

FOR FURTHER INFORMATION CONTACT:

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John Howard,

Director, National Institute for Occupational Safety and Health.

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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 76, FR 1167, dated January 7, 2011) is amended to reflect the reorganization of the National Center for Emerging and Zoonotic Infectious Diseases, Office of Infectious Diseases, 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 Division of Healthcare Quality Promotion (CVLD) and insert the following:

Division of Healthcare Quality Promotion (CVLD). The mission of the Division of Healthcare Quality Promotion (DHQP) is to protect patients; protect healthcare personnel; and promote safety, quality, and value in both national and international healthcare delivery systems. In carrying out its mission, DHQP: (1) Measures, validates, interprets, and responds to data relevant to healthcare-associated infections (HAI); antimicrobial resistance; adverse drug events; blood, organ and tissue safety; and immunization safety; and other related adverse events or medical errors in healthcare affecting patients and healthcare personnel; (2) investigates and responds to emerging infections and related adverse events among patients and healthcare personnel; (3) develops

and maintains the National Healthcare Safety Network (NHSN), a tool for monitoring healthcare-associated infections, measuring healthcare outcomes and processes, and monitoring healthcare worker vaccination and selected health measures in healthcare facilities; (4) assesses rates of infections caused by resistant-bacteria in the U.S. through active surveillance, review of national healthcare data sets, and laboratory surveillance programs; (5) conducts epidemiologic, and basic and applied laboratory research to identify new strategies to prevent infections/antimicrobial resistance, and related adverse events or medical errors, especially those associated with medical or surgical procedures, indwelling medical devices, contaminated products, dialysis, and water; (6) collaborates with academic and public health partners to design, develop, and evaluate the efficacy of interventions for preventing infections and reducing antimicrobial resistance, and related adverse events or medical errors; (7) develops and disseminates evidence-based guidelines and recommendations to prevent and control HAI, antimicrobial resistance, and related adverse events or medical errors; (8) promotes the nationwide implementation of Healthcare Infection Control Practices Advisory Committee (HICPAC) recommendations and other evidence-based interventions to prevent HAI, antimicrobial resistance, and related adverse events or medical errors among patients and healthcare personnel; (9) evaluates the impact of evidence-based recommendations and interventions across the spectrum of healthcare delivery sites; (10) develops, implements, and evaluates the effectiveness of interventions to prevent transmission of healthcare-associated human immunodeficiency virus (HIV) and other bloodborne pathogen, infections; (11) serves as the National Reference Laboratory for the identification and antimicrobial susceptibility testing of staphylococci, anaerobic bacteria, non-tuberculous mycobacterial, and those gram-negative bacilli causing healthcare associated infections; (12) serves as the technical reference laboratory for detection and characterization of other pathogens related to healthcare; and for characterizing the contribution of the healthcare environment to HAI; (13) coordinates guidance and research related to infection control across the agency and with national and international partners; (14) monitors vaccine safety and conducts research to

evaluate the safety of available and new vaccines; (15) promotes the integration of the healthcare delivery system in federal/state/local public health preparedness planning; (16) trains Epidemic Intelligence Service Officers and other trainees; (17) coordinates antimicrobial resistance activities at CDC; (18) works in a national leadership capacity with public and private organizations to enhance antimicrobial resistance prevention and control, surveillance and response, and applied research; (19) coordinates blood, organ, and other tissue safety at CDC; and (20) provides expertise and assistance to HHS and other Federal agencies on efforts and activities related to health reform.

Office of the Director (CVLD1). (1) Manages, directs, and coordinates the activities of the DHQP; (2) provides leadership and guidance on policy and communications/media; (3) works with Federal agencies, CDC's Office of Prevention through Healthcare, and other partners on activities related to Health Reform; (4) coordinates state and local activities to monitor and prevent HAI; (5) provides liaison with other governmental agencies, international organizations, and other outside groups; (6) coordinates, in collaboration with the appropriate CIO and CDC components, global health activities relating to the prevention of healthcare-associated infections/antimicrobial resistance, and related adverse events or medical errors; (7) coordinates activities, guidance, emergency response, and research related to infection control in healthcare settings across the agency and with national and international partners; (8) works with other federal agencies, state governments, medical societies, and other public and private organizations to promote collaboration and to integrate healthcare preparedness in federal/state/local public health preparedness planning; (9) oversees the coordination of antimicrobial resistance activities at CDC; (10) represents CDC as co-chair of the federal Interagency Task Force on Antimicrobial Resistance; (11) coordinates with other agencies, state governments, medical societies, and other public and private organizations to enhance antimicrobial resistance prevention and control, surveillance and response, and applied research; (12) leads CDC's activities on blood, organ, and other tissue safety; (13) represents CDC on the Advisory Committee on Blood Safety and Availability and the Advisory Committee on Organ Transplantation; (14) works with other federal agencies, state governments, and

other public and private organizations to enhance blood, organ, and other tissue safety through coordination of investigation, prevention, response, surveillance, applied research, health communication, and public policy; and (15) advises the Director, NCEZID, on science, policy and communication matters concerning DHQP activities.

