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SUPPLEMENTARY INFORMATION: FDA held a workshop on “Clinical Trial Designs in Emerging Infectious Diseases” in partnership with the National Institute of Allergy and Infectious Diseases, the HHS Office of the Assistant Secretary for Preparedness and Response, and the Centers for Disease Control and Prevention as a step in collecting information. The objectives of the workshop were to: (1) Discuss the deployment of investigational products in the context of emerging infectious diseases, drawing on the lessons learned in the Ebola virus epidemic; (2) explore the strengths and weaknesses of different clinical trial designs for establishing the safety and efficacy of investigational products for the treatment and/or prevention of life-threatening emerging infectious diseases (EID) in resource-limited settings from scientific, ethical, and operational perspectives; (3) identify areas of consensus and areas needing further discussion, with the goal of formulating acceptable options for the deployment of investigational products in clinical trials for future EIDs; and (4) discuss planning and other factors that can impact on the ability to establish clinical trials in a timely fashion to evaluate investigational therapies. The meeting agenda, transcripts, and web cast recordings are available on the FDA Web site at <http://www.fda.gov/emergency-preparedness-counterterrorism-medical-countermeasures/about-mcmi/ucm466153.htm>. The meeting agenda and transcripts will also be available in the docket.

FDA is opening this docket to provide an avenue for the public to submit additional information that may be relevant to the design and conduct of clinical trials for establishing the safety and efficacy of investigational products for the treatment and/or prevention of life-threatening emerging infectious diseases. Individuals submitting comments are specifically invited to address the scientific, ethical, and practical considerations that should be taken into account when designing and implementing clinical trials for future emerging infectious diseases in resource-limited settings.

Dated: December 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-32724 Filed 12-28-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 66545–66546 dated October 29, 2015).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Bureau of Health Workforce (RQ). Specifically, this notice: (1) Abolishes the Office of Workforce Development and Analysis (RQA); (2) abolishes the Office of Health Careers (RQB); and (3) updates the functional statement for the Bureau of Health Workforce (RQ).

Chapter RQ—Bureau of Health Workforce

Section RQ-10, Organization

Delete the organizational structure for the Bureau of Health Workforce (RQ) and replace in its entirety.

The Bureau of Health Workforce is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration.

1. Office of the Associate Administrator (RQ);
2. Division of Policy and Shortage Designation (RQ1);
3. Division of Business Operations (RQ2);
4. Division of External Affairs (RQ3);
5. National Center for Health Workforce Analysis (RQ4);
6. Division of Medicine and Dentistry (RQ5);
7. Division of Nursing and Public Health (RQ6);
8. Division of Practitioner Data Bank (RQ7);
9. Division of Participant Support and Compliance (RQ8);
10. Division of Health Careers and Financial Support (RQ9);
11. Division of National Health Service Corps (RQC); and
12. Division of Regional Operations (RQD).

Section RQ-20, Functions

Delete the functional statement for the Bureau of Health Workforce (RQ) and replace in its entirety.

This notice reflects organizational changes in Bureau of Health Workforce (RQ). Specifically, this notice: (1) Abolish the Office of Workforce Development and Analysis; (RQA); (2) abolishes the Office of Health Careers (RQB); and (3) updates the functional statement for the Bureau of Health Workforce (RQ).

Bureau of Health Workforce (RQ)

The Bureau of Health Workforce (BHW) improves the health of the nation’s underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation’s health care workforce. BHW programs support a diverse, culturally competent workforce by addressing components including: Education and training; recruitment and retention; financial support for students, faculty, and practitioners; supporting institutions; data analysis; and evaluation and coordination of health workforce activities. These efforts support development of a skilled health workforce serving in areas of the nation with the greatest need.

Office of the Associate Administrator (RQ)

The Office of the Associate Administrator provides overall leadership, direction, coordination, and planning in support of the BHW’s programs designed to help meet the health professions workforce needs of the nation and improve the health of the nation’s underserved communities and vulnerable populations. The office guides and directs the bureau’s workforce analysis efforts and provides guidance and support for advisory councils. Additionally, the office provides direction by coordinating the recruitment, education, training, and retention of diverse health professionals in the healthcare system and supporting communities’ efforts to build more integrated and sustainable systems of care. Specifically: (1) Directs and provides policy guidance for workforce recruitment, student and faculty assistance, training, and placement of health professionals to serve in underserved areas; (2) directs the bureau’s health professions workforce data collection and analysis efforts in support of BHW’s programs, and provides oversight for the evaluation of grantee performance and program outcomes; (3) guides and supports work

