DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Medical Device Quality System Regulation Educational Forum on Risk Management Through the Product Life Cycle; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled ''Medical Device Quality System Regulation Educational Forum on Risk Management through the Product Life Cycle.'' This public workshop is intended to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

Date and Time: The public workshop will be held on April 2, 2010, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the new Cowboy Stadium in Irving, TX. Directions to the facility are available at the FMDIC Web site at *http://www.fmdic.org/*.

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *david.arvelo@fda.hhs.gov*.

Registration: FMDIC has a $250 early registration fee. Discounts for full-time students and government employees with valid identification are available. Early registration ends March 19, 2010. Registration is $300 thereafter. For more information on fees and/or to register online, please visit *http://www.fmdic.org/*. As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and e-mail, along with a check or money order for the appropriate amount payable to the FMDIC, to William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843–3120. Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $300 payable to the FMDIC. The registration fee will be used to offset expenses of hosting the event, including food, venue, and equipment.

If you need special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

Transcripts: Transcripts of this event will not be available due to the format of this workshop. Digital event handouts will be posted online at *http://www.fmdic.org/* or may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm.12A–16, Rockville, MD 20857, after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the medical device QSR. The following topics will be discussed at the workshop: (1) Standards and guidance, (2) risk management in design, (3) risk management in execution, and (4) risk management and post market surveillance.

Dated: December 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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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 74 FR 48089–48090 dated September 21, 2009).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice establishes the Office of Special Health Affairs (RA1) and the Office of Planning, Analysis and Evaluation (RA5) within the Office of the Administrator; transfers the functions and renames the Office of Minority Health and Health Disparities (RA9) and the Office of International Health Affairs (RAH) to the Office of Special Health Affairs (RA1); establishes the Office of Strategic Priorities (RA13) within the Office of Special Health Affairs (RA1); renames the Office of Equal Opportunity and Civil Rights (RA2); abolishes the Office of Health Information Technology (RT) and moves the functions to the Office of Planning, Analysis and Evaluation (RA5), the Office of Rural Health Policy (RH) and the Bureau of Primary Health Care (RC); and updates the functional statement for the Healthcare Systems Bureau (RR), the Bureau of Health Professions (RP), and the Office of Operations (RB).

Chapter RA—Office of the Administrator

Section RA–10, Organization

Delete in its entirety and replace with the following:

The Office of the Administrator (RA) is headed by the Administrator, Health Resources and Services Administration, who reports directly to the Secretary. The OA includes the following components:

(1) Immediate Office of the Administrator (RA);

(2) Office of Equal Opportunity, Civil Rights, and Diversity Management (RA2);

(3) Office of Planning, Analysis, and Evaluation (RA5);

(4) Office of Communications (RA6);

(5) Office of Special Health Affairs (RA1); and

(6) Office of Legislation (RAE).

Section RA–20, Functions

(1) Update the functional statement for the Immediate Office of the Administrator (RA); (2) rename the Office of Equal Opportunity and Civil rights (RA2); (3) establish the Office of Planning, Analysis and Evaluation (RA5); (4) establish the Office of Special Health Affairs (RA1); (5) delete the functional statement for the Office of International Health Affairs (RAH), rename and transfer the function to the Office of Special Health Affairs (RA1); (6) delete the functional statement for the Office of Minority Health and Health Disparities (RA9), rename and transfer the function to the Office of Special Health Affairs (RA1); and (7) delete the functional statement for the Office of Planning and Evaluation, and transfer the function to the Office of Planning, Analysis and Evaluation (RA5).

Immediate 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; and (8) provides overall leadership, direction, coordination, and planning in the support of the Agency's special health programs.

Office of Equal Opportunity, Civil Rights and Diversity Management (RA2)

Directs, coordinates, develops, and administers HRSA's equal opportunity and civil rights activities. Specifically: (1) Provides advice, counsel, and recommendations to HRSA personnel, including regional divisions, on equal opportunity and civil rights and represents HRSA in all equal employment opportunity (EEO) areas; (2) administers affirmative action programs designed to ensure equality of opportunity in employment; (3) manages the Civil Service complaints system and prepares final HRSA decisions; (4) manages the complaints system for Public Health Service (PHS) Commissioned Corps personnel under the provisions of PHS Personnel Instruction 6 and issues proposed depositions; (5) develops and directs implementation of the requirements of Section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975 and the Americans With Disabilities Act, as they apply to recipients of HRSA funds; (6) provides technical assistance and guidance to HRSA on developing education and training programs regarding equal opportunity and civil rights; (7) approves and executes settlement agreements and attorney fees; (8) applies all applicable laws, guidelines, rules and regulations in accordance with those of the HHS Office of Equal Employment Opportunity and Civil Rights; and (9) provides leadership and guidance in HRSA's efforts to maintain and improve a diverse workforce.

Office of Planning, Analysis, and Evaluation (RA5)

Office of the Director (RA5)

Serves as the Administrator's primary staff unit for coordinating the Agency's strategic planning process, and for conducting analysis, evaluation and research planning process, including: (1) Maintains liaison between the Administrator, other OPDIVs, higher levels of the Department and other Departments on all matters involving analysis of program policy undertaken in the Agency; (2) prepares policy analysis papers and planning documents as required in the Administration's strategic planning and other process; (3) analyzes budgetary data with regard to planning guidelines; (4) collaborates with the Office of Operations in the development of budgets, performance plans, and other administration reporting requirements; and (5) provides medical claims support.

Intergovernmental Affairs: (1) 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; (2) 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; (3) interacts with various commissions such as the Delta Regional Authority, Appalachian Regional Commission, Denali Commission and the United States and Mexico Border Health Commission; and (4) serves as the primary liaison to Department intergovernmental staff.

Office of Planning and Evaluation (RA51)

(1) Serves as the Administrator's primary staff for coordinating the Agency's strategic, evaluation and research planning processes; (2) prepares policy analysis papers and other planning documents as required in the Administration's strategic planning process; (3) analyzes budgetary data with regard to planning guidelines; (4) collaborates in the development of budgets, performance plans, and performance reports required under the Government Performance and Accountability Report; (5) coordinates activity related to the prevention agenda, Healthy People activities and other departmental and Agency initiatives; (6) analyzes and coordinates the information needs of the Agency, including coordination of the public use reports clearance function; (7) analyzes policy issues surrounding the application and promotion of healthcare information technology in HRSA programs; and (8) serves as the focal point for health systems organization and financing issues, with particular emphasis on the Agency's relationship with the Centers for Medicare & Medicaid Services and safety net providers.

Division of Health Information Technology & Quality (RA52)

Provides support and policy direction for HRSA's programs for quality improvement. Serves as the focal point for developing policy to promote the coordination and advancement of health information technology to HRSA's programs, including user networks, and the use of electronic health record systems. Specific responsibilities include: (1) Develops a nationwide health information technology and telehealth strategy for HRSA that focuses on the health care safety net and the needs of the uninsured, underserved, and special needs populations; (2) develops HRSA's Health Information Technology (HIT) and telehealth policy; (3) ensures successful dissemination of appropriate information technology advances, such as electronic health records systems or provider networks, to HRSA programs; (4) works collaboratively with States, foundations, national organizations,

private sector providers, as well as departmental agencies and other Federal departments in order to promote the adoption of health information technology by HRSA's grantees; (5) ensures the health information technology policy and programs of HRSA are coordinated with those of other HHS components; (6) assesses the impact of health information technology initiatives in the community, especially for the uninsured, underserved, and special needs populations; (7) coordinates outreach and consultation with public and private parties of interest (within the extent of the law), including consumers, providers, payers, and administrators focusing on the needs of the uninsured, underserved, and special needs populations; and (8) develops and translates policy to promote the coordination and advancement of health information technology to HRSA's programs.

Office of Special Health Affairs (RA1)

Office of the Director (RA1)

Provides overall leadership, direction, coordination, and planning in the support of the Agency's special health programs. Specifically, (1) plans and directs activities to advance health equity and improve minority health and eliminate health disparities; (2) develops strategies to maximize HRSA's participation in efforts to improve health care for vulnerable populations worldwide; and (3) provides leadership and direction to improve the delivery and quality of oral health care, mental health and other priority health concerns.

