

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 81 FR 84583–84591, dated November 23, 2016) is amended to reflect the reorganization of the Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, Office of Infectious Disease, Centers for Disease Control and Prevention.

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

Delete and replace the title and the mission and function statements for the *Division of Viral Disease (CVGE)* and insert the following:

Division of Viral Disease (CVGE). The Division of Viral Diseases (DVD) prevents disease, disability, and death through immunization and by control of respiratory, enteric, and related viral diseases. In carrying out this mission, the DVD: (1) Conducts surveillance and related activities; supports and provides technical assistance to state and local health departments to conduct surveillance and related activities to monitor the impact of vaccination and other prevention programs; and determine patterns of infection and disease; (2) conducts epidemiologic and laboratory studies to define patterns of, and risk factors for, infection, disease, and disease burden; estimates vaccine effectiveness, determines cost effectiveness of vaccines, and evaluates other aspects of immunization practices; identifies and evaluates non-vaccine prevention strategies; and provides epidemiological and laboratory expertise to other Nation Centers (NCs), collaborators, and partners on vaccine and other prevention strategies; (3) provides consultation on viral vaccine preventable, respiratory, and enteric diseases, and the use of vaccines and other measures to prevent infections; (4) provides consultation and support and/or participates in investigations of national and international outbreaks of viral vaccine preventable and other respiratory and enteric viral diseases, and recommends appropriate control

measures; (5) provides scientific leadership and advice, analyzes available data, and develops science-based statements for viral vaccines to the Advisory Committee on Immunization Practices (ACIP) and other groups to support the development and evaluation of immunization practices and policies domestically and internationally; (6) provides laboratory support for surveillance and epidemiologic studies and maintains reference/diagnostic services and expertise; (7) conducts studies of immunology and pathogenesis of disease and the biology, biochemical, genetic and antigenic characteristics of the agents; (8) develops, evaluates, and improves diagnostic methods and reagents, and transfers assays and techniques to other public health laboratories; (9) facilitates and participates in the development and evaluation of antiviral compounds, vaccines, and vaccination programs; (10) provides and supports public health training; (11) responds to and assists internal and external partners on other public health problems of national and international significance, as needed; (12) provides technical support to state immunization programs for all aspects of vaccine-preventable diseases and their vaccines; (13) provides leadership in vaccine science; and (14) supports CDC's Immunization Safety Office in vaccine safety risk assessment and leadership in vaccine safety risk management.

Office of the Director (CVGE1). (1) Manages, directs, and coordinates the activities of the division; (2) provides leadership and guidance in policy formulation, program planning and development, program management, and operations of the division; (3) identifies needs and resources for ongoing and new initiatives and assigns responsibilities for their development; (4) prepares, reviews, and coordinates informational, scientific, and programmatic documents; (5) oversees the division's activities and expenditures; (6) assures the overall quality of the science conducted by the division; (7) provides overall guidance and direction for the division's surveillance, research, and other scientific and immunization activities; (8) provides overall guidance and direction for division's epidemiologic, laboratory, and outbreak response capacity and activities; (9) oversees and facilitates the division's scientific support to other groups within CDC, the national and international healthcare, and public health communities regarding viral respiratory and enteric

diseases and viral immunization programs; (10) guides and facilitates efficient coordination and cooperation for administrative, programmatic, and scientific activities within the division and with other groups inside and outside of CDC; and (11) provides division leadership, expertise, and technical collaboration for the application of statistics, economics, operations research, geography, other quantitative sciences, and data management to prevent disease, disability and death through immunization and control of respiratory, enteric, and related viral diseases.

Analysis and Data Management Activity (CVGE12). (1) Coordinates quantitative science and data management planning, policy development, and project monitoring and evaluation; (2) designs and develops statistical, economic, cost, resource allocation, geospatial and data management strategies, models, and methodologies in the public health arena; and (3) collaborates with scientists, program experts, and senior public health officials throughout the division to implement these strategies, models, and methodologies in support of respiratory, enteric and related viral diseases surveillance and prevention studies, prevention resource allocation issues, and prevention program activities.

Respiratory Viruses Branch (CVGEB). (1) Conducts surveillance, laboratory assistance, and related activities, and supports and provides technical assistance to state and local health departments to conduct surveillance and related activities to monitor the impact of prevention programs, and determine patterns of infection and disease; (2) conducts and provides laboratory support and expertise for epidemiologic and laboratory studies to define patterns of and risk factors for infection, disease, and disease burden; (3) provides epidemiology and laboratory consultation and support and/or participates in investigations of national and international outbreaks of viral respiratory diseases, and recommends appropriate control measures; (4) provides scientific, both epidemiologic and laboratory, leadership and advice; (5) analyzes available data, and develops science-based statements for potential respiratory viral vaccines to the ACIP and other groups to support the development and evaluation of immunization practices and policies in the U.S and internationally; (6) provides and supports public health training; (7) responds to and assists internal and

external partners on other public health problems of national and international significance, as needed; (8) provides laboratory support for surveillance and epidemiologic studies and maintains reference/diagnostic services and expertise; (9) conducts studies of immunology and pathogenesis of disease and the biology, biochemical, genetic, and antigenic characteristics of the agents; (10) develops, evaluates, and improves diagnostic methods and reagents, and transfers assays and techniques to other public health laboratories and provides and supports laboratory training; (11) facilitates and participates in the development and evaluation of antiviral compounds, vaccines, and vaccination programs; and (12) responds to and assists internal and external partners on other public health problems of national and international significance as needed.

