

TABLE 3—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS—Continued
[Numbers as of September 30, 2009]

Off-schedule open PMRs	NDA/ANDA (% of total PMR)	BLA (% of total PMR) ¹
Combined total	33 (8.5%)	8 (9%)

¹ See note 1 for table 1 of this document.

TABLE 4—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS
[Numbers as of September 30, 2009]

On-Schedule Open PMCs	NDA/ANDA (% of total PMC)	BLA (% of total PMC) ¹
Pending	449 (46%)	82 (25%)
Ongoing	147 (15%)	84 (26%)
Submitted	271 (28%)	78 (24%)
Combined total	867 (89%)	244 (75%)

¹ See note 1 for table 1 of this document.

TABLE 5—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS
[Numbers as of September 30, 2009]

Off-Schedule Open PMCs	NDA/ANDA (% of total PMC)	BLA (% of total PMC) ¹
Delayed	100 (10%)	79 (24%)
Terminated	11 (1%)	2 (1%)
Combined total	111 (11%)	81 (25%)

¹ See note 1 for table 1 of this document.

TABLE 6—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS
[October 1, 2008 to October 1, 2009]

	NDA/ANDA (% of total)	BLA (% of total) ¹
Concluded PMRs:		
Requirement met (fulfilled)	28 (60%)	5 (56%)
Requirement not met (released and new revised requirement issued)	7 (15%)	2 (22%)
Requirement no longer feasible or product withdrawn (released)	12 (25%)	2 (22%)
Total	47	9
Concluded PMCs:		
Commitment met (fulfilled)	259 (79%)	32 (82%)
Commitment not met (released and new revised requirement/commitment issued)	21 (6%)	0
Commitment no longer feasible or product withdrawn (released)	48 (15%)	7 (18%)
Total	328	39

¹ See note 1 for table 1 of this document.

Dated: November 3, 2010.

David Dorsey,

*Acting Deputy Commissioner for Policy,
Planning and Budget.*

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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 75 FR 61157-61160 dated October 4, 2010).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the Office of Information Technology (RB5) functional statement to better align functional responsibility, improve the management and delivery of information technology services, improve management and

administrative efficiencies, and optimize use of available staff resources.

Chapter RB5—Office of Information Technology

Section RB5–10, Organization

Delete in its entirety and replace with the following:

The Office of Information Technology (RB5) is headed by the Chief Information Officer, who reports directly to the Chief Operating Officer (RB) who reports directly to the Administrator, Health Resources and Services Administration. The Office of Information Technology includes the following components:

- (1) Office of the Director (RB5);
- (2) Division of Capital Planning, Architecture and Project Management (RB52);
- (3) Division of Data and Information Services (RB55);
- (4) Division of Enterprise Solutions and Applications Management (RB56);
- (5) Division of IT Management Support Services (RB57);
- (6) Division of IT Operational Support Services (RB58); and
- (7) Division of Web Support and Collaboration Services (RB59).

Section RB5–20, Functions

(1) Delete the functional statement for the Office of Information Technology (RB5) and replace in its entirety.

Office of the Director and Chief Information Officer (RB5)

The Chief Information Officer (CIO) is responsible for the organization, management, and administrative functions necessary to carry out the responsibilities of the CIO including: (1) Provides 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 departmental Office of Human Resources Management on IT recruitment and training issues.

The Chief Information Security Officer (CISO), reporting to the CIO, provides leadership for, and collaborates 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 Federal Information Security Management Act (FISMA) or other agency security and privacy initiatives, and also carries out the responsibilities including: (1)

Implements, coordinates, and administers 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; (2) executes the Agency's Risk Management Program, evaluates and assists with the implementation of safeguards to protect major information systems, and IT infrastructure; and (3) manages 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 Capital Planning, Architecture and Project Management (RB52)

The Division of Capital Planning, Architecture and Project Management (CPAPM) coordinates HRSA's capital planning and investment control (CPIC), Enterprise Architecture (EA) and Enterprise Project Life Cycle (EPLC) processes for Information Technology (IT) including: (1) Provides direct planning development and support to assure that IT activities support and achieve agency business planning and mission objectives; (2) coordinates the development and review of policies and procedures for IT Capital Planning and Investment Control, Earned Value Management, Enterprise Architecture, IT project management, and the EPLC methodology; (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 analyze it as appropriate; coordinates control and evaluation review of ongoing IT projects and investments, including support to the HRSA Enterprise Governance Board (EGB) and the Technical and Business Review Board (TBRB) in conducting such reviews; (5) operates a Project Management Office to promote, mentor and monitor effective use of the EPLC; improve project management skills, communications and functional user involvement; assists with project prioritization; reduce project risk and monitors progress and budget; and (6) coordinates 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, and incorporating security standards as a component of the EA process.