Office of Health Equity (RA11)

Serves as the principal advisor and coordinator to the Agency for the special needs of minority and disadvantaged populations, including: (1) Provides leadership and direction to address HHS and HRSA Strategic Plan goals and objectives related to improving minority health and eliminating health disparities; (2) establishes and manages an Agency-wide data collection system for minority health activities and initiatives including the White House Initiatives for Historically Black Colleges and Universities, Educational Excellence for Hispanic Americans, Tribal Colleges and Universities, Asian Americans and Pacific Islanders, and Departmental Initiatives; (3) implements activities to increase the availability of data to monitor the impact of Agency programs in improving minority health and eliminating health disparities; (4) participates in the formulation of HRSA's goals, policies, legislative proposals, priorities, and strategies as they affect health professional organizations and institutions of higher education and others involved in or concerned with the delivery of culturally-appropriate, quality health services to minorities and disadvantaged populations; (5) consults with Federal agencies and other public and private sector agencies and organizations to collaborate in addressing health equity, including enhancing cultural competence in health service providers; (6) establishes short-term and long-range objectives; and (7) participates in the focus of activities and objectives in assuring equity in access to resources and health careers for minorities and the disadvantaged.

Office of Global Health Affairs (RA12)

Serves as the principal advisor to the Administrator on global health issues. (1) Provides leadership, coordination, and advancement of international health activities relating to health care services for vulnerable and at-risk populations and for training programs for health professionals; and (2) provides leadership within HRSA for the support for international health and coordinates policy development with the Office of Global Health Affairs (OGHA) and other departmental agencies.

Office of Strategic Priorities (RA13)

Serves as the principal advisor to the Administrator on major health priorities including, but not limited to oral and mental health. (1) Provides leadership and coordination to improve oral and mental health infrastructure, delivery, and systems of care; (2) establishes short-term and long-term goals and objectives to improve the quality of oral and mental health care; (3) collaborates with other departmental and Federal agencies to promote oral and mental health by building public-private partnerships; (4) coordinates oral and mental health activities across HRSA programs; and (5) establishes program goals, objectives and priorities to improve oral and mental health status and outcomes to eliminate disparities.

Section RA–30, 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.

Chapter RB—Office of Operations

Section RB–20, Functions

Delete the functional statement for the Office of Operations and replace in its entirety.

Office of Operations

Office of the Chief Operating Officer (RB)

(1) Provides leadership for operational activities, interaction and execution of Agency initiatives across the Health Resources and Services Administration; (2) plans, organizes and manages annual and multi-year budgets and resources and assures that the conduct of Agency administrative and financial management activities effectively support program operations; (3) provides an array of Agency-wide services including information technology, procurement management, facilities, workforce management, and budget execution and formulation; (4) maintains overall responsibility for policies, procedures, monitoring of internal controls and systems related to payment and disbursement activities; (5) provides management expertise, staff advice, and support to the Administrator in program and policy formulation and execution; (6) provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA; (7) coordinates IT workforce issues and works closely with the Department on IT recruitment and training issues; and (8) administers functions of the Chief Financial Officer.

Office of Budget (RB1)

(1) Reviews funds control measures to assure that no program, project or activity of HRSA obligates or disburses funds in excess of appropriations or obligates funds in violation of authorized purposes; (2) provides advice and assistance to senior HRSA management to verify the accuracy, validity, and technical treatment of budgetary data in forms, schedules, and reports, or the legality and propriety of using funds for specific purposes; (3) maintains primary liaison to expedite the flow of financial management work and materials within the Agency and/or between Agency components and HHS, Office of Management and Budget (OMB), and congressional staff; (4) provides overall financial-based analyses and fiduciary review for senior HRSA management in order to assure appropriate workforce planning, funds control guidance, and analytical

technical assistance in all phases of the budgetary process; and (5) develops the long-range program and financial plan for the Agency in collaboration with the Office of Planning, Analysis and Evaluation, and other administrative Agency components.

Division of Budget Formulation and Presentation (RB11)

(1) Manages and coordinates development of the Administration's budget for HRSA from independent submissions prepared by Bureau/Office contacts; (2) formulates the total HRSA financial plan for the Administrator, and evaluates and assures total Agency budget requests conform to current Administration policy and economic assumptions; (3) coordinates performance measures pursuant to the Government Performance and Results Act with budget proposals; (4) represents, supports and defends the HRSA budget in meetings/hearings before the Office of the Secretary, OMB, and the Congress; (5) provides policy direction and guidance for the preparation and consolidation of the budget and its transmittal to OMB through information technology; (6) analyzes proposed legislation and subsequent congressional action for budgetary implications; (7) prepares periodic summary analysis and impact statements on budget allowances and applicable congressional actions; (8) develops all financial and personnel staffing aspects of HRSA's implementation plans for establishing new or phasing out existing programs; (9) develops analyses of proposed budget estimates and supporting narrative through the use of available financial data reporting systems for Agency senior management; (10) maintains liaison with the Office of the Secretary and the OMB, the General Accountability Office, other Government organizations, and the Congress on HRSA's financial management matters; (11) consults with the Office of Program Evaluation to provide guidance and advice in implementing performance systems, including the Performance Assessment and Rating Tool assessments, Key Performance Indicators, and HRSA's Government Performance Results Act program; (12) collaborates with other parts of HRSA in the development and implementation of long-range program and financing plans; (13) completes chain-of-command requirements in timing and reporting of cleared information to parties outside the Executive Branch (*i.e.,* the Congress, media, public); and (14) appropriately safeguards all embargoed information and all draft materials to maintain integrity of data, and secure work information.

Division of Budget Execution and Management (RB12)

(1) Provides budget policy interpretation, management guidance and direction for senior HRSA management; (2) conducts the HRSA budget control process in conformance with statutory requirements and OMB guidelines; (3) approves program spending plans and obtains apportionment of funds from the OMB; (4) establishes and maintains a system of budgetary fund and position control; (5) provides senior HRSA management status and activity reports on total funds control and position control activities throughout the fiscal year; (6) administers and reviews requests for apportionments and allotments; (7) reviews, controls, and reports obligations and expenditures through central monitoring and advice to Bureau/Office management officials; (8) verifies funds available to Central HRSA Offices, and the propriety of using appropriated and non-appropriated funds for the requested purposes for which the funds have been proposed for expenditure through commitment accounting; (9) develops and interprets budgetary policies and practices for operating units of the Agency including analysis and approval for all equipment, supplies, travel, transportation and services procured by HRSA, and ensures the validity, legality and proper accounting treatment of expenditures processed through the Unified Financial Management System (UFMS); (10) controls the Agency's processes of allotment, allocation, obligation, and expenditure of funds in approved annual operating plans for all HRSA accounts; (11) monitors Bureau obligations in current allocations, disbursements and outlays and notifies Bureaus of potential deficiencies in allotments and allowances for specific periods for corrective action by Bureau staff; (12) maintains primary liaison between HRSA and the Program Support Center's Financial Operations Center for accounting functions; (13) maintains tracking of inputs into HRSA account for the central HHS accounting system (UFMS), which includes the examination, verification, and maintenance of accounts and accounting data within the accounting system; (14) provides standardized accounting codes across the Agency, performs technical audit functions, develops and/or installs revised accounting procedures, and serves as primary administrator of systems accounting functions within HRSA; (15) provides appropriate tracking of all ''fee-for-service'' charges to HRSA from other HHS components and outside entities; and (16) manages the centralized HRSA Pay Management for allocation of staff and position management.

Division of Program Budget Services (RB13)

(1) Provides direct budget execution services to assigned program components working with appropriate program management officials; (2) coordinates budget services through formalized and integrated communications with program management officials or their designees to ensure effective and efficient delivery of services to its customers; (3) supports the formulation of annual budgets, develops spending plans and manages budget activities ensuring funds are expended in accordance with congressional intent; (4) provides reports on program activities to Budget Execution and Management Staff for control of commitment accounting within allotments and allowances and for position control activities; (5) analyzes and maintains reports on disbursements and changing obligations within closed year accounts for assigned program components; and (6) assures all open documents are closed without outstanding balances.

