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 66 FR 1363–1364, dated January 8, 2001) is amended to retitle and revise the functional statement of the Hospital Infections Program (HIP), National Center for Infectious Diseases (NCID).

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

Delete in its entirety the titles and functional statements for the Hospital Infections Program (CRM) and insert the following:

Division of Healthcare Quality Promotion (CRM). Protects patients, protects healthcare personnel, and promotes safety, quality, and value in the healthcare delivery system by providing national leadership for (1) Measuring, validating, interpreting, and responding to data relevant to healthcare outcomes, healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors among patients and healthcare personnel; (2) investigating and responding to outbreaks and emerging infections and related adverse events among patients, healthcare providers, or associated with the healthcare environment; (3) detecting, evaluating, monitoring, and responding to emerging antimicrobial resistant pathogens and infections; (4) creating and evaluating the efficacy of new interventions designed to prevent infections/antimicrobial resistance, related adverse events, and medical errors; (5) promoting clinical microbiology laboratory quality; (6) promoting water quality in healthcare settings; (7) identifying effective interventions that prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors among patients and healthcare personnel; (8) promoting the nationwide implementation of these interventions; and (9) evaluating the impact of their implementation across the spectrum of healthcare delivery sites.

Office of the Director (CRM1). (1) Manages, directs, and coordinates the activities of the Division of Healthcare Quality Promotion (DHQP); (2) provides leadership and guidance on policy, program planning and development, program management, and operations; (3) provides DHQP-wide administrative and program services and coordinates or ensures coordination with the appropriate National Center for Infectious Diseases (NCID) and Centers for Disease Control and Prevention (CDC) staff offices on administrative and program matters; (4) provides liaison with other governmental agencies, international organizations, and other outside groups; (5) coordinates, in collaboration with the appropriate NCID and CDC components, global health activities relating to the prevention of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (6) manages the division local area network (LAN) and coordinates the evolving LAN design with the Information Resources Management Office and the NCID LAN administrator; (7) provides hardware and software support to DHQP personnel in response to the changing information technology environment; and (8) advises the Director, NCID, on policy matters concerning DHQP activities.

Epidemiology and Laboratory Branch (CRM2). (1) Coordinates rapid and effective epidemiologic and 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 (including consultation; organism recovery and identification; microbiologic, toxin, chemical, and molecular assays; and strain typing) for investigations of recognized and emerging bacterial agents (including those resistant to available antimicrobials) in healthcare settings; (3) implements surveillance and response systems to detect emerging threats, including those related to agents of bioterrorism, among patients and healthcare personnel; (4) investigates novel and emerging mechanisms of antimicrobial resistance among targeted pathogens found in healthcare settings; (5) conducts epidemiologic and basic and applied laboratory research to identify new strategies to prevent infections/antimicrobial resistance, related adverse events, and medical errors, especially those associated with indwelling medical devices, contaminated products, dialysis, and water; (6) evaluates the accuracy of commercial microbial identification and susceptibility testing systems and products through research and facilitates their improvement; (7) provides leadership in reducing microbiology laboratory errors that affect patient outcomes by evaluating laboratory proficiency and promoting laboratory quality improvements; (8) investigates the role of biofilms, particularly those detected in indwelling medical devices and medical water systems, in medicine and public health; and (9) in collaboration with other CDC Centers, Institutes, and Offices (CIOs) and partners, provides expertise (*e.g.* environmental sampling, microbial assays, environmental engineering, disinfection strategies), research opportunities, and laboratory support for investigations of environmental sources of infections and related adverse events, including those related to bioterrorism.

Epidemiology Section (CRM22). (1) Coordinates and ensures rapid and effective response to requests from state and local health departments and healthcare organizations for assistance with investigations of outbreaks and emerging threats associated with infections, antimicrobial resistance, and related adverse events throughout the healthcare delivery system; (2) provides comprehensive epidemiologic support (including detection systems, consultation, field investigation, risk factor evaluation, and control strategies) for investigations of recognized and emerging bacterial pathogens (including those resistant to available antimicrobials) in healthcare settings and potential bioterrorism events; (3) evaluates the relationship between bacterial strain characteristics and epidemiologic characteristics of pathogens associated with healthcare infections/antimicrobial resistance; and (4) develops and evaluates the efficacy of interventions designed to prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors across the spectrum of healthcare delivery sites.

