

Proposed Project: Reporting Form for the MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center (HTC) Affiliates Having Factor Replacement Product (FRP) Programs—New

The Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) is planning to implement an annual reporting form required of grantees of the MCHB National Hemophilia Program and their HTC affiliates having a factor replacement product (FRP) program. The purpose of the form is to provide systematic information and data comprising a financial overview of the FRP programs of the HTCs receiving funding through grantees of the MCHB

National Hemophilia Program. The proposed form will constitute a new reporting requirement for the MCHB National Hemophilia Program grantees and their affiliate HTCs having FRP programs.

Data from the form will provide quantitative information on the financial and services provision aspects of each of the HTC FRP programs under each of the MCHB National Hemophilia Program grantees, specifically: (a) Patient FRP program participation, (b) FRP program revenue, (c) FRP program costs, (d) FRP program net income, and (e) use of FRP program net income. This form will provide data useful to grantees and their affiliate HTCs having FRP programs as well as to the MCHB

National Hemophilia Program in assessing FRP program performance including FRP program operational costs appropriateness, FRP program cost efficiency, and FRP program services benefits-information that is essential to evaluating HTCs having FRP programs, grantees, and the MCHB National Hemophilia Program.

Each HTC having an FRP program is to submit their report to their grantee and each grantee is to submit the individual reports of each of their affiliate HTCs having an FRP program to the MCHB National Hemophilia Program as a part of their annual grant application.

The burden estimate for this project is as follows:

FORM HRSA/MCHB FACTOR REPLACEMENT PRODUCT (FRP) DATA SHEET FOR HEMOPHILIA TREATMENT CENTERS HAVING FRP PROGRAMS

| Number of respondents | Average number of responses per respondent | Total responses | Hours per response | Total burden hours |
|-----------------------|--|-----------------|--------------------|--------------------|
| 68 | 1 | 68 | 30 | 2040 |

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: September 13, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

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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 (DHHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; 67 FR 46519, July 15, 2002; and 68 FR 787-793, January 7, 2003; as last amended at 68 FR 64357-64357, November 13, 2003; 68 FR 64357-64357-64358.)

This notice reflects several organizational changes in the Health Resources and Services Administration.

Specifically, this notice updates the functional statement of the Office of Planning and Evaluation (RA5); Office of Information Technology (RAG); Bureau of Primary Health Care (RC); Maternal and Child Health Bureau (RM); Bureau of Health Professions (RP); and the HIV/AIDS Bureau (RV). This notice also changes the organizational titles of the Special Programs Bureau (RR) to the Healthcare Systems Bureau and the Office of Management and Program Support (RS) to the Office of Administration and Financial Management. The major components of the reorganization, in addition to streamlining and delayering the organization, includes: (1) The transfer of the Ricky Ray Hemophilia/ Relief Fund Act of 1998 administration from the Bureau of Health Professions (RP) to the Healthcare Systems Bureau (RR); (2) the transfer of the 340B Drug Pricing Program from the Bureau of Primary Health Care (RC) to the Healthcare Systems Bureau (RR); (3) the transfer of the Poison Control Center Enhancement and Awareness Act administration from the Maternal and Child Health Bureau (RM) to the Healthcare Systems Bureau (RR); (4) the consolidation of all grants and Federal assistance activities to the newly established Office of Federal Assistance Management (RJ); and (5) the transfer of the Border Health function from the Office of International Health Affairs (RAH) to the Office of Rural Health Policy (RH).