Office of Financial Policy and Controls (RB2)

(1) Chief Financial Officer serves as liaison with all HRSA Bureau/Office components and outside customers to provide financial information, resolve problems, and provide information on payment, and disbursement issues; (2) maintains overall responsibility for policies, procedures, monitoring of internal controls and systems related to payment and disbursement activities; (3) coordinates the development and improvement of HRSA's financial systems with the UFMS; (4) samples obligation documents and payment requests from a variety of private sector and Government sources to determine the validity and legality of the requests; (5) compiles and submits a variety of cash management and travel reports required by the Department of the Treasury and various other outside agencies; (6) provides leadership to define the control environment with Senior HRSA management to perform risk assessments identifying the most significant areas necessary for internal control placements; (7) analyzes internal reports to provide management information on special interest topics;

(8) develops needs assessment for financial management training based on Government-wide and HHS standards; and (9) assures Treasury requirements and OMB suggestions for best practices are implemented in training plan for Agency-wide use.

Division of Internal Controls (RB21)

(1) Coordinates risk assessments identifying the most significant areas necessary for internal control placements; (2) analyzes and reconciles disbursements made for HRSA by other Federal activities, and insures that disbursements are consistent with Federal Appropriations Law requirements, GAO policies, interagency elimination entry requirements, and other governing financial regulations; (3) analyzes year-end unliquidated obligations for compliance with Federal Appropriations Laws and the Economy Act, and recommends funding changes to senior HRSA management; (4) reviews and reconciles all U.S. Treasury Department reports and transmissions; (5) performs ongoing quality control reviews of various payment and disbursement processes and systems in the Office of Operations; (6) develops needs assessment for financial management training based on Government-wide and HHS standards; and (7) assures Treasury requirements and OMB suggestions for best practices are implemented in training plan for Agency-wide use.

Division of Financial Policy and Analysis (RB22)

(1) Defines the control environment (*e.g.,* programs, operations, or financial reporting) with Senior HRSA management; (2) maintains overall responsibility for policies, procedures, monitoring of internal controls and systems related to payment and disbursement activities; (3) conducts analyses to inform Office of Operations and Senior HRSA management of relevant financial information, potential problems/solutions, and information on payment, travel, and disbursement issues; (4) reviews policy documents, Inter/Intra-Agency agreements and Agency materials for financial consistency with internal controls and disbursement requirements; (5) conducts analyses of management and operational problems in terms of financial management information; (6) analyzes the design, implementation, enhancement and documentation of automated financial systems within the Office of Operations to assist management in operating more efficiently; (7) provides consultative services to systems implementers within HRSA on a broad range of issues including policy, data integrity, systems integration and interfacing issues as they relate to financial management systems; (8) provides technical support and assistance to operating components and users in the integration of financial systems and the access and interpretation of financial system data; (9) analyzes and offers recommendations concerning the costs and benefits of alternative methods of financing Agency programs and administrative operations; (10) prepares long-range resource projections for the acquisition and use of funds to support specific Agency projects and programs; (11) facilitates the review of HRSA audit activities in compliance with the Chief Financial Officer's Act of 1990; and (12) provides support to the Annual Financial Statements by monitoring statement of net cost, preparing management representation correspondence, cycle memoranda and serves as audit liaison to the combined HHS Combined Financial Statement.

Office of Acquisitions Management and Policy (RB3)

(1) Provides leadership in the planning, development, and implementation of policies and procedures for contracts; (2) exercises the sole responsibility within HRSA for the award and management of contracts; (3) provides advice and consultation of interpretation and application of the Department of Health and Human Services' policies and procedures governing contracts management; (4) develops operating procedures and policies for the Agency's contracts programs; (5) establishes standards and guides for and evaluates contracts operations throughout the Agency; (6) coordinates the Agency's positions and actions with respect to the audit of contracts; (7) maintains liaison directly with or through Agency Bureaus or Offices with contractors, other organizations, and various components of the Department; (8) provides leadership, guidance, and advice on the promotion of the activities in HRSA relating to procurement and material management governed by the Small Business Act of 1958, Executive Order 11625, and other statutes and national policy directives for augmenting the role of private industry, and small and minority businesses as sources of supply to the Government and Government contractors; and (9) plans, directs, and coordinates the Agency's sourcing program.

Division of Contracts Operations (RB31)

(1) Responsible for soliciting, negotiating, awarding, and administering negotiated contracts in support of HRSA programs and activities; (2) provides professional, in-depth advice and consultation to HRSA staff regarding the various phases of the acquisition cycle relating to contracts awarded by the Agency; (3) conducts pre-award reviews of proposed contracts that exceed the requirements called for in the Federal and departmental acquisition regulations; (4) plans and coordinates acquisition reviews of contracting activities within HRSA headquarters and the field components; and (5) responds to congressional inquiries and requests for acquisition information from other Federal agencies and non-Federal sources.

Division of General Acquisitions (RB32)

(1) Plans, negotiates and awards simplified acquisitions for headquarters and field components; (2) administers HRSA's acquisition data retrieval system; (3) oversees system and inputs data to the automated contracts reporting system, and reviews the PRISM reports and obtains specific information from various outside sources; (4) takes necessary actions regarding close out of both negotiated contracts and simplified acquisitions in support of HRSA programs; (5) provides a full range of in-depth advice and consultation regarding acquisition matters relating to the simplified acquisition to headquarters and field contracting activities; (6) conducts and monitors the performance of the HRSA purchase card IMPAC program for headquarters and field offices; (7) responds to congressional inquiries and requests for information from other departments and non-Federal sources on simplified acquisitions; (8) reviews and provides necessary recommendations on the disposition of awards which result in mistakes of bids, protests, and unauthorized obligations; (9) administers the training and certification program for acquisition officials; (10) manages close-out of completed contracts and purchase orders; and (11) manages the Inter/Intra-Agency agreement process.

Office of Management (RB4)

Provides Agency-wide leadership, program direction, and coordination of all phases of administrative management. Specifically, the Office of Management: (1) Provides management expertise, staff advice, and support to the Administrator in program and policy formulation and execution; (2)

provides administrative management services including human resources, procurement, property, space planning, safety, physical security, and general administrative services; (3) conducts Agency-wide workforce analysis studies and surveys; (4) plans, directs, and coordinates the Agency's activities in the areas of human resources management, including labor relations, personnel security, performance and alternative dispute resolution; (5) coordinates the development of policy and regulations; (6) oversees the development of annual operating objectives and coordinates HRSA work planning and appraisals; (7) directs and coordinates the Agency's organizations, functions and delegations of authority programs; (8) manages the Continuity of Operations (COOP) program for the Offices supported by the Office of Management; (9) administers the Agency's Executive Secretariat and committee management functions; (10) provides staff support to the Agency Chief Travel Official; and (11) provides staff support to the Deputy Ethics Counselor.

Division of Policy Review and Coordination (RB41)

(1) Advises the Administrator and other key Agency officials on cross-cutting policy issues and assists in the identification and resolution of cross-cutting policy issues and problems; (2) establishes and maintains tracking systems that provide Agency-wide coordination and clearance of policies, regulations and guidelines; (3) plans, organizes and directs the Agency's Executive Secretariat with primary responsibility for preparation and management of written correspondence; (4) arranges briefings for Department officials on critical policy issues and oversees the development of necessary briefing documents; (5) administers administrative early alert system for the Agency to assure senior Agency officials are informed about administrative actions and opportunities; (6) coordinates the preparation of proposed rules and regulations relating to Agency programs and coordinates Agency review and comment on other Department regulations and policy directives that may affect the Agency's programs; (7) manages and maintains a records management program for the Agency; (8) oversees and coordinates the Agency's committee management activities; (9) coordinates the review and publication of Federal Register Notices; (10) provides advice and guidance for the establishment or modification of administrative delegations of authority; (11) provides advice and guidance for the establishment or modification of program delegations of authority; and (12) contributes to the analysis, development and implementation of Agency-wide administrative policies through coordination with relevant Agency program components and other related sources.

Division of Workforce Management (RB42)

(1) Conducts Agency-wide workforce analysis studies and surveys; (2) develops comprehensive workforce strategies that meet the requirements of the President's Management Agenda, programmatic needs of HRSA, and the governance and management needs of HRSA leadership; (3) evaluates employee development practices to develop and enhance strategies to ensure HRSA retains a cadre of public health professionals and reduces risks associated with turnover in mission critical positions; (4) provides advice and guidance for the establishment or modification of organization structures, functions, and delegations of authority; (5) manages ethics and personnel security programs; (6) administers the Agency's performance management programs, including the SES Performance Review Board; (7) manages quality of work life, flexi place, and incentive and honor awards programs; (8) coordinates with the service provider the provision of human resources management, working with the service provider to communicate human resources requirements and monitoring the provider's performance; (9) directs and serves as a focal point for the Agency's intern and mentoring programs; (10) manages the Alternative Dispute Resolution Program; (11) provides support and guidance on human resources issues for the Offices supported by the Office of Management; and (12) oversees the commissioned corps liaison activities including the day-to-day operations of workforce management.