Diagnostic Microbiology Section (CRM23). (1) Provides laboratory support and expertise for outbreak investigations and special studies of aerobic and anaerobic bacteria causing healthcare-associated infections; (2) evaluates the relationship between bacterial strain characteristics and epidemiologic characteristics of pathogens; (3) provides reference diagnostic services for identification and classification of the *Micrococcaceae*, many *Enterobacteriaceae*, and all anaerobic

bacteria; (4) develops, evaluates, and improves novel or existing laboratory methods for identifying and characterizing bacteria causing health-associated infections; (5) evaluates *in vitro* reagents and products that show public health promise in improving the identification and characterization of bacterial pathogens; (6) conducts biochemical, immunochemical, and genetic studies of bacterial pathogens to determine marker systems useful for epidemiologic purposes such as determining pathogenicity, or virulence; (7) provides reference diagnostic activities for detection of staphylococcal toxins in isolates obtained from clinical specimens and environmental sources, including those that may be associated with bioterrorism events; (8) serves as the World Health Organization (WHO) National Klebsiella Center; (9) manages the bacteriology laboratory component of the College of American Pathologists (CAP) proficiency testing program for NCID/CDC; and (10) provides leadership in laboratory quality improvement practices directed toward reducing laboratory errors that affect healthcare outcomes.

Environmental and Applied Microbiology Section (CRM24). (1) Provides laboratory support and expertise for epidemic evaluations, consultation, and field investigations of healthcare-associated infections involving medical devices, therapeutic or diagnostic products and devices, environmental reservoirs of microorganisms/pathogens, or issues involving water quality; (2) investigates and defines environmental factors associated with healthcare-associated infections/antimicrobial resistance and related adverse events that affect healthcare outcomes; (3) conducts basic and applied laboratory research to identify new strategies to prevent infections/antimicrobial resistance, related adverse events, and medical errors, especially those associated with indwelling medical devices, contaminated products, dialysis, and water; (4) investigates and defines the role of biofilms and develops and evaluates methods to control them in water distribution systems and on indwelling medical devices; (5) develops and evaluates reliable methods to detect and quantify bacterial endotoxin, bioterrorism agents associated with institutional outbreaks, and dialysis-associated diseases; (6) develops and evaluates reliable methods and protocols for the disinfection and sterilization of medical devices, formites, potable water, recreational water, and water associated with healthcare-associated infections/antimicrobial resistance, in collaboration with other NCID divisions, the Environmental Protection Agency (FDA), and the Food and Drug Administration (FDA); (7) provides laboratory and field capability in environmental microbiology, and collaborates with other NCID organizations in epidemic investigations, evaluation of bioterrorism events, and field studies requiring expertise in environmental microbiology; (8) serves as the NCID/CDC lead for information, recommendations, and technical support concerning environmental sterilization, disinfection, and disposal/handling of medical waste; and (9) serves as the NCID/CDC lead for information, recommendations, and technical support concerning dialysis-associated infections and related adverse events, sterilization and disinfection strategies, water quality, and bacterial endotoxins.

Anti-infectives Investigation Section (CRM25). (1) Provides laboratory support for investigations of antimicrobial-resistant infections conducted by DHQP Epidemic Intelligence Service (EIS) officers and staff; (2) provides reference antimicrobial susceptibility testing services to state health departments, healthcare organizations, and other laboratories; (3) evaluates and reports on the accuracy of commercial antimicrobial susceptibility testing methods; (4) develops and evaluates new methods for detecting bacterial resistance to antimicrobial agents, in collaboration with the National Committee for Clinical Laboratory Standards; (5) improves the proficiency of microbiology laboratories by providing quality control and proficiency testing organisms to clinical laboratories in the United States and throughout the world in cooperation with state health departments, Emory University Rollins School of Public Health, and the WHO; (6) serves as a WHO Collaborating Center on Global Antimicrobial Resistance Monitoring in Bacteria; (7) collaborates with state health departments to perform surveys of antimicrobial susceptibility testing procedures in clinical laboratories; (8) investigates the molecular basis of antimicrobial resistance in bacteria through DNA hybridization studies, DNA sequence analysis, iso-electric focusing, and other analytical methods; and (9) provides bacterial strain typing services to evaluate dissemination of resistant organisms.

Prevention and Evaluation Branch (CRM3). (1) Supports local, state, national, and international efforts to prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors using evidence-based recommendations and state-of-the art informatics and health communications strategies that enhance rapid and reliable information exchange; (2) develops and demonstrates the effectiveness of health communications, guidelines, recommendations, and other interventions to prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors across the spectrum of healthcare delivery sites; (3) promotes the implementation of effective guidelines, recommendations, and other interventions to prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (4) evaluates the impact of implementation of effective guidelines, recommendations, and other interventions on healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (5) provides consultation, guidance, and technical support to domestic and international partners on the prevention of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; and (6) develops and disseminates training tools and other strategies that enhance local capacity to protect patients and healthcare personnel and to promote quality healthcare.

Interventions and Evaluation Section (CRM32). (1) Collaborates with partners to promote healthcare safety, quality, and value across the spectrum of healthcare delivery sites; (2) coordinates the development of and disseminates evidence-based guidelines and recommendations to prevent and control healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (3) evaluates the effectiveness of interventions to prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (4) promotes the implementation and evaluates the impact of guidelines, recommendations, performance measurement systems, best practices, and other strategies to prevent healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (5) develops, implements, and evaluates the effectiveness and impact of interventions to prevent transmission of healthcare-associated human immunodeficiency virus (HIV) and

other bloodborne pathogen infections; and (6) develops, implements, and evaluates the effectiveness and impact of interventions to prevent the dissemination of infections endemic in the community (e.g., as tuberculosis and influenza) in healthcare settings.