Program Implementation and Integration Activity (CVLD13). (1) Provides leadership and guidance for program planning and development, program management, and operations; (2) provides DHQP-wide administrative and program services and coordinates or ensures coordination with the appropriate CIOs and CDC staff offices on administrative and program matters including budget formulation and execution and human resource management; (3) oversees the coordination of federal and state programs and new initiatives to prevent HAI (e.g., the HAI Recovery Act State Cooperative Agreement program); (4) interprets general program and administrative policy directives for implications on management and execution of DHQP's programs; (5) serves as lead and primary contact and liaison with relevant CDC staff offices on all matters pertaining to DHQP's procurement needs and activities; (6) provides management and coordination for DHQP-occupied space and facilities including laboratory space and facilities; (7) provides oversight and management of the distribution, accountability, and maintenance of CDC property and equipment including laboratory property and equipment; and (8) provides program and administrative support for HICPAC.

Clinical and Environmental Microbiology Branch (CVLDB). (1) Collaborates with the Prevention and Response Branch to provide laboratory response to outbreaks and emerging threats associated with infections/antimicrobial resistance and related adverse events throughout the healthcare delivery system; (2) provides comprehensive laboratory support and expertise for investigations of recognized and emerging bacterial agents in healthcare settings; (3) develops methods to assess contamination of environmental surface; (4) investigates novel and emerging mechanisms of antimicrobial resistance among targeted pathogens found in healthcare settings; (5) detects toxins/virulence factors of bacteria causing HAI to understand their transmission and pathogenicity; (6) conducts research in collaboration with partners to develop new, accurate methods of detecting antimicrobial resistance in bacteria and

to improve reporting of antimicrobial susceptibility testing results to physicians to improve antimicrobial use; (7) conducts laboratory research to identify new strategies to prevent infections/antimicrobial resistance, related adverse events, and medical errors, especially those associated with invasive medical devices, contaminated products, dialysis, and water; (8) maintains capacity to evaluate commercial microbial identification and antimicrobial susceptibility testing systems and products and facilitates their improvement to provide accurate patient test results; (9) investigates the role of biofilms, particularly those detected in indwelling medical devices and medical water systems, in medicine and public health, and identifies novel methods to eliminate colonization and biofilm formation on foreign bodies; (10) investigates the role of the water distribution systems in healthcare facilities in order to understand and prevent waterborne healthcare associated infections; and (11) provides expertise, research opportunities, training, and laboratory support for investigations of infections and related adverse events to other CDC CIOs and to our partners in areas related to quality clinical microbiology laboratory practices, investigation of emerging pathogens and environmental microbiology.

Prevention and Response Branch (CVLDC). (1) Coordinates rapid response to assess and control strategically selected outbreaks and emerging threats (i.e., healthcare associated infections, related adverse events, including related infections in the community, and antimicrobial resistance) and communicates the results of response activities with federal and state agencies, healthcare providers, and the public to prevent similar adverse events in the future; (2) supports local, state, and national efforts to prevent HAI and related adverse events using evidence-based recommendations; (3) develops and/or evaluates the effectiveness of interventions to prevent HAI and related adverse events or medical errors across the spectrum of healthcare delivery sites including acute and long-term inpatient care, dialysis, and ambulatory settings; (4) provides epidemiology support for investigation and study of both recognized and emerging bacterial healthcare pathogens and related community pathogens, including antimicrobial resistant forms of these pathogens; (5) provides epidemiology support to Clinical and Environmental Microbiology Branch to identify new strategies to prevent infections

associated with indwelling medical devices, contaminated products, dialysis, and water; (6) develops, promotes, and monitors implementation of evidence-based guidelines/recommendations, and other proven interventions to prevent HAI and related adverse events, and occupational infections/exposures among healthcare personnel; (7) develops, promotes, and monitors implementation of interventions to prevent transmission of healthcare-associated HIV infections and conducts case investigations of occupational HIV infections; (8) conducts and supports research and evaluates impact of public health practices to prevent HAIs and related adverse events and monitors progress in reaching national prevention goals; and (9) provides expert consultation, guidance, and technical support to other branches in the division, across the agency, to government (e.g., Centers for Medicare Services and the VA Administration) and non-governmental payers of healthcare, and other domestic and international partners, and the U.S. public on the epidemiology and prevention of HAI and related adverse events, and exposures/injuries among healthcare personnel.