Division of Management Services (RB43)

(1) Provides administrative management services including procurement, property, space planning, safety, physical security, and general administrative services; (2) ensures implementation of statutes, Executive Orders, and regulations related to official travel, transportation, and relocation; (3) provides oversight for the HRSA travel management program involving use of travel management services/systems, passenger transportation, and travel charge cards; (4) provides planning, management and oversight of all interior design projects, move services and furniture requirements; (5) develops space and furniture standards and related policies; (6) provides analysis of office space requirements required in supporting decisions relating to the acquisition of commercial leases and manages the furniture inventory; (7) provides advice, counsel, direction, and support to employees to fulfill the Agency's primary safety responsibility of providing a workplace free from recognizable safety and health concerns; (8) manages, controls, and/or coordinates all matters relating to mail management within HRSA, including developing and implementing procedures for the receipt, delivery, collection, and dispatch of mail; (9) maintains overall responsibility for the HRSA Forms Management Program which includes establishing internal controls to assure conformity with departmental policies and standards, including adequate systems for reviewing, clearing, costing, storing and controlling forms; and (10) manages the Continuity of Operations (COOP) program for the Offices supported by the Office of Management.

Office of Information Technology (RB5)

The Chief Information Officer (CIO) is responsible for the organization, management, and administrative functions necessary to carry out the responsibilities of the office including: (1) Organizational development, investment control, budget formulation and execution, policy development, strategic and tactical planning, and performance monitoring; (2) provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA; and (3) coordinates IT workforce issues and works closely with the Department on IT recruitment and training issues.

The Chief Technology Officer (CTO) is responsible for HRSA's emerging and advanced technology integration program consistent with HRSA's missions and program objectives including: (1) Managing technology planning and coordinating the Agency's Enterprise Architecture (EA) efforts with the capital planning process, ensuring the suitability and consistency of technology investments with HRSA's EA and strategic objectives; (2) incorporating security standards as a component of the EA process; (3) providing leadership for strategic planning that leverages information systems security, program strategies,

and advanced technology integration to achieve program objectives through innovative technology use; and (4) providing leadership and establishing policy to address legislative or regulatory requirements, such as Section 508 of the Rehabilitation Act, and providing oversight for Agency IT configuration management and control.

The Chief Information Security Officer (CISO) is responsible for: (1) Leadership and collaboration with Agency staff to oversee the implementation of security and privacy policy in the management of their IT systems, and plans all activities associated with the Federal Information Security Management Act (FISMA) or other agency security and privacy initiatives; (2) implementing, coordinating, and administering security and privacy programs to protect the information resources of HRSA in compliance with legislation, Executive Orders, directives of the Office of Management and Budget (OMB), or other mandated requirements; (*e.g.,* Presidential Decision Directive 63, OMB Circular A–130, the National Security Agency, the Privacy Act, and other Federal agencies); (3) executing the Agency's Risk Management Program, and evaluates and assists with the implementation of safeguards to protect major information systems, and IT infrastructure; (4) coordinating with the Division of IT Operations and Customer Service to develop and implement HRSA level policies, procedures, guidelines, and standards for the incorporation of intrusion detection systems, vulnerability scanning, forensic and other security tools used to monitor automated systems and subsystems to safeguard HRSA's electronic information and data assets; and (5) managing the development, implementation, and evaluation of the HRSA information technology security and privacy training program to meet the requirements as mandated by OMB Circular A–130, the Computer Security Act, and Privacy Act.

Division of Business Information Management (RB51)

(1) Provides consultation, assistance, and services to HRSA to promote and manage information dissemination and collaboration practices using appropriate electronic media; (2) evaluates and integrates emerging technology to facilitate the translation of data and information from data repositories into electronic formats for internal and external dissemination; (3) collaborates with the Office of Communications on the design, deployment, and maintenance of HRSA's Internet and Intranet Web sites including development and implementation of related policies and procedures; (4) develops and maintains an overall data and information management strategy for HRSA that is integrated with HHS and Government-wide strategies; (5) identifies information needs across HRSA and develops approaches for meeting those needs using appropriate technologies including development and maintenance of an enterprise reporting platform; (6) provides for data quality and ensures that data required for enterprise information requirements are captured in appropriate enterprise applications and that necessary data repositories are built and maintained; (7) enhances and expands use and utility of HRSA's data by providing basic analytic and user support, develops and maintains a range of information products for internal and external users and demonstrates potential uses of information in supporting management decisions; and (8) provides leadership and establishes policy to address legislative or regulatory requirements in its areas of responsibility.

Division of Capital Planning and Project Management (RB52)

(1) Coordinates the development and review of policies and procedures for IT Capital Planning and Investment Control, Earned Value Management, IT portfolio management, IT project management, and the enterprise performance lifecycle methodology; (2) administers the Department's multi-year strategic information resources planning process, including developing and administering the Department's Strategic IT Plan; (3) supports the Budget Office in its evaluation of IT initiatives, and preparation of Agency, departmental, and OMB Budget Exhibits and documents; (4) works to obtain required information and analyzes it as appropriate; (5) coordinates control and evaluation review of ongoing IT projects, including support to the HRSA ITIRB in conducting such review; (6) promotes and follows a consistent methodology for project management and improves Agency-wide project management; and (7) operates a Project Management Office to improve management, communications, and functional user involvement, assists with project prioritization, and monitors progress and budget.

Division of Enterprise Solutions Development and Management (RB53)

(1) Provides leadership, consultation, and IT project management services in the definition of Agency business applications architectures, the engineering of business processes, the building and deployment of applications, and the development, maintenance and management of enterprise systems and data collections efforts; (2) responsible for technology evaluation, application and data architecture definition, controlling software configuration management, data modeling, database design, development and management and stewardship services for business process owners; (3) manages the systems development lifecycle by facilitating business process engineering efforts, systems requirements definition, and provides oversight for application change management control; and (4) provides enterprise application user training, Tier-3 assistance, and is responsible for end-to-end application building, deployment, maintenance and data security assurance.

Division of IT Operations and Customer Services (RB54)

(1) Provides leadership, consultation, training, and management services for HRSA's enterprise computing environment; (2) directs and manages the support and acquisition of HRSA network and desktop hardware, servers, wireless communication devices, and software licenses; (3) is responsible for the HRSA Data Center and the operation and maintenance of a complex, high-availability network infrastructure on which mission-critical applications are made available 24 hours per day, 7 days per week; (4) provides oversight for outsourced electronic mail, Internet and connectivity, web and video conferencing, and co-managed firewall and security monitoring services; (5) controls infrastructure configuration management, installations and upgrades, security perimeter protection, and system resource access; (6) coordinates IT activities for Continuity of Operations Planning (COOP) Agency-wide, including provisioning and maintaining IT infrastructure and hardware at designated COOP locations to support emergency and COOP requirements; (7) accounts for property life cycle management and tracking of Agency-wide IT capital equipment; and (8) provides oversight for outsourced Tier-1 and Tier-2 Help Desk Call Center technical assistance, maintains workstation hardware and software configuration management controls, and provides oversight of outsourced network and desktop services to staff in HRSA Regional Offices.

Section RB–30, 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.

Chapter RH—Office of Rural Health Policy

Section RH–10, Organization

Delete in its entirety and replace with the following:

The Office of Rural Health Policy (RH) is headed by the Associate Administrator for Rural Health Policy, who reports directly to the Administrator. The Office of Rural Health Policy (RH) includes the following components:

(1) Office of the Associate Administrator (RH);

(2) Hospital State Division (RH1);

(3) Community Based Division (RH2);

(4) Border Health Division (RH3); and

(5) Office for the Advancement of Telehealth (RH4).

Section RH–20, Functions

Delete the functional statement for the Office of the Associate Administrator and replace in its entirety.