Polio and Picornavirus Laboratory Branch (CVGEC). (1) Provides laboratory assistance, technical expertise and support for surveillance and related activities to monitor impact of vaccination and other prevention programs, and determine patterns of infection and disease; (2) provides laboratory support and technical expertise for epidemiologic and laboratory studies to define patterns and risk factors for infection, disease, and disease burden; (3) studies vaccine-related issues; (4) identifies and evaluate non-vaccine prevention strategies; (5) provides laboratory consultation and technical expertise regarding use of vaccines and other measures to prevent infections to other NCs, collaborators, and partners; (6) provides laboratory consultation and support and/or participates in investigations of national and international outbreaks of viral vaccine preventable and other respiratory and enteric viral diseases; (7) provides laboratory leadership and technical expertise to develop science-based statements to Global Polio Eradication Initiative, the ACIP, and other groups to support the development and evaluation of immunization practices and policies in the U.S and internationally; (8) provides epidemiology and laboratory consultation and support and/or participates in investigations of national and international outbreaks of viral respiratory diseases, and recommends appropriate control measures; (9) provides scientific, both epidemiologic and laboratory, leadership and advice; (10) provides laboratory support for surveillance and epidemiologic studies and maintains reference/diagnostic services and expertise; (11) conducts

studies of immunology and pathogenesis of disease and the biology, biochemical, genetic, and antigenic characteristics of the agents; (12) develops, evaluates, and improves diagnostic methods and reagents, transfers assays and techniques to national and international public health laboratories, and provides and supports training for laboratorians; (13) facilitates and participates in the development and evaluation of antiviral compounds, vaccines, and vaccination programs; (14) responds to and assists internal and external partners on other public health problems of national and international significance as needed; and (15) serves as the National Reference Laboratory (poliovirus and enteroviruses), World Health Organization (WHO) Collaborating Center for Poliovirus and Enteroviruses Virus Reference and Research, and WHO Global Specialized Polio Reference Laboratory.

Viral Vaccine Preventable Diseases Branch (CVGED). (1) Conducts surveillance, provides laboratory assistance, technical expertise, and support for surveillance and related activities to monitor the impact of vaccination on the prevention of viral disease and to determine patterns of infection and disease; (2) conducts epidemiologic and laboratory studies to define patterns of and risk factors for infection, disease, and disease burden; (3) estimates vaccine effectiveness, evaluates other aspects of immunization practices; (4) identifies and evaluates non-vaccine prevention strategies; (5) provides epidemiological and laboratory expertise and technical support to other NCs, collaborators, and partners across center working groups on vaccines and other prevention strategies; (6) supports the development of vaccine practices and policies by providing consultation and epidemiologic and laboratory expertise to other federal agencies, state health departments, ministries of health, WHO, PAHO, private industry, academia and other governmental organizations on viral vaccine preventable diseases, and on the use of vaccines and other measures to prevent infections; (7) provides laboratory consultation and support and/or participates in investigations of national and international outbreaks of viral vaccine preventable diseases and recommends appropriate control measures; (8) assists internal and external partners on other public health problems of national and international significance; (9) provides scientific leadership and advice, analyzes available data, and develops science-based statements for viral vaccines to

the ACIP and other groups to support the development and evaluation of immunization practices and policies in the U.S and internationally; (10) responsible for human papilloma virus (HPV), measles, mumps, rubella (MMR), domestic polio, zoster, and varicella vaccine policy in the United States by working with ACIP; (11) provides and supports public health training; (12) responds to public inquires and prepares communication materials; (13) works with health economists to determine cost effectiveness of vaccination strategies; (14) provides laboratory support for surveillance and epidemiologic studies and maintains reference and diagnostic services and expertise; (15) assists in investigation of adverse events following vaccination; (16) conducts studies of immunology and pathogenesis of disease and the biological, biochemical, genetic, and antigenic characteristics of viral agents; (17) develops, evaluates, and improves diagnostic methods and reagents; (17) transfers assays and techniques to other public health laboratories; (18) provides and supports laboratory training; (19) serves as the National Reference Laboratory for MMR, and varicella zoster virus and the PAHO Regional and WHO Global Specialized Laboratory for measles and rubella; and (20) works closely with the laboratory that handles HPV to define and conduct epidemiologic investigations.