of advisory councils, and coordinates the bureau's Federal Advisory Committees' management activities; (4) provides leadership, and guides bureau programs in recruiting and retaining a diverse workforce; (5) establishes program goals, objectives, and priorities, and provides oversight as to their execution; (6) maintains effective relationships within HRSA and with other federal and nonfederal agencies, state, and local governments, and other public and private organizations concerned with health workforce development and improving access to health care for the nation's underserved; (7) represents the bureau, agency, and federal government, as designated, on national committees maintaining effective relationships within HRSA and with other federal and non-federal agencies, state and local governments, and other public and private organizations concerned with health personnel development, and improving access to health care for the nation's underserved; (8) plans, directs, coordinates, and evaluates bureau-wide management activities, *i.e.*, budget, personnel, procurements, delegations of authority, and responsibilities related to the awarding of the BHW funds; and (9) coordinates, reviews, and provides clearance of correspondence and official documents entering and leaving the bureau.

Executive Office (RQ)

The Executive Office collaborates with BHW leadership to plan, coordinate, and direct bureau-wide administrative management activities. Specifically: (1) Executes the bureau's budget; (2) provides human resource services regarding all aspects of personnel management, workforce planning, and the allocation and utilization of personnel resources; (3) coordinates the business management functions for the bureau's grants programs; (4) plans, directs, and coordinates bureau-wide administrative management activities, *i.e.*, budget, personnel, procurements, delegations of authority, and responsibilities related to the awarding of BHW funds; (5) coordinates and supports the Bureau's quality and internal control efforts; (6) provides additional support services including the acquisition, management, and maintenance of supplies, equipment, space, training, and travel; and (7) assumes special projects or takes responsibility for issues as tasked by the bureau's leadership.

Division of Policy and Shortage Designation (RQ1)

The Division of Policy and Shortage Designation serves as the focal point for the development of the BHW programs and policies. Specifically: (1) Leads and coordinates the analysis, development, and drafting of policies impacting bureau programs; (2) coordinates program planning, and tracking of legislation and other information related to BHW's programs; (3) directly supports national efforts to analyze and address equitable distribution of health professionals for access to health care for underserved populations; (4) reviews requests for and designates health professional shortage areas and medically-underserved areas and populations; (5) finalizes designation policies and procedures for both current and proposed designation criteria; (6) oversees grants to state primary care offices and conducts all business management aspects of the review, negotiation, award, and administration of these grants; (7) provides oversight, processing, and coordination for the HHS sponsored J1-visa program; (8) works collaboratively with other components within HRSA and HHS, and with other federal agencies, state, and local governments, and other public and private organizations on issues affecting BHW's programs and policies; (9) performs environmental scanning on issues that affect BHW's programs and assesses the impact of programs on underserved communities; (10) monitors BHW's activities in relation to HRSA's strategic plan; (11) develops budget projections and justifications; and (12) serves as the bureau's focal point for program information.

Division of Business Operations (RQ2)

The Division of Business Operations serves as the focal point for the bureau's data management systems, reports, data analysis, and automation of business processes to support the administration of BHW programs. Specifically: (1) Provides leadership for implementing BHW's systems development, enhancement, and administration; (2) designs and implements data systems to assess and improve program performance; (3) provides user support and training to facilitate the effectiveness of the bureau's information systems and deliver excellent customer service to internal and external stakeholders; and (4) ensures that data management systems and other tools continue to evolve to support changes to program policy, process, and data throughout the bureau.

Division of External Affairs (RQ3)

The Division of External Affairs provides communication and public affairs expertise to the bureau and serves as the focal point for the development of all external communication as well as dissemination of public information and promotional materials in support of the bureau's programs and activities. Specifically the division: (1) Leads, coordinates, and conducts outreach and engagement strategies for various audiences including students, clinicians, health care sites, and critical shortage facilities, as well as workforce grantees and applicants; (2) coordinates and conducts the bureau's virtual events for clinicians, grantees, sites, and applicants; (3) establishes and manages partner collaborations with national organizations and academic institutions; (4) develops and implements communication initiatives to promote the bureau's programs to target audiences; and (5) maintains responsibility for all targeted communication initiatives.