Office of the Associate Administrator (RH)

The Office of the Associate Administrator is headed by the Associate Administrator who, in conjunction with other management officials within HRSA, is responsible for the overall leadership and management of the Office of Rural Health Policy. The Office of Rural Health Policy serves as a focal point within the Department and as a principal source of advice to the Administrator and Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the Nation's rural areas and border areas, providing leadership and interacting with stakeholders in the delivery of health care to underserved and at risk populations. Specifically, the Office of Rural Health Policy is organized around the following primary issue areas:

Delivery of Health Services: (1) Collects and analyzes information regarding the special problems of rural health care providers and populations; (2) works with States, State hospital associations, private associations, foundations, and other organizations to focus attention on, and promote solutions to, problems related to the delivery of health services in rural communities; (3) provides staff support to the National Advisory Committee on Rural Health and Human Services; (4) stimulates and coordinates interaction on rural health activities and programs in the Agency, Department and with other Federal agencies; (5) supports rural health center research and keeps informed of research and demonstration projects funded by States and foundations in the field of rural health care delivery; (6) establishes and maintains a resource center for the collection and dissemination of the latest information and research findings related to the delivery of health services in rural areas; (7) coordinates congressional and private sector inquiries related to rural health; (8) advises the Agency, Administrator and Department on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in the programs established under titles XVIII and XIX of the Social Security Act on the financial viability of small rural hospitals, the ability of rural areas to attract and retain physicians and other health professionals; (9) oversees compliance by CMS with the requirement that rural hospital impact analyses are developed whenever proposed regulations might have a significant impact on a substantial number of small rural hospitals; (10) supports specialized rural programs on minority health, mental health, preventive health education, oral health, and occupational health and safety; (11) directs the management of a nationwide rural health grants program; (12) directs the management of a program of State grants which support collaboration within State offices of rural health; and (13) funds radiation exposure screening and education programs that screen eligible individuals adversely affected by the mining, transport and processing of uranium and the testing of nuclear weapons for cancer and other diseases.

Hospital State Division (RH1)

The Hospital State Division serves as the focal point within the Office of Rural Health Policy to support rural hospital and State grant programs focused on rural populations. Specifically, the Hospital State Division is organized around the following primary issue areas: (1) Plans and manages a program of State grants which support collaboration within State offices of rural health; (2) works with States, State hospital associations, private associations, foundations, and other organizations to focus attention on, and promote solutions to, problems related to the delivery of health services in rural communities; and (3) provides coordinated technical assistance to grantees and rural communities.

Community Based Division (RH2)

The Community Based Division serves as the focal point within the Office of Rural Health Policy to support rural community grant programs. Specifically, the Community Based Division is organized around the following primary issue areas: (1) Plans and manages several nationwide rural health grants programs; (2) supports programs on rural health, public health, and health status improvement; (3) funds public and private non-profit entities for the operation of clinics that provide diagnosis, treatment and rehabilitation of active and retired coal miners and others with respiratory ailments (black lung) and other occupational related respiratory disease impairments; (4) funds radiation exposure screening and education programs that screen eligible individuals adversely affected by the mining, transport and processing of uranium and the testing of nuclear weapons for cancer and other diseases; and (5) provides technical assistance to grantees and rural communities.

Border Health Division (RH3)

The Border Health Division provides leadership and direction to coordinate the Agency's assets in border regions. Specifically, the Border Health Division: (1) Assures that the Agency's engagement with regions of the border is strategic, performance based, builds partnerships and alliances, and maximizes utilization of Agency assets; (2) assures Agency-wide coordination by establishing border health program policies and procedures including tracking mechanisms; (3) conducts management and evaluation studies to improve the health delivery system on the border; (4) serves as the secretariat and chair for the Agency's Border Health Workgroup; (5) plans, directs, and coordinates the Agency's border health activities; and (6) plans, coordinates and facilitates the Agency agreements activities with border health issues.

Office for the Advancement of Telehealth (RH4)

Serves as the operational focal point for coordinating and advancing the use of telehealth technologies across all of HRSA's programs including, but not limited to, the provision of healthcare at a distance (telemedicine); distance-based learning to improve the knowledge of Agency grantees, and others; and improved information dissemination to both consumers and

providers about the latest developments in telemedicine. The Office for the Advancement of Telehealth carries out the following functions, specifically: (1) Develops and coordinates telehealth network and telehealth resource centers grant programs; (2) provides professional assistance and support in developing telehealth initiatives; (3) administers grant programs to promulgate and evaluate the use of appropriate telehealth technologies among HRSA grantees and others; and (4) disseminates the latest information and research findings related to the use of telehealth technologies in Agency programs and underserved areas, including findings on ''best practices.''

Section RH–30, 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.

Chapter RC—Bureau of Primary Health Care

Section RC–10, Organization

Delete in its entirety and replace with the following:

The Bureau of Primary Health Care (RC) is headed by the Associate Administrator for Primary Health Care, who reports directly to the Administrator. The Bureau of Primary Health Care (RC) includes the following components:

(1) Office of the Associate Administrator (RC);
(2) Office of Minority and Special Populations (RCG);
(3) Office of Policy and Program Development (RCH);
(4) Office of Quality and Data (RCK);
(5) Eastern Division (RCN);
(6) Central Mid-Atlantic Division (RCP);
(7) Western Division (RCQ); and
(8) Health Information Technology State and Community Assistance Division (RCR).

Section RC–20, Functions

Delete the functional statement for the Bureau of Primary Health Care and replace in its entirety.

Office of the Associate Administrator (RC)

Provides overall leadership, direction, coordination, and planning in support of Bureau of Primary Health Care (BPHC) programs that are designed to improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. Specifically, (1) establishes program goals, objectives and priorities, and provides oversight as to their execution; (2) plans, directs, coordinates and evaluates Bureau-wide management activities; (3) maintains effective relationships within HRSA and with other Department of Health and Human Services (HHS) organizations, other Federal agencies, State and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the Nation's underserved and vulnerable populations; and (4) plans, directs, and coordinates Bureau-wide administrative management activities, (*i.e.,* budget, finance, personnel, procurements, delegations of authority, emergency planning, training, executive secretariat), and has responsibilities related to the awarding of BPHC grant and contract funds.

Office of Minority and Special Populations (RCG)

Serves as the organizational focus for the coordination of Bureau activities relating to the delivery of health services to minority and special populations, including migrant and seasonal farmworkers, homeless persons, and residents of public housing. Specifically, (1) ensures that the needs and special circumstances of minority and special populations and the provider organizations that serve them are addressed in BPHC programs and policies; (2) advises BPHC about the needs of minority and special populations; (3) identifies, provides and coordinates assistance to communities, community-based organizations and BPHC programs related to the development, delivery and expansion of services targeted to minority and special populations; (4) coordinates Bureau activities for minority and special populations within HRSA and HHS, and with other Federal agencies, State and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the Nation's underserved and vulnerable populations; and (5) provides support to the National Advisory Council on Migrant Health.

Office of Program and Policy Development (RCH)

Serves as the organizational focus for the development of BPHC programs and policies. Specifically, (1) leads and monitors the development and expansion of health centers and health systems infrastructure; (2) identifies, provides and coordinates assistance to communities, community-based organizations and BPHC programs related to the development and expansion of health centers and health systems infrastructure; (3) manages the Bureau's loan guarantee program; (4) oversees and coordinates the Federally Qualified Health Center (FQHC) Look-Alike program; (5) leads and coordinates the analysis, development and drafting of policy impacting BPHC's programs; (6) consults and coordinates 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 BPHC's programs and policies; (7) performs environmental scanning on issues that affect BPHC's programs; (8) monitors BPHC's activities in relation to HRSA's Strategic Plan; and (9) serves as the Bureau's focal point for communication and program information.

Office of Quality and Data (RCK)

Serves as the organizational focus for quality and program performance reporting. Specifically, (1) provides leadership for implementing BPHC clinical and quality strategies; (2) oversees BPHC Federal Tort Claims Act (FTCA) malpractice programs, reviewing clinical, quality improvement, risk management, and patient safety activities to improve policies and programs for primary health care services, including clinical information systems; (3) serves as the Bureau's focal point for the design and implementation of data systems to assess and improve program performance; (4) coordinates BPHC clinical, quality and performance reporting activities within HRSA and HHS, and with other Federal agencies, State and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the Nation's underserved and vulnerable populations; and (5) identifies, provides and coordinates assistance to BPHC programs around clinical, quality and performance reporting activities.