Chapter RA—Office of the Administrator

Section RA-10, Organization

Delete in its entirety and replace with the following:

The Office of the Administrator (OA) 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 and Civil Rights (RA2);
- (3) Office of Planning and Evaluation (RA5);
- (4) Office of Communications (RA6);
- (5) Office of Minority Health (RA9);
- (6) Office of Legislation (RAE);
- (7) Office of International Health Affairs (RAH); and
- (8) Office of Information Technology (RAG)

Section RA-20, Functions

(1) Delete the functional statements for the Office of Financial Policy and Oversight (RAJ); the Division of Financial Integrity (RAJ1); and the Division of Grants Policy (RAJ2) and move the functions to the newly established Office of Federal Assistance Management (RJ);

(2) Delete the Division of Border Health (RAH1) and move the functions to the Office of Rural Health Policy (RH); and (3) Delete the functional

statements for the Office of Planning and Evaluation (RA5) and the Office of Information Technology (RAG) in their entirety and replace it with the following:

Office of Planning and Evaluation (RA5)

(1) Serves as the Administrator's primary staff unit for coordinating the Agency's strategic, evaluation and research planning processes; (2) oversees communication and maintains liaison between the Administrator, other OPDIVs, higher levels of the Department and other Departments on matters involving analysis of program policy undertaken in the Agency; (3) prepares policy analysis papers and other planning documents as required in the Administration's strategic planning process; (4) analyzes budgetary data with regard to planning guidelines; (5) collaborates in the development of budgets, performance plans, and performance reports required under the Government Performance and Results Act (GPRA); (6) coordinates activity related to the prevention agenda, Healthy People activities and other Departmental and Agency initiatives; (7) analyzes and coordinates the information needs of the Agency, including coordination of the public use reports clearance function; (8) analyzes policy issues surrounding the application and promotion of healthcare information technology in HRSA programs; and (9) 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 and Medicaid Services and safety net providers.

Office of the Director and Chief Information Officer (RAG)

Responsible for the organization, management, and administrative functions necessary to carry out the responsibilities of the CIO including: organization development, investment control, budget formulation and execution, policy development, strategic and tactical planning, and performance monitoring. The CIO provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA. The CIO coordinates IT workforce issues and works closely with the Departmental Office of Human Resources Management on IT recruitment and training. The Chief Technology Officer (CTO) is responsible for the HRSA emerging and advanced technology integration program

consistent with HRSA missions and program objectives. The CTO manages technology planning and AV/multimedia technology support. The CTO provides leadership for strategic planning that leverages information systems security, program strategies, and advanced technology integration to achieve program objectives through innovative technology use.

Division of Electronic Information and Data Management (RAG1)

Provides consultation, assistance, and services to HRSA to promote and manage communication and collaboration practices using Web technology. EIDM evaluates and integrates emerging technology to facilitate the translation of data and information into electronic or Web-enabled format for internal and external Web dissemination. EIDM is responsible for the collective design, deployment, and maintenance of HRSA's Web presence including development and implementation of World Wide Web-related policies and procedures. EIDM develops and maintains an overall knowledge management strategy for HRSA that is integrated with HHS and Government-wide strategies. EIDM identifies information needs across HRSA and develops approaches for meeting those needs using Web-based technologies. EIDM ensures that data required for enterprise information requirements are captured in appropriate enterprise applications; 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; and demonstrates potential uses of information in supporting management decisions.

Division of Capital Planning, Architecture and Security (RAG2)

Performs long-range strategic planning, develops and implements an integrated HRSA Enterprise Architecture, prepares and submits HRSA IT Budget Exhibits to OMB, and manages the Agency's IT Security Program. CPAS develops and implements the Agency's Capital Planning and Investment Control (CPIC) policies and procedures in accordance with HHS standards, ensures the integration of CPIC business processes with budgeting, enterprise architecture, strategic planning, and maintains/operates HRSA's IT Portfolio Management Tool (PMT). CPAS manages and implements the Agency-wide IT security program, which includes development and dissemination of HRSA IT security

policy and guidance, monitoring of HRSA organizational components, and direction of the Agency's Incident Response Team. CPAS collaborates with Agency staff to oversee the implementation of security policy in the management of their IT systems, and directs all planning and auditing activities associated with FISMA or other departmental security initiatives. CPAS is responsible for 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, and incorporating security standards as a component of the EA process. CPAS also provides leadership and establishes policy to address legislative or regulatory requirements, such as Government Paperwork Elimination Act, Section 508 of the Rehabilitation Act, or other information collection activities.