Surveillance Branch (CVLDD). (1) Monitors and evaluates on the national level the extent, distribution, and impact of healthcare-associated infections, antimicrobial use and resistance, adverse drug events, healthcare worker safety events, and adherence to clinical processes and intervention programs designed to prevent or control adverse exposures or outcomes in healthcare; (2) provides leadership and consultative services for statistical methods and analysis to investigators in the branch, division, and other organizations responsible for surveillance, research studies, and prevention and control of HAI and other healthcare-associated adverse events; (3) improves methods and enables wider use of clinical performance measurements by healthcare facilities and public health entities for specific interventions and prevention strategies designed to safeguard patients and healthcare workers from risk exposures and adverse outcomes through collaborations with extramural partners; (4) collaborates with public and private sector partners to further standardize, integrate, and streamline systems by which healthcare organizations collect, manage, analyze, report, and respond to data on clinical guideline adherence, HAI, including transmission of multi-drug resistant organisms and other HAI; (5) coordinates, further develops,

enables wider use, and maintains NHSN to obtain scientifically valid clinical performance indices and benchmarks that promote healthcare quality and value at the facility, state, and national levels; (6) conducts applied research to identify and develop innovative methods to detect and monitor HAI and antimicrobial resistance; (7) conducts special studies and provides national estimates of targeted, healthcare-associated adverse events, antimicrobial use and resistance patterns, and the extent to which prevention and control safeguards are in use to protect at-risk patients across the spectrum of healthcare delivery sites; (8) uses NHSN and other data sources to conduct special studies and provide national estimates of targeted occupational illnesses and injuries among healthcare workers and the extent to which preventive safeguards are in use across the spectrum of healthcare delivery sites; and (9) leads CDC's national adverse drug events surveillance activities and seeks to translate population-based surveillance data into evidence-based policies and targeted, innovative and collaborative interventions.

Immunization Safety Office (CVLDE).

(1) Assesses the safety of new and currently available vaccines received by children, adolescents and adults; (2) coordinates vaccine safety activities at CDC; (3) conducts public health surveillance to identify adverse events following immunization; (4) in collaboration with the Food and Drug Administration, coordinates and maintains the Vaccine Adverse Event Reporting System, a national reporting system that serves as an early-warning system to detect medical problems that may be related to vaccines; (5) coordinates and maintains the Vaccine Safety Datalink, a collaborative effort with managed care organizations, to assess adverse events following immunization; (6) administers the Clinical Immunization Safety Assessment network, a national network of medical research centers with expertise in immunization safety conducting clinical research on immunization-associated health risks; (7) participates in the Brighton Collaboration, an international collaboration of scientists from around the world working to develop, evaluate, and disseminate globally accepted standard case definitions for adverse events following immunization and guidelines for collection, analysis, and presentation of vaccine safety data; and (8) works with other federal agencies, state governments, and other public and

private organizations to assess and promote the safety of vaccines.

Dated: March 10, 2011.

James D. Seligman,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee (MDCC).

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: April 20, 2011.

Time: 8 a.m. to 4:30 p.m.

Agenda: The 2011 meeting of the MDCC will review Federal agency activities in the muscular dystrophies, brief participants on the NIH grant database, NIH RePORTER, discuss therapy development resources at the NIH, and review joint NIH/FDA activities and initiatives in rare diseases. The MDCC will also discuss new opportunities in therapy development based upon a representative example of a new mechanistic finding and the lessons learned in current drug development programs. A panel will review and discuss the challenges of conducting clinical trials in the muscular dystrophies.

An agenda will be posted prior to the meeting on the MDCC Web site: http://www.ninds.nih.gov/find_people/groups/mdcc/index.htm.

Place: Hilton Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland 20852-1699.

Contact Person: John D. Porter, PhD, Executive Secretary, Muscular Dystrophy Coordinating Committee, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Boulevard, NSC 2172, Bethesda, MD 20892, (301) 496-5739, porterjo@ninds.nih.gov.

Any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: March 11, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Open Meeting Notice

Notice is hereby given that the National Institutes of Health (NIH), Department of Health and Human Services, will hold a scientific workshop.

Title: "State of the Knowledge Workshop on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Research".

Dates: April 7-8, 2011.

Time: 8 a.m. to 5 p.m.

Place: Building 31, Conference Rooms 6C8/9/10, NIH campus, Bethesda, Maryland.

Purpose of the Meeting: This workshop will bring together subject matter experts who will discuss multiple aspects of ME/CFS, including epidemiology, etiology, pathophysiology, diagnosis, and treatment. The workshop panelists will identify gaps in knowledge and opportunities for advancing biomedical research.

This workshop is open to the public. Please note that attendance is limited. We encourage registration for those attending in person (*see* Web address below). For those unable to attend, the workshop will be available via NIH VideoCasting (<http://videocast.nih.gov/>) both during and after the event.

Individuals with disabilities who need reasonable accommodation should indicate their needs on registration or contact Infinity Conference Group by telephone at 703-925-9455, ext. 0, or e-mail at icg@infinityconferences.com.

For more information including an agenda, registration, and visitor information, please visit the workshop Web site: <https://www.infinityconferences.com/InfiniBase/Templates/157557/Index.htm>.

Contact Person: Dennis Mangan, PhD; Chair, Trans-NIH ME/CFS Research Working Group, Office of Research on