National Center for Health Workforce Analysis (RQ4)

The National Center for Health Workforce Analysis is the focal point for the coordination and management of the bureau's health professions workforce data collection, analysis, and evaluation efforts. The National Center for Health Workforce Analysis leads and monitors the development of workforce projections relating to BHW programs and acts as a national resource for such information and data.

Division of Medicine and Dentistry (RQ5)

The Division of Medicine and Dentistry serves as the bureau's lead for the program administration and oversight of medical and dental programs. Specifically: (1) Administers grants to educational institutions and other eligible organizations for the development, improvement, and operation of educational programs for primary care physicians (pre-doctoral, residency), physician assistants, dentists and dental hygienists, including support for community-based training and funding for faculty development to teach in primary care specialties training; (2) provides technical assistance and consultation to grantee institutions and other governmental and private organizations on the operation of these educational programs; (3) evaluates programmatic data and promotes the dissemination and application of findings arising from

supported programs; (4) collaborates within the bureau to identify and support analytical studies to determine the present and future supply and requirements of physicians, dentists, dental hygienists, and physician assistants by specialty, geographic location, and for state planning efforts; (5) encourages community-based training opportunities for primary care providers, particularly in underserved areas; (6) provides leadership and staff support for the Advisory Committee on Training in Primary Care Medicine and Dentistry, Advisory Committee on Interdisciplinary Community-Based Linkages, and for the Council on Graduate Medical Education; and (7) represents the bureau, agency, and federal government, as designated, on national committees maintaining effective relationships within HRSA and with other federal and non-federal agencies, state and local governments, and other public and private organizations concerned with health personnel development, and improving access to health care for the nation's underserved.

Division of Nursing and Public Health (RQ6)

The Division of Nursing and Public Health serves as the bureau's lead for the administration and oversight of nursing, behavioral and public health programs. Specifically: (1) Administers grants and provides technical assistance to educational institutions and other eligible entities in support of nursing education, practice, retention, diversity, and faculty development; (2) administers grants and provides technical assistance to educational institutions and other eligible entities in support of behavioral and public health education and practice; (3) addresses nursing workforce shortages through projects that focus on expanding enrollment in baccalaureate programs, and develops internships, residency programs, and other training mechanisms to improve the preparation of nurses, and behavioral and public health professionals, providing care for underserved populations; (4) collaborates within the bureau to identify and support analytical studies to determine the present and future supply and requirements for nurses, and behavioral and public health professionals; (5) evaluates programmatic data and promotes the dissemination and application of findings arising from supported programs; (6) provides staff support, and the Director, on behalf of the Secretary, serves as the Chair of the National Advisory Council on Nurse Education

and Practice; and (7) represents the bureau, agency, and federal government, as designated, on national committees maintaining effective relationships within HRSA and with other federal and non-federal agencies, state and local governments, and other public and private organizations concerned with health personnel development, and improving access to health care for the nation's underserved.

Division of Practitioner Data Bank (RQ7)

The Division of Practitioner Data Bank coordinates with the department and other federal entities, state licensing boards, national, state, and local professional organizations, to promote quality assurance efforts and deter fraud and abuse by administering the National Practitioner Data Bank (NPDB). Specifically, the division: (1) Monitors adverse licensure information on all licensed health care practitioners and health care entities; (2) develops, proposes, and monitors efforts for (a) credentialing assessment, granting of privileges, monitoring and evaluating programs for physicians, dentists, other health care professionals, (b) professional peer review to promote an evaluation of the competence, professional conduct, or the quality and appropriateness of patient care provided by health care practitioners, and (c) risk management and utilization reviews; (3) encourages and supports evaluation and demonstration projects and research using NPDB data on medical malpractice payments and adverse actions taken against practitioners' licenses, clinical privileges, professional society memberships, and eligibility to participate in Medicare/Medicaid; (4) ensures integrity of data collection, follows all disclosure procedures without fail; (5) conducts and supports research based on the NPDB data; (6) maintains active consultative relations with professional organizations, societies, and federal agencies involved with the NPDB; (7) works with the Secretary's office to provide technical assistance to states undertaking malpractice reform; and (8) maintains effective relations with the Office of the General Counsel, the Office of the Inspector General, and HHS concerning practitioner licensing and data bank issues.