Viral Gastroenteritis Branch (CVGEE) (1) Provides epidemiologic and laboratory assistance studies and related activities to better understand the evolution, (molecular) epidemiology and immunity of rotavirus, norovirus and other gastroenteritis viruses; (2) provides consultation on the safety and impact of rotavirus vaccination and other prevention programs (rotavirus, norovirus); (3) provides consultation and technical assistance to state and local health departments to monitor the burden of disease and epidemiology of gastroenteritis virus infections (rotavirus, norovirus); (4) provides consultation and support on the research and development of new rotavirus vaccines and other prevention technologies; (5) provides consultation and support and/or participates in investigations of national and international outbreaks of viral vaccine preventable and other enteric viral diseases, and recommends appropriate control measures; (6) provides scientific leadership and advice, analyzes available data, and develops science-based statements for rotavirus vaccines to the ACIP and other groups to support the development and evaluation of

immunization practices and policies in the U.S and internationally; (7) provides and supports public health training; (8) responds to and assists internal and external partners on other public health problems of national and international significance, as needed; (9) serves as the National Reference Laboratory (rotavirus and norovirus) and other agents of viral gastroenteritis; and (10) serves as the WHO Global Reference Center for Rotavirus and other agents of viral gastroenteritis.

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

Delete in its entirety the title for the *Center for Surveillance, Epidemiology and Laboratory Service (CPN)* and insert the following title which includes the Oxford comma: *Center for Surveillance, Epidemiology, and Laboratory Service (CPN)*.

Delete in its entirety the title and the mission and function statements for the *Division of Laboratory Systems (CPNB)* and insert the following:

Division of Laboratory Systems (CPNB). The mission of the Division of Laboratory Systems (DLS) is to strengthen the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency.

Office of the Director (CPNB1). (1) Provides leadership and guidance on

development of strategic goals, objectives, and milestones to advance the vision and mission of the Division of Laboratory Systems (DLS), the Center for Surveillance Epidemiology and Laboratory Services (CSELS), and CDC; (2) ensures optimal planning and allocation of resources to achieve program objectives, conducts management and operations analyses, and oversees required reporting; (3) provides administrative management support, advice, and guidance to DLS regarding administrative policies, fiscal management, property management, human resources, and travel; (4) leads coordination and stewardship of DLS procurement, grants, cooperative agreements, materials management, interagency agreements, and extramural resources; (5) fosters collaborations and cross-cutting activities with other CDC components and external organizations to support the mission, activities, and operations of DLS; (6) enhances internal and external partnerships and partner/stakeholder communication; (7) provides leadership in evaluating and improving program performance, monitoring progress and accomplishments to ensure that programmatic goals are achieved with measurable impact; (8) manages issues, policy development, and tracks regulatory and legislative activities; (9) manages CDC Specimen Policy Board and the CDC/ATSDR Specimen Packaging, Inventory, and Repository (CASPIR) Advisory Committee; (10) collaborates with leadership of the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) in advancement of the Clinical Laboratory Improvement Amendments (CLIA) program and oversees CDC responsibilities therein; (11) provides scientific oversight for DLS, performing scientific review and clearance for DLS publications, presentations, and reports; (12) provides DLS communications, Web support, responses to media requests, and communication outreach efforts; and (13) coordinates requests from other CDC programs for international technical assistance among DLS capabilities.

Training and Workforce Development Branch (CPNBC). (1) Provides leadership and support of laboratory workforce through initiatives that strengthen recruitment, retention, management, and training; (2) supports the development, promotion, adoption, and implementation of competencies relevant to the laboratory workforce; (3) develops frameworks, models, and resources that support competency-

based laboratory training, fellowships, and education; (4) engages agency and laboratory community experts to collaboratively assess and develop effective training products to maintain a competent, prepared, and sustainable national and global laboratory workforce; (5) designs and implements training pertaining to clinical and public health laboratory methodology, technology, quality and safety and practice for public health, clinical, CDC, and other federal agency laboratory professionals; and (6) evaluates the efficiency and effectiveness of public health laboratory education and training, including measuring the outcomes of all training to ensure the effective transfer of knowledge and skills to improved laboratory practice.

Quality and Safety Systems Branch (CPNBD). (1) Develops, promotes, implements, and evaluates intervention strategies to improve quality and safety in clinical and public health laboratory systems; (2) provides scientific and technical support for the Clinical Laboratory Improvement Amendments (CLIA) program to assure the quality, including safety, of clinical and public health laboratory testing nationwide; (3) facilitates and conducts studies to provide scientific evidence and assess the impact of CLIA regulations and voluntary guidelines for laboratory quality and safety; (4) provides expertise and guidance in the development or revision of CLIA technical standards and voluntary guidelines for laboratory quality and safety, especially in light of new and evolving laboratory technology and practices; (5) develops, disseminates, promotes, and evaluates the impact of educational materials to support the understanding of and compliance with CLIA regulations and voluntary quality and safety guidelines; (6) hosts and manages the Clinical Laboratory Improvement Advisory Committee (CLIAC) and its workgroups on behalf of a tri-agency partnership among CDC, CMS, and FDA; (7) provides information to the laboratory medicine and public health communities, as well as policy makers, regarding the interpretation and application of the CLIA technical standards and other issues of laboratory quality and safety; (8) provides technical assistance in the review of laboratory accreditation and state licensure programs, and CLIA-approved proficiency testing programs; (9) facilitates and supports collaborations with federal partners and other stakeholders (including other CDC programs upon request) for the exchange of information about