Eastern Division (RCN)

Manages BPHC primary health care grant programs and activities within HHS Regions 1, 2 and 4. Specifically, for Regions 1, 2 and 4: (1) Manages the post-award administration of the Bureau's primary health care grant programs; (2) serves as the BPHC representative to organizations receiving Bureau grants; (3) promotes a continued

focus on efficient and effective care for underserved and vulnerable populations; (4) communicates and interprets program statutory/regulatory requirements, policy, expectations and reporting requirements, providing technical guidance to grantees on the management and integration of community-based systems of care, the adaptation of successful strategies/models, and the resolution of difficult issues; (5) monitors the performance of BPHC primary health care grantees, making programmatic recommendations and providing assistance to improve performance, where appropriate; (6) reviews findings and recommendations of periodic and episodic grantee assessments, developing actions needed to assure continuity of services to underserved and vulnerable populations and appropriate use of Federal resources; (7) identifies, provides and coordinates training and technical assistance activities for BPHC primary health care grant programs, including State-based training and technical assistance; (8) conducts State and regional surveillance on issues that affect BPHC grant programs; and (9) provides consultation to and coordinates activities within HRSA and HHS, and with other Federal agencies, State and local governments, and other public and private organizations involved in the implementation of program activities.

Central Mid-Atlantic Division (RCP)

Manages BPHC primary health care grant programs and activities within HHS Regions 3, 5 and 6. Specifically, for Regions 3, 5 and 6: (1) Manages the post-award administration of the Bureau's primary health care grant programs; (2) serves as the BPHC representative to organizations receiving Bureau grants; (3) promotes a continued focus on efficient and effective care for underserved and vulnerable populations; (4) communicates and interprets program statutory/regulatory requirements, policy, expectations and reporting requirements, providing technical guidance to grantees on the management and integration of community-based systems of care, the adaptation of successful strategies/models, and the resolution of difficult issues; (5) monitors the performance of BPHC primary health care grantees, making programmatic recommendations and providing assistance to improve performance, where appropriate; (6) reviews findings and recommendations of periodic and episodic grantee assessments, developing actions needed to assure continuity of services to underserved and vulnerable populations and appropriate use of Federal resources; (7) identifies, provides and coordinates training and technical assistance activities for BPHC primary health care grant programs, including State-based training and technical assistance; (8) conducts State and regional surveillance on issues that affect BPHC grant programs; and (9) provides consultation to and coordinates activities within HRSA and HHS, and with other Federal agencies, State and local governments, and other public and private organizations involved in the implementation of program activities.

Western Division (RCQ)

Manages BPHC primary health care grant programs and activities within HHS Regions 7, 8, 9 and 10. Specifically, for Regions 7, 8, 9 and 10: (1) Manages the post-award administration of the Bureau's primary health care grant programs; (2) serves as the BPHC representative to organizations receiving Bureau grants; (3) promotes a continued focus on efficient and effective care for underserved and vulnerable populations; (4) communicates and interprets program statutory/regulatory requirements, policy, expectations and reporting requirements, providing technical guidance to grantees on the management and integration of community-based systems of care, the adaptation of successful strategies/models, and the resolution of difficult issues; (5) monitors the performance of BPHC primary health care grantees, making programmatic recommendations and providing assistance to improve performance, where appropriate; (6) reviews findings and recommendations of periodic and episodic grantee assessments, developing actions needed to assure continuity of services to underserved and vulnerable populations and appropriate use of Federal resources; (7) identifies, provides and coordinates training and technical assistance activities for BPHC primary health care grant programs, including State-based training and technical assistance; (8) conducts State and regional surveillance on issues that affect BPHC grant programs; and (9) provides consultation to and coordinates activities within HRSA and HHS, and with other Federal agencies, State and local governments, and other public and private organizations involved in the implementation of program activities.

Division of National Hansen's Disease Program (RC7)

Manages the National Hansen's Disease Program in accordance with regulations of the Public Health Service; establishes policies and procedures, maintains standards and represents the program to other agencies and the public; provides leadership necessary to ascertain and maintain equal employment opportunities; develops, executes, and maintains effective public relations which are required because of the nature of the institution. Directs, supervises, and evaluates the functions of Ambulatory Care.

Division of Health Information Technology State and Community Assistance (RCR)

Serves as the operational focal point for coordinating and advancing the adoption of health information technology across all of HRSA's programs, including, but not limited to, user networks, clinical management systems, and the use of electronic medical record systems. Ensures information dissemination to HRSA grantees and other consumers and providers about the latest developments in health care information technology, and the impact of health information technology on other activities designed to improve the health status of the Nation. The Division of Health Information Technology State and Community Assistance carries out the following functions: (1) Develops and coordinates health information technology (HIT) programs and policies; (2) provides professional assistance and support in developing HIT initiatives among HRSA grantees; (3) administers grant programs to promote and evaluate the use of appropriate HIT among grantees and others; (4) advises HRSA grantees on strategies to maximize the potential of new and existing HIT technologies for meeting quality and technical assistance objectives; (5) disseminates the latest information and research findings related to the use of HIT technologies in the Agency programs and underserved areas, including findings on ''best practices;'' and (6) provides guidance on HIT policy for safety net providers through the Associate Administrator to the Office of the National Health Information Technology Coordinator and the other components of the Department, with other Federal and State agencies and with the private sector to promote and overcome barriers to effective HIT programs.

Section RC–30, 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.

Chapter RR—Healthcare Systems Bureau

Section RR–20, Functions

Delete the functional statement for the Health Care Systems Bureau and replace in its entirety.

(1) Administers the Organ Procurement and Transplantation Network (OPTN) to facilitate the allocation of donor organs to patients waiting for an organ transplant and the Scientific Registry of Transplant Recipients that provides analytic support to the OPTN in the development and assessment of organ allocation and other OPTN policies; (2) administers the C.W. Bill Young Cell Transplantation Program to increase the number of unrelated blood stem cell transplants and improve the outcomes of blood stem cell transplants; (3) administers the National Cord Blood Inventory (NCBI) to increase the number of high quality cord blood units available for transplantation; (4) develops and maintains a national program of grants and contracts to organ procurement organization and other entities to increase the number of organs made available for transplantation; (5) manages the national program for compliance with the Hill-Burton uncompensated care requirement and other assurances; (6) directs and administers an earmarked grant program for the construction/renovation/equipping of health care and other facilities; (7) directs and administers the National Vaccine Injury Compensation Program; (8) directs and administers the Smallpox Emergency Personnel Protection Act Program; (9) serves as the focal point for providing leadership and direction to States to develop plans for providing access to affordable health insurance coverage for all citizens; (10) directs and administers the Poison Control Center Enhancement and Awareness Act; (11) manages and promotes the 340B Drug Pricing Program; (12) implements and administers the Countermeasures Injury Compensation Program (CICP) under Public Readiness and Emergency Preparedness (PREP) Act authorities; (13) coordinates HRSA activities related to emergency preparedness planning, policy, and continuity of operations, including the operation of the HRSA Emergency Operations Center, and serves as HRSA's liaison to HHS and interagency partners on emergency preparedness matters; (14) ensures HRSA's commissioned corps is ready to respond to public health challenges and emergencies identified by the Secretary; (15) in conjunction with the Office of Force Readiness and Deployment, ensures the readiness and deployment capability of officers assigned to HRSA; and (16) directs and administers the State Health Access Program that awards grants to States to expand access to affordable healthcare coverage for people who are uninsured.

Division of Transplantation (RR1)

On behalf of the Secretary of Health and Human Services (HHS), administers all statutory authorities related to the operation of the Nation's organ procurement and transplantation system, the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program. The Organ Transplantation program supports: (1) The operation of the Organ Procurement and Transplantation Network (OPTN), which facilitates the matching of donor organs to patients in need of organ transplants; (2) the operation of the Scientific Registry of Transplant Recipients (SRTR), which facilitates the ongoing evaluation of the scientific and clinical status of organ transplantation; (3) public education programs to increase awareness about the need for organ donation; (4) peer-reviewed grants and contracts with public and private nonprofit entities to conduct studies and demonstration projects designed to increase organ donation and recovery rates; (5) grants to States to support organ donation awareness programs; (6) public education, outreach programs, and studies designed to increase the number of organ donors, including living donors; (7) the development and dissemination of educational materials to inform health care professionals and other appropriate professionals on issues surrounding organ, tissue and eye donation; (8) grants to qualified organ procurement organizations and hospitals to establish programs to increase the rate of organ donation; (9) financial assistance to living donors to help defray travel, subsistence and other incidental non-medical expenses; (10) supports mechanisms to evaluate the long-term effects of living organ donation; and (11) manages the Secretary's Advisory Committee on Organ Transplantation as it advises the Secretary of the HHS on the activities of the OPTN.