Division of Data and Information Services (RB55)

The Division of Data and Information Services (DIS) develops and maintains an overall data and information management strategy for HRSA that is integrated with HHS and Government-wide strategies, including: (1) Serves as HRSA's coordination center for data transparency and Open Government data initiatives; (2) provides for HRSA's data quality and ensures that data required for HRSA's enterprise information requirements are captured in appropriate enterprise applications and that necessary data repositories are built and maintained; (3) evaluates and integrates emerging technology to facilitate the translation of data and information from data repositories into electronic formats for internal and external dissemination; (4) identifies information needs across HRSA and develops approaches for meeting those needs using appropriate technologies, including development and maintenance of an enterprise reporting platform and a geospatial data warehouse; (5) 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; (6) provides leadership and establishes policy to address legislative or regulatory requirements in its areas of responsibility; and (7) advises HRSA's Chief Information Officer (CIO) on technical and analytical support it can make available to other HRSA Bureaus and Offices, particularly in support of the HRSA Public Health Steering Committee and the HRSA Office of Planning, Analysis and Evaluation (OPAE).

Division of Enterprise Solutions and Applications Management (RB56)

The Division of Enterprise Solutions and Applications Management (ESAM) 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, including: (1) Manages the application and data architecture definition, controlling software

configuration management, data modeling, database design, development, management and stewardship services for enterprise and small system business process owners; (2) manages the systems development lifecycle by facilitating business process engineering efforts, systems requirements definition, and provides oversight for application change management control; (3) provides enterprise application user training, Tier-3 assistance, and is responsible for end-to-end application building, deployment, maintenance and data security assurance; (4) defines the Agency business applications architecture, engineers technology for business processes, builds, deploys, maintains and manages enterprise systems and data collections efforts; (5) applies business applications architecture to process specific systems; (6) builds, deploys, maintains and manages organization specific systems and unique data collection efforts; and (7) directs database maintenance, modification, security, and management services for system process owners.

Division of IT Management Support Services (RB57)

The Division of IT Management Support Services (ITMSS) represents the CIO and other OIT divisions on IT policy and other administrative and IT management issues, including: (1) Collects customer feedback from the programmatic and business areas of the Agency and provides a central point for a variety of IT management and support functions; (2) provides oversight and management of budget formulation and execution; (3) serves as the focal point to HRSA contracts and provides centralized procurement services for the Office of Information Technology; (4) serves as the coordinator for Inter-agency and Service Level Agreements; (5) oversees the acquisition of HRSA IT hardware, wireless communication devices, and software licenses; (6) accountable for property life cycle management and tracking of Agency-wide IT capital equipment; (7) provides oversight for outsourced network and desktop services to staff in HRSA Regional Offices (ROs); (8) provides telecommunications accountability, oversight, and support; and (9) serves as the focal point for HRSA-wide initiatives that impact the OIT.

Division of IT Operational Support Services (RB58)

The Division of IT Operational Support Services (ITOSS) (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) controls infrastructure configuration management, installations and upgrades, security perimeter protection, and system resource access; (5) 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; (6) maintains workstation hardware and software configuration management controls; (7) in close coordination with the CISO, the ITOSS implements 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; (8) the Chief Technology Officer (CTO), reporting to the ITOSS Division Director is responsible for assessing emerging technologies and the subsequent impact on current infrastructure restraints and program objectives; (9) coordinates and engages with all OIT Divisions and Branches to insure that advanced technology is being utilized to achieve program objectives through innovative technology use; and (10) provides leadership and establishes policy and provides oversight for Agency IT configuration management.

Division of Web Support and Collaboration Services (RB59)

The Division of Web Support and Collaboration Services (WSCS) (1) provides consultation, assistance and services to HRSA to promote and manage information dissemination, collaboration and business process improvement solutions through the use of Web-based tools; (2) in collaboration with the Office of Communications, is responsible for the design, deployment and maintenance of HRSA's internal and external Web sites including development and implementation of related policies and procedures; and (3) supports the collaboration and business needs of HRSA by providing and supporting an enterprise-wide collaboration platform, business process

management tools and Web-conferencing tools.

Section RB5-30, 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 upon date of signature.

Dated: November 1, 2010.

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Free Trade Agreements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-day notice and request for comments; Extension and revision of an existing information collection: 1651-0117.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Free Trade Agreements. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on September 7, 2010 (Volume 75, Page 54352), allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before December 9, 2010.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and