zoonotic disease investigation, laboratory systems and biosafety, and training in field epidemiology and laboratory methods through the GDD Centers and other CDC field locations; (4) provides epidemic intelligence and response capacity to provide an early warning about international disease threats, and coordinates with partners throughout the U.S. government to provide rapid response; (5) leads and administers CDCs GDD program through coordination with relevant implementing programs across the Agency; (6) provides leadership, guidance, technical assistance support and resources for global infectious disease surveillance, applied epidemiologic and laboratory research, and response to emerging infectious disease threats; (7) provides resources and assists in developing country-level epidemiologic, laboratory, and other capacity to ensure country emergency preparedness and response to outbreaks and incidents of local importance and of international interests; and (8) maintains staff in the CDC Emergency Operations Center to manage, direct, coordinate and evaluate biosurveillance data from domestic and international networks and serve as a central focus for global outbreak and incident response activities.

Global Health Security Branch (CWJC). The Global Health Security Branch (GHSB): (1) Serves as the principal point of coordination at CDC for global health security activities at HHS/OS, the DoS, the Department of Defense (DoD), USAID, USDA, other U.S. government agencies, and international and multilateral organizations; (2) aligns the activities formerly conducted by CDC units supporting the Biosecurity Engagement Program (BEP), the Defense Threat Reduction Agency Program and the International Influenza Unit (IIU); (3) provides support and coordination regarding the development of policies

and priorities on international influenza; (4) serves as liaison with HHS and technical agency (CDC, NIH, FDA) representative for international pandemic preparedness related to budget formulation, program development, strategic planning, and global health policy development; (5) provides leadership, coordination, management and oversight of technical agency reports, briefing documents, and talking points for the HHS Secretary and staff related to global health policy; (6) provides technical assistance through training, and capacity building in supporting efforts to reduce the threat from chemical, biological, and nuclear disasters that are either natural or man-made; (7) provides liaison with the DoS Biosecurity Engagement Program and DoD Defense Threat Reduction Agency to coordinate on global biological threats; and (8) coordinates international aspects of CDC's terrorism preparedness and emergency response activities in collaboration with OPHPR.

International Emergency and Refugee Health Branch (CWJD). The International Emergency and Refugee Health Branch (IERHB) applies public health and epidemiologic principles to improve the health of refugees, internally displaced persons (IDPs) and populations affected by complex humanitarian and other international emergencies. Specifically, it: (1) Coordinates, supervises, and monitors, CDC's work in international emergency settings and in refugee or displaced populations in collaboration with other U.S. government agencies, United Nations agencies, and non-governmental organizations; (2) provides direct technical assistance to refugees/IDPs and emergency affected populations in the field, focusing on rapid health and nutrition assessments, public health surveillance, epidemic investigations, communicable disease prevention and control and program evaluation; (3) develops and implements operational research aimed at developing more effective public health and nutrition interventions in emergency-affected populations; (4) plans, implements, and evaluates training courses and workshops to help strengthen CDC technical capacity in emergency public health of CDC, as well as that of other U.S. government agencies, international and private voluntary organizations, and schools of public health; (5) develops technical guidelines on public health issues associated with international complex humanitarian emergencies; (6) serves as the CDC liaison with other international, bilateral, and non-governmental relief organizations



involved with humanitarian emergencies; and (7) helps prepare CDC country offices, host countries, and local partners to respond to the full range of public health emergencies.

Delete in its entirety the title and functional statements for the Division of Global AIDS (CVJG) within the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention.

Delete in its entirety the title and functional statement for the International Emergency and Refugee Health Branch (CTBBD) within the Division of Emergency and Environmental Health Services of the National Center for Environmental Health.

Dated: April 19, 2010.

**William P. Nichols,**

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

[FR Doc. 2010-9910 Filed 4-29-10; 8:45 am]

**BILLING CODE 4163-18-M**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2006-24163]

#### **National Environmental Policy Act; Final Environmental Impact Statement on U.S. Coast Guard Pacific Area Operations: Districts 11 and 13**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** The U.S. Coast Guard announces the availability of the Final Environmental Impact Statement (FEIS) to implement enhanced environmental protection measures, as necessary, for marine protected species (MPS) and marine protected areas (MPAs) that occur in the Coast Guard's District 11 (California) and 13 (Oregon and Washington) areas of responsibility (AORs). The FEIS analyzes the potential environmental impacts of specific Coast Guard vessel and aircraft operations on MPS and MPAs when engaged in the following missions and activities: law enforcement, national security, search and rescue (SAR), aids to navigation (ATON), and oil pollution and vessel grounding response. We request your comments on the FEIS.

**DATES:** Comments and related material must either be submitted to our online docket via <http://www.regulations.gov> on or before June 1, 2010 or reach the Docket Management Facility by that date.

**ADDRESSES:** You may submit comments identified by docket number USCG-2006-24163 using any of the following methods:

(1) *Federal eRulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call or e-mail LCDR Jeff Bray, Office of Environmental and Real Property Law, Coast Guard; telephone 202-372-3752, e-mail [JEFF.R.BRAY@USCG.MIL](mailto:JEFF.R.BRAY@USCG.MIL). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Public Participation and Request for Comments**

We encourage you to submit comments and related material on the FEIS. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

*Submitting comments:* If you submit a comment, please include the docket number for this notice (USCG-2006-24163) and provide a reason for each suggestion or recommendation. You may submit your comments and material online, or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Notices" and insert "USCG-2006-24163" in the "Keyword" box.

Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

*Viewing the comments, Draft Environmental Impact Statement (DEIS), FEIS, and associated documents:* To view the comments, FEIS, DEIS, and other documents, go to <http://www.regulations.gov>, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box, insert "USCG-2006-24163" and click "Search." Click the "Open Docket Folder" in the "Actions" column. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility. In addition, the Coast Guard has posted the FEIS at the following Web site: <http://pacareaeis.uscg.e2m-inc.com>.

*Privacy Act:* Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act, system of records notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

#### **Background and Purpose**

##### *Final Environmental Impact Statement*

We have prepared an FEIS to implement enhanced protective measures, as necessary, for MPS and MPAs that occur in the Eleventh Coast Guard District (California) (D11) and Thirteenth Coast Guard District (Washington and Oregon) (D13) AORs. The FEIS analyzes the potential environmental impacts of specific Coast Guard vessel and aircraft operations on MPS and MPAs when engaged in law enforcement, national security, SAR, ATON, and oil pollution and vessel grounding response.

The Coast Guard published a notice of intent to prepare an EIS in the **Federal**