Health Communications Section (CRM33). (1) With input from DHQP branches, NCID/CDC Centers, Institutes and Offices (CIO's), partners and stakeholders, develops, implements, and evaluates the effectiveness of the DHQP health communications strategic plan to (a) deliver effective messages to target audiences that protect patients, protect healthcare personnel, and promote quality healthcare and (b) inform patients, partners, the public, decision makers, and other constituents about these issues; (2) coordinates provision of DHQP technical support and consultation to partners and constituents on the prevention of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (3) develops and tests health communication materials in a variety of media, including but not limited to electronic and print; (4) develops and implements a real-time communication network for the delivery of information to intramural and extramural partners and stakeholders; (5) disseminates information to medical, technical, scientific, and lay audiences and news media about healthcare-associated infections/antimicrobial resistance, adverse events, and medical errors; (6) develops, coordinates, and maintains DHQP website; (7) develops and tests material, technologies, and strategies for training programs to prevent and control healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (8) develops and implements national health communication campaigns to promote the prevention and control of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors; (9) evaluates the effectiveness of DHQP's health communication strategies to determine the impact and contribution to prevention and control of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical; and (10) oversees DHQP's scientific and editorial clearance process for all print and non-print materials and ensures adherence to and consistency with CDC's scientific and editorial policies and clearance processes.

Healthcare Outcomes Branch (CRM4). (1) Evaluates the impact of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors on healthcare outcomes and costs in order to establish priorities for DHQP intervention programs; (2) improves methods to measure healthcare outcomes, performance, and cost-effectiveness of intervention strategies; (3) improves systems by which health organizations collect, manage, analyze, report, and respond to data on healthcare outcomes, healthcare-associated adverse events, and medical errors; (4) implements and coordinates the National Healthcare Safety Network (NHSN) (a representative sample of healthcare organizations that report data on targeted healthcare-associated adverse events and medical errors) to obtain locally relevant and scientifically valid benchmarks and performance measurements that promote healthcare quality and value; (5) provides national estimates of targeted adverse events and medical errors among selected populations of patients across the spectrum of healthcare delivery sites; and (6) provides national estimates of targeted occupational illnesses and injuries among healthcare workers across the spectrum of healthcare delivery sites.

Quality Research Section (CRM42). (1) Evaluates the impact of healthcare-associated infections/antimicrobial resistance, related adverse events, and medical errors on patient outcomes, healthcare costs, and resource utilization; (2) develops scientifically valid and locally relevant methods of risk adjustment for interpreting and comparing performance measures and healthcare outcomes and costs among targeted populations; (3) develops analytic methods to provide reliable national estimates of the frequency and impact of targeted adverse health events among patients and healthcare personnel; and (4) develops analytic methods to evaluate the relationship among healthcare structure, processes of care, and healthcare outcomes.

Performance Measurement Section (CRM43). (1) with collaborating partners, establishes, maintains, and expands the NHSN to collect, report, monitor, interpret, and disseminate data relevant to healthcare safety, quality, and value; (2) with collaborating partners, develops and validates standard definitions of monitored healthcare events in targeted populations and healthcare settings. These events may include medical device-associated infections/adverse events/errors, drug-associated adverse events/errors, antimicrobial use/misuse, blood product-associated infections/adverse events/errors, procedure-associated infections/adverse events/errors, laboratory-associated adverse events/errors, vaccine-preventable and antimicrobial-resistant infections, and occupational exposures and infections; (3) develops, implements, and validates protocols for reporting monitored health events in targeted populations and healthcare settings; (4) develops analytic tools to create performance measures and other locally relevant data to enhance quality promotion activities; (5) collaborates with NCID, other CDC CIOs, and other information system partners to ensure that the NHSN and related information systems adhere to relevant standards and emerging architecture for integrated surveillance and information management; (6) coorindates translation of NHSN functional specifications and CDC standards to software developers and maintains ongoing communication with developers as the system evolves; (7) coordinates NHSN data management, data warehousing, and analysis systems; (8) develops information system capacity and transfer protocols to acquire data from various existing databases and sources to provide national estimates of monitored adverse health events among patients and healthcare personnel; (9) develops, updates, and disseminates public use de-identified data sets relevant to healthcare outcomes, infections and other adverse events, and medical errors; (10) investigates novel strategies for data acquisition and electronic reporting of adverse event and relevant data from healthcare organization information systems; and (11) identifies novel strategies for electronic detection, automated reporting, and interpretation of healthcare-associated infections/antimicrobial resistance, related adverse health events, and medical errors.

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Jeffrey P. Koplan,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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AGENCY: Food and Drug Administration, HHS.