The Division administers two closely related national blood stem cell programs, the C. W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory (NCBI) to facilitate blood stem cell transplants (using adult volunteer donors or umbilical cord blood units) to treat individuals with leukemia and other life-threatening blood and genetic diseases, who lack a related donor. In administering these two programs, the Division: (1) Provides a national system for recruiting and tissue-typing potential bone marrow donors, particularly in racial and ethnic minority populations; (2) funds and oversees collection of high quality cord blood units from diverse population; (3) supports the Advisory Council on Blood Stem Cell Transplantation as it advises the Secretary of the HHS and the Administrator of the Health Resources and Services Administration (HRSA) on the activities of the C.W. Bill Young Cell Transplantation Program and the NCBI Program; (4) stays informed of the medical, scientific, research, and financial environment for blood stem cell transplantation; (5) develops policy in the area of blood stem cell transplantation, in coordination with the C.W. Bill Young Cell Transplantation Program and NCBI contractors, other DHHS agencies, and the U.S. Navy; (6) administers and oversees the contracts for the operation of the C.W. Bill Young Cell Transplantation Program and NCBI, advising on contractor projects and participating in contractor committees; (7) consults with the Department of State (through HRSA's Office of International Health) regarding the possible foreign policy implications of proposed international agreements between the C.W. Bill Young Cell Transplantation Program and NCBI contractors and transplant centers and other organizations outside the U.S.; and (8) initiates, and conducts directly or contracts for, studies to advance the knowledge of blood and marrow transplantation, to address patient needs, to increase donor recruitment in targeted populations, and to address financial issues in transplantation.

Division of Facilities Compliance and Recovery (RR2)

This Division substantiates health facilities' compliance with Hill-Burton uncompensated services and care assurance and administers the Health Care and Other Facilities (HCOF) program. Specifically, the Division: (1) Establishes, develops, monitors, and enforces the implementation of Hill-Burton regulations, policies, procedures,

and guidelines for use by staff and health care facilities; (2) maintains a system for receipt, analysis and disposition of audit appeals by Hill-Burton obligated facilities and for receiving and responding to patient complaints; (3) processes and determines or recommends to the Director, approval or disapproval of recovery claims, waiver actions, and management contracts of Title VI and XVI grant recipient facilities subject to review; (4) manages the recovery of Federal grant funds process for Titles VI and XVI; (5) manages the national Hill-Burton Hotline to ensure that consumers receive timely and accurate information on the program; (6) administers the process for awarding new HCOF grants, including ensuring compliance with historic preservation and other laws and regulations related to construction projects, maintaining a computerized database of key project information, and providing technical assistance in application preparation to potential grantees under Section 1610(b) and the ''Health Care and Other Facilities'' grant programs; (7) monitors grant projects during construction to assure compliance with the terms of the award, reviews requests for changes in scope to grant projects, and obtains information needed to close out completed grant projects; and (8) provides architectural and engineering services in accordance with the Intra-agency Agreement between HRSA and the Administration for Children and Families.

Division of Vaccine Injury Compensation (RR4)

This Division administers all statutory authorities related to the operation of the National Vaccine Injury Compensation Program (VICP) by the: (1) Evaluation of petitions for compensation filed under the VICP through medical review and assessment of compensability for all complete claims; (2) processing of awards for compensation made under the VICP; (3) promulgation of regulations to revise the Vaccine Injury Table; (4) provision of professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV); (5) development and maintenance of all automated information systems necessary for program implementation; (6) provision and dissemination of program information; and (7) promotion of safer childhood vaccines. VICP maintains a working relationship with other relevant Federal and private sector partners in its administration and operation.

Office of Pharmacy Affairs (RR7)

The Office promotes access to clinically and cost effective pharmacy services by maximizing the value of the 340B Drug Pricing Program for entities eligible to participate by: (1) Managing the PHS Pharmaceutical Pricing Agreements with pharmaceutical manufacturers who participate in the Medicaid program; (2) maintaining a database of covered entities and organizations eligible to become covered entities, including status of certifications, where required, and identification of contracted pharmacies, when used by covered entities; (3) publishing guidelines and/or regulations to assist covered entities, drug manufacturers, and wholesalers to use the Drug Pricing Program and comply with the requirements of Section 340B of the Public Health Service Act; (4) implementing and overseeing the 340B Prime Vendor Program that provides drug distribution and price negotiation services for participating covered entities; (5) coordinating the 340B implementation activities of programs in the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Indian Health Service, and the Office of Public Health and Science that provide support to entities eligible to access the Drug Pricing Program; (6) providing a full range of technical assistance to eligible and participating entities; (7) working with the Centers for Medicare and Medicaid Services and the Department of Veterans Affairs, which operate related drug rebate and discount programs, to coordinate policies and operations; and (8) maintaining liaison with grantee associations, professional organizations, the pharmaceutical industry, and trade associations concerning drug pricing and pharmacy issues.

The Office also supports HRSA health centers, States, and other delivery systems as they develop quality programs for affordable drug benefits through: (1) Managing clinical pharmacy demonstration projects; (2) assisting health centers and other grantees to make optimum use of resources available for pharmacy services; (3) demonstrating innovative methods of delivering pharmacy services; (4) providing technical assistance to grantees, States, local governments, and other health care delivery systems to plan and implement pharmacy benefits; (5) serving as a Federal Government resource for pharmacy practice through the development and maintenance of cooperative relationships with national pharmacy and governmental organizations; (6) the provision of technical assistance for pharmacy practice; and (7) the provision of model pharmacy products (such as sample contracts and business plans) for safety-net health care providers.

Section RR–30, 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.

Chapter RP—Bureau of Health Professions

Section RP–20, Functions

Delete the functional statement for the Bureau of Health Professions and replace in its entirety.

Office of the Associate Administrator (RP)

Provides national leadership in coordinating, evaluating, and supporting the development and utilization of the Nation's health personnel. Specifically: (1) Directs the national health professions education, student assistance, and development programs and activities; (2) provides policy guidance and staff direction to the Bureau; (3) maintains liaison with other Federal and non-Federal organizations and agencies with health personnel development interest and responsibilities; (4) provides guidance and direction for technical assistance activities in the international aspects of health personnel development; (5) provides guidance and assistance to the Regional Health Administrators or regional staff as appropriate; (6) directs and coordinates Bureau programs in support of Equal Employment Opportunity; (7) coordinates and provides guidance on the Freedom of Information Act and Privacy Act activities; (8) plans, directs, coordinates, and evaluates Bureau-wide administrative management activities; and (9) serves as the Bureau's focal point for correspondence control.

Office of Shortage Designation (RP2)

Provides national leadership and management of the designation of health professional shortage areas and medically-underserved populations. Specifically: (1) Maintains and enhances the Agency's critical role in the Nation's efforts to address equitable distribution of health professionals and access to health care for underserved populations; (2) encourages and fosters an ongoing, positive working relationship with other

Federal, State and private sector partners regarding health professional shortage areas and medically-underserved populations; (3) approves designation requests and finalizes designation policies and procedures for both current and proposed designation criteria; (4) negotiates and approves State designation agreements (*e.g.,* use of databases, population estimates, Statewide Rational Service Areas); and (5) oversees grants to State primary care offices.

Office of Workforce Policy and Performance Management (RP3)

Serves as the Bureau focal point for program planning, evaluation, coordination, and analysis, including analysis and operations review of Information Management systems; health professions data analysis and research; and for health professions quality assurance efforts. Maintains liaison with governmental, professional, voluntary, and other public and private organizations, institutions, and groups for the purpose of providing information exchange. Specifically the office is responsible for the following activities: (1) Stimulates, guides, and coordinates program planning, reporting, and evaluation activities of the Divisions and staff offices; (2) provides staff services to the Associate Administrator for program and strategic planning and its relation to the budgetary and regulatory processes; (3) develops issue papers and congressional reports relating to Bureau programs; (4) coordinates the development and implementation of the Bureau's evaluation program; (5) coordinates Bureau performance measurement and reporting; (6) sponsors and conducts research, special studies, and forecasting models on important issues that affect the national, State and local health workforce including studies relevant to current and future policies of the Bureau and their impact on the supply and demand for health professionals and the health industry at large; (7) provides technical assistance to States, educational institutions, professional associations and other Federal agencies relative to health personnel analytical information and analysis; and (8) develops and coordinates the Bureau data collection and modeling in conjunction with other entities involved in data collection and analysis, such as the Agency for Healthcare Research and Quality (AHRQ), the National Center for Health Statistics (NCHS), the Centers for Medicare and Medicaid Services (CMS), and the Administration on Aging (AOA).