Division of Participant Support and Compliance (RQ8)

The Division of Participant Support and Compliance serves as the organizational focal point for the bureau's centralized, comprehensive customer service function to support individual program participants. The

Division provides regular and ongoing communication, technical assistance, and support to program participants through the period of obligated service and closeout. Specifically: (1) Manages the staff and daily operations of the bureau's centralized customer service function; (2) initiates contact with and monitors program participants throughout their service; (3) manages clinician support, employment verification, site status changes/transfers, in-service reviews; (4) provides oversight and approval of the default, suspension, and waiver processes; (5) oversees the approval process and response for exception requests and congressional inquiries; (6) manages the 6-month verification process; (7) conducts closeout activities for each program participant and issues completion certificates; (8) manages the monthly payroll for NURSE Corps Loan Repayment Program participants; and (9) maintains program participants' case files in the bureau's management information system.

Division of Health Careers and Financial Support (RQ9)

The Division of Health Careers and Financial Support serves as the point of contact for responding to inquiries; disseminating program information; providing technical assistance; administering grants, developing appropriate policies and procedures; and processing applications and awards pertaining to health workforce scholarship, loan, loan repayment, and pipeline development programs. Specifically: (1) Reviews, ranks, and selects participants and grantees for NURSE Corps, Faculty Loan Repayment Program, Native Hawaiian Health Scholarship Program, and other discretionary grant programs that provide scholarships, loans, and loan repayment to students, health professionals and faculty; (2) verifies and processes loan and lender related payments in prescribed manner and maintains current information on NURSE Corps and other scholarship, loan, and loan repayment applications and awards through automated BHW information systems; (3) manages NURSE Corps scholar in-school activities; (4) facilitates NURSE Corps scholar placement; and (5) administers grants and provides technical assistance to educational institutions and other eligible entities for the development of a diverse and culturally competent health workforce.

Division of National Health Service Corps (RQC)

The Division of National Health Service Corps serves as the point of contact for responding to inquiries, disseminating program information, providing technical assistance, and processing applications and awards pertaining to the NHSC scholarship and loan repayment programs. Specifically: (1) Reviews, ranks, and selects participants for the scholarship and loan repayment programs; (2) verifies and processes loan and lender related payments in prescribed manner and maintains current information on scholarship and loan repayment applications and awards through automated BHW information systems; (3) manages scholar in-school and post-graduate training activities; (4) administers the NHSC State Loan Repayment Program; and (5) provides leadership and staff support for the NHSC National Advisory Committee.

Division of Regional Operations (RQD)

The Division of Regional Operations serves as the regional component of BHW, cutting across divisions and working with the bureau programs that fund participants to serve in Health Professions Shortage Areas. Specifically, the Regional Offices support the bureau by: (1) Providing support for the recruitment and retention of primary health care providers in Health Professions Shortage Areas; (2) coordinating with state and regional level partners and stakeholders, and health professions schools in support of the BHW programs and initiatives; (3) reviewing and approving/disapproving NHSC site applications and recertification's; (4) completing NHSC site visits and providing technical assistance to sites; and (5) managing the scholar placement process.

Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: December 11, 2015.

James Macrae,

Acting Administrator

[FR Doc. 2015-32749 Filed 12-28-15; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute on Aging; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group Behavior and Social Science of Aging Review Committee.

Date: February 4–5, 2016.

Time: 3:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Kimberly Firth, Ph.D., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue Suite 2C212, Bethesda, MD 20892, 301-402-7702 kimberly.firth@nih.gov.

Name of Committee: National Institute on Aging Initial Review Group Neuroscience of Aging Review Committee.

Date: February 4–5, 2016.

Time: 4:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Jeannette L. Johnson, Ph.D., Deputy Review Branch Chief, National Institutes of Health, National Institute on Aging Gateway Building Bethesda, MD 20892, 301-402-7705 johnsonj9@nia.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 22, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-32660 Filed 12-28-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Cancer Institute; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant and contract applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant and contract applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Omnibus R03 & R21 SEP-2.

Date: February 1–2, 2016.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Eun Ah Cho, Ph.D., Scientific Review Officer, Special Review Branch Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Bethesda, MD 20892-9750, 240-276-6342, choe@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Validation of Mobile Technologies for Clinical Assessment, Monitoring and Intervention.

Date: February 2, 2016.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 5E030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Scott A. Chen, Ph.D., Scientific Review Officer, Research and Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W604, Rockville, MD 20850, 240-276-6038, chensc@mail.nih.gov,

Name of Committee: National Cancer Institute Special Emphasis Panel; Modulating Microbiome for Cancer Therapy.

Date: February 17, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W554, Rockville, MD 20850, (Telephone Conference Call).