

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Designation Planning and Preparation	54	57	3,078	23.40	72,025.20
SDMS Application	54	57	3,078	11.33	34,873.74
Total	54	57	3,078	34.73	106,898.94

Jackie Painter,

Director, Division of the Executive Secretariat.

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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), Office of the Administrator (RA), Office of Planning, Analysis and Evaluation (RA5) and the Bureau of Health Workforce (RQ). Specifically, this notice: (1) Establishes the Office of Global Health (RAI) within the Office of the Administrator (RA); (2) transfers the function of the Office of Global Health Affairs (RQA1) from the Bureau of Health Workforce to the Office of the Administrator (RA); (3) transfers the Border Health function from the Office of External Engagement (RA57) within the Office of Planning, Analysis and Evaluation (RA5) to the Office of Global Health (RAI); (4) abolishes the Office of Global Health Affairs (RQA1) within the Bureau of Health Workforce (RQ); and (5) updates the functional statement for the Bureau of Health Workforce (RQ), Office of Planning, Analysis and Evaluation (OPAE) and the Office of the Administrator (RA).

Chapter RA—Office of the Administrator (RA)

Section RA–10, Organization

Delete the organizational structure for the Office of the Administrator (RA) and replace in its entirety.

The Office of the Administrator is headed by the Administrator, who reports directly to the Secretary, Department of Health and Human Services.

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Legislation (RAE);
- (3) Office of Communications (RA6);
- (4) Office of Health Equity (RAB);
- (5) Office of Equal Opportunity, Civil Rights, and Diversity Management (RA2);
- (6) Office of Planning, Analysis and Evaluation (RA5);
- (7) Office of Women's Health (RAW); and
- (8) Office of Global Health (RAI).

Section RA–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of the Administrator (RA), Office of Planning, Analysis and Evaluation (RA5). Specifically, this notice: (1) Transfers the function of the Office of Global Health Affairs (RQA1) to the Office of the Administrator (RA); (2) transfers the Border Health function from the Office of External Engagement (RA57) within the Office of Planning, Analysis and Evaluation (RA5) to the Office of Global Health (RAI); and (3) updates the functional statement for the Bureau of Health Workforce (RQ), the Office of Planning, Analysis and Evaluation (RA5) and the Office of the Administrator (RA).

Office of the Administrator (RA)

- (1) Leads and directs programs and activities of the Agency and advises the Office of the Secretary of Health and Human Services on policy matters concerning them; (2) provides consultation and assistance to senior Agency officials and others on clinical and health professional issues; (3) serves as the Agency's focal point on efforts to strengthen the practice of public health as it pertains to the HRSA mission; (4) establishes and maintains verbal and written communications with health organizations in the public and private sectors to support the mission of HRSA; (5) coordinates the

Agency's strategic, evaluation and research planning processes; (6) manages the legislative and communications programs for the Agency; (7) administers HRSA's equal opportunity and civil rights activities; (8) provides overall leadership, direction, coordination, and planning in the support of the Agency's special health programs; (9) manages the health, wellness, and safety of women and girls with the support of the Office of Women's Health, through policy, programming and outreach education; and (10) provides leadership within HRSA for the support of global health and coordinates policy development with the HHS Office of Global Affairs, other departmental agencies, bilateral/multilateral organizations, and other international organizations and partners.

Office of Global Health (RAI)

The Office of Global Health serves as the principal advisor to the Administrator on global health issues. Specifically: (1) Provides leadership, coordination, and advancement of global health programs relating to sustainable health systems for vulnerable and at-risk populations and for HRSA training programs; (2) provides support for the agency's international travel and the Department of State's International Visitors Leadership Program; (3) provides management and oversight of international programs aimed at -improving quality and innovation in human resources for health, health professions recruitment, education, faculty development, retention, and applied research systems; (3) provides leadership within HRSA for the support of global health and coordinates policy development with the HHS Office of Global Affairs, other departmental agencies, bilateral/multilateral organizations, and other international organizations and partners; (4) monitors HRSA's border health activities and investments to promote collaboration and improve health care access to those living along the U.S.-Mexico border; and (5) supports and conducts programs

associated with the international migration and recruitment of health personnel, foreign and immigrant health workers, and veterans.

Office of External Engagement (RA57)

(1) Serves as the principal Agency resource for facilitating external engagement; (2) coordinates the Agency's intergovernmental activities; (3) provides the Administrator with a single point of contact on all activities related to important state and local government, stakeholder association, and interest group activities; (4) coordinates Agency cross-Bureau cooperative agreements and activities with organizations such as the National Governors Association, National Conference of State Legislature, Association of State and Territorial Health Officials, National Association of Counties, and National Association of County and City Health Officials; (5) interacts with various commissions such as the Delta Regional Authority, Appalachian Regional Commission, and Denali Commission; (6) serves as the primary liaison to Department intergovernmental staff; and (7) serves as the Agency liaison to manage and coordinate study engagements with the Government Accountability Office and the HHS Office of the Inspector General, Office of Evaluation and Inspections.

Chapter RQ—Bureau of Health Workforce (RQ)

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) Office of Workforce Development and Analysis (RQA);
- (6) National Center for Health Workforce Analysis (RQA2);
- (7) Division of Medicine and Dentistry (RQA3);
- (8) Division of Nursing and Public Health (RQA4);
- (9) Division of Practitioner Data Bank (RQA5);
- (10) Office of Health Careers (RQB);
- (11) Division of Participant Support and Compliance (RQB1);
- (12) Division of Health Careers and Financial Support (RQB2);

- (13) Division of National Health Service Corps (RQB3); and
- (14) Division of Regional Operations (RQB4).

Section RQ-20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Bureau of Health Workforce (RQ). Specifically, this notice: (1) Transfers the function of the Office of Global Health Affairs (RQA1) to the Office of the Administrator (RA); and (2) updates the functional statement for the Bureau of Health Workforce (RQ) and the Office of the Administrator (RA).

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.

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 8, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015-31594 Filed 12-15-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA-2015-D-3638]

Minutes of Institutional Review Board Meetings: Guidance for Institutions and Institutional Review Boards; Draft Guidance; Extension of the Comment Period

AGENCY: The Office for Human Research Protections, Office of the Assistant

Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are extending the comment period for the draft guidance entitled "Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs." A notice of availability requesting comments on the draft guidance document appeared in the **Federal Register** of November 5, 2015. The Agencies are taking the initiative to extend the comment period for an additional 30 days because the timing of the due date for comments intersects with comment periods on other **Federal Register** documents requiring review by the same group of stakeholders. This extension will allow interested persons additional time to submit comments.

DATES: OHRP and FDA are extending the comment period on the draft guidance entitled "Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs." Submit either electronic or written comments by February 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the