Division of Nursing (RPB)

Serves as the principal focus for nursing education and practice. Specifically: (1) Provides national leadership and professional nursing expertise in the areas of policy development, budget, planning, coordination, evaluation and utilization of nursing personnel resources; (2) serves, on behalf of the Secretary, as the Chair of the National Advisory Council on Nurse Education and Practice; (3) supports and conducts programs which address the development, supply, utilization, and quality of nursing personnel; (4) promotes the involvement of States and communities in developing and administering nursing programs and assists States and communities in improving nursing services and educational programs; (5) encourages coordination of nursing-related issues within and across departmental entities; (6) facilitates coordination of nursing-related issues with other governmental agencies and consults with them on national or international nursing workforce planning and development issues; (7) maintains liaison with external health professional groups, the academic community, consumers, and State and community groups with a common interest in the Nation's capacity to deliver nursing services; (8) advances and promotes the development of effective models of nursing practice and education; (9) stimulates initiatives in the area of international nursing information exchange and nursing workforce planning and development; and (10) provides overall direction and management of Division human and financial resources.

Division of Medicine and Dentistry (RPC)

Serves as the principal focus with regard to education, practice, and research of health personnel, with special emphasis on allopathic and osteopathic physicians, podiatrists, dentists, physician assistants and clinical psychologists. Specifically: (1) Provides professional expertise in the direction and leadership required by the Bureau for planning, coordinating, evaluating, and supporting development and utilization of the Nation's health personnel for these professions; (2) supports and conducts programs with respect to the need for and the development, use, credentialing, and distribution of such personnel; (3) engages with other Bureau programs in cooperative efforts of research, development, and demonstration on the interrelationships between the members of the health care team, their tasks, education requirements, training modalities, credentialing and practice; (4) conducts and supports studies and evaluations of physician, dentist, physician assistant, podiatrist and clinical psychologist personnel requirements, distribution and availability, and cooperates with other components of the Bureau and Agency in such studies; (5) analyzes and interprets physician, dental, physician assistant, podiatrists and clinical psychologists programmatic data collected from a variety of sources; (6) conducts, supports, or obtains analytical studies to determine the present and future supply and requirements of physicians, dentists, physician assistants, podiatrists and clinical psychologists by specialty and geographic location, including the linkages between their training and practice characteristics; (7) conducts and supports studies to determine potential national goals for the training and distribution of physicians in graduate medical education programs and develops alternative strategies to accomplish these goals; (8) supports and conducts programs with respect to activities associated with the international migration, domestic training, and utilization of foreign medical graduates and U.S. citizens studying abroad; (9) maintains liaison with relevant health professional groups and others, including consumers, having common interest in the Nation's capacity to deliver health services; (10) provides consultation and technical assistance to public and private organizations, agencies, and institutions, including Regional Offices, other agencies of the Federal Government, and international agencies and foreign governments on all aspects of the Division's functions; (11) provides administrative and staff support for the Advisory Committee on Training and Primary Care Medicine and Dentistry and for the Council on Graduate Medical Education; (12) represents the Bureau, Agency and Federal Government, as designated, on national committees and/or the Accreditation Council for Graduate Medical Education (ACGME) and the Accreditation Council for Continuing Medical Education (ACCME); (13) administers support programs for the development, improvement, and the operation of general, pediatric, and public health dental educational programs; (14) designs, administers and supports activities relating to dentists; (15) provides technical assistance and consultation to grantee institutions and

other governmental and private organizations on the operation of these educational programs; (16) promotes the dissemination and application of findings arising from programs supported; (17) develops congressional and other mandated or special program-specific reports and publications on dental educational processes, programs and approaches; and (18) promotes, plans, and develops collaborative educational activities in clinical psychology.

Division of Student Loans and Scholarships (RPD)

Serves as the focal point for overseeing loan and scholarship programs supporting health professionals. Specifically: (1) Directs and administers the Health Professions and Nursing Student Loan and Scholarship Programs, the Federal Assistance to Disadvantaged Health Professions Scholarship Program, the Health Educational Assistance Loan Program, and the Primary Care Loan Program; (2) monitors and assesses educational and financial institutions with respect to capabilities and management of Federal support for students and of tracking of obligatory service requirements; (3) develops and conducts training activities for staff of educational and financial institutions; (4) maintains liaison with and provides assistance to program-related public and private professional organizations and institutions; (5) maintains liaison with the Office of the General Counsel, and the Office of the Inspector General, DHHS, components of the Department of Education and the Department of Defense, and State agencies concerning student assistance; (6) coordinates financial aspects of programs with educational institutions; and (7) develops program data needs, formats, and reporting requirements, including collection, collation, analysis and dissemination of data.

Division of Diversity and Interdisciplinary Education (RPF)

Serves as the principal focal point for interdisciplinary health professions issues and programs, including geriatric training, and for activities to increase the diversity of the health professional workforce. Specifically: (1) Provides leadership and direction for the development and implementation of Bureau objectives as they relate to diverse and disadvantaged populations; (2) develops and recommends health resources and health career opportunities for diverse and disadvantaged populations; (3) initiates, stimulates, supports, coordinates, and evaluates Bureau programs for improving the availability and accessibility of health careers for diverse and disadvantaged populations; (4) conducts special studies and collects baseline data to identify specific factors contributing to the health and health-related problems of diverse and disadvantaged populations, and to develop strategies for improving health services and career opportunities for diverse and disadvantaged populations; (5) conducts extramural programs, including the use of grants and contracts, specifically designed to promote equity in access to health careers; (6) promotes, designs, supports and administers activities relating to the planning and development of nationally integrated health professions education programs; (7) promotes, plans and develops collaborative, interdisciplinary activities in the specialty areas of behavioral/mental health, rural health, geriatrics and the associated health professions, and other new and developing health disciplines; (8) promotes quality improvement in health professions education through collaboration and partnerships with national and international institutes and centers for quality improvement; (9) promotes and supports academic-community partnerships whose goal is the development of interdisciplinary, community-based programs designed to improve access to health care through improving the quality of health professions education and training; (10) serves as the Federal focus for the development and improvement of education for professional public health, preventive medicine, environmental health, and health administration practice, including undergraduate, graduate, and continuing professional development; and (11) provides administrative and staff support for the Advisory Committee on Interdisciplinary, Community-Based Linkages.

Division of Practitioner Data Banks (RPG)

Coordinates with the Department and other Federal entities, State licensing boards, and national, State and local professional organizations to promote quality assurance efforts and deter fraud and abuse by administering the National Practitioner Data Bank (NPDB) as authorized under Title IV of the Health Care Quality Improvement Act of 1986 and Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, and administering the Healthcare Integrity and Protection Data Bank (HIPDB) for the Office of Inspector General. Specifically: (1) Maintains active consultative relations with professional organizations, societies, and Federal agencies involved in the NPDB and HIPDB; (2) develops, proposes and monitors efforts for (a) credentials assessment, granting of privileges, and monitoring and evaluating programs for physicians, dentists, and other health care professionals including quality assurance, (b) professional review of specified medical events in the health care system including quality assurance, and (c) risk management and utilization reviews; (3) encourages and supports evaluation and demonstration projects and research concerning quality assurance, medical liability and malpractice; (4) conducts and supports research based on NPDB and HIPDB information; (5) works with the Secretary's office to provide technical assistance to States undertaking malpractice reform; and (6) maintains liaison with the Office of the General Counsel and the Office of the Inspector General, HHS, concerning practitioner licensing and data bank issues.

Section RP–30, 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 January 4, 2010.

Dated: December 28, 2009.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2009–0127]

Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement—009 External Investigations System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974 the Department of Homeland Security is updating and reissuing a system of records notice titled, ''Department of Homeland Security U.S. Immigration and Customs