Division of Enterprise Solutions Development and Management (RAG3)

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. ESDM is responsible for technology evaluation, application and data architecture definition, and data modeling and stewardship services for business process owners. ESDM facilitates business process engineering efforts, systems requirements definition, and provides oversight for application change management control. ESDM 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 Management (RAG4)

Provides leadership, consultation, and management services for HRSA's enterprise computing environment. ITOM directs and manages the support of HRSA network hardware, application servers, telecommunication network, communication devices, software licenses, workstation tools for navigation, backup, printing, mail/messaging, and Web server operation and management. ITOM controls infrastructure configuration management, installations and upgrades, security perimeter protection, and system resource access. ITOM

coordinates IT for Continuity of Operations Planning (COOP) Agency-wide and ensures adequate support for HRSA's COOP, including telecommunications to support emergency and COOP requirements. ITOM supports the telephone system requirements of the Agency and represents HRSA at working groups and committees addressing secure telecommunications issues.

Division of Business Services Management (RAG5)

Provides consultation, assistance, and services to assist and empower Agency staff and external business partners in the application of information technology to support program objectives of HRSA. In support of HRSA's programs, BSM maintains and supports an Agency IT training center and is also responsible for a variety of career development and workforce IT training. BSM is accountable for IT life cycle management and tracking of Agency-wide IT capital equipment. BSM provides oversight for outsourced Tier-1 Help Desk Call Center activities and Tier-2 and Tier-3 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.

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 (BPHC) is headed by the Associate Administrator for Primary Health Care who reports directly to the Administrator, Health Resources and Services Administration. The BPHC includes the following components:

- (1) Office of the Associate Administrator (RC)
- (2) Office of Minority and Special Populations (RCE)
- (3) Division of Health Center Development (RCH)
- (4) Division of Health Center Management (RCJ)
- (5) Division of Clinical Quality (RCK)
- (6) Division of State and Community Assistance (RCL)
- (7) Division of National Hansen's Disease Program (RC7)
- (8) Division of Immigration Health Services (RC9)

Section RC-20, Functions

- (1) Delete the functional statement for the Office of Policy, Evaluation and Data (RCI); and (2) delete the functional

statements for the Division of Health Center Development (RCH); the Division of Clinical Quality (RCK); and Division of Immigration Health Services (RC9) in their entirety and replace with the following:

Office of the Associate Administrator (RC)

Provides overall leadership, direction, coordination, and strategic planning in support of Bureau programs. Specifically: (1) Has lead responsibility to bring primary health care services to the nation's neediest communities; (2) serves as a central point of contact for Bureau communication and information; (3) establishes program policies, goals, and objectives and provides oversight as to their execution; (4) interprets program policies, guidelines, and priorities; (5) stimulates, coordinates and evaluates program development and progress; (6) maintains effective relationships with HRSA, other Department and Health and Human Services (HHS) organizations, other Federal agencies, State and local governments, and other public and private organizations concerned with primary health and improving the health status of the Nation's underserved and vulnerable populations; and (7) plans, directs, coordinates and evaluates Bureau-wide administrative management activities; (8) assures the BPHC's funding recommendations are consistent with authorizing legislation, program expectations and HHS and HRSA policies; (9) provides leadership, direction and overall coordination of the analysis and clearance of policy across the bureau; (10) provides leadership, direction, and overall coordination of the analysis and clearance of policy across Bureau programs; (11) serves as the focal point for the development and monitoring of the Bureau's Strategic Plan and annual spending plans; (12) serves as focal point for external communication, publication, and dissemination; (13) provides consultation to and coordinates activities with other components within HRSA, other Federal agencies, consumer and constituency groups, national and state organizations involved in policy; and (14) manages the Bureau's executive secretariat functions; (15) serves as focal point to design, establish and implement an evaluation for assessing and improving program performance; (16) directs and coordinates performance review and monitoring activities related to: GPRA, OMB, PART, GAO, OIG, and IOM reports; (17) coordinates and serves as the external liaison with governmental

and private-sector advisory groups that have a policy and/or performance impact on the Bureau; (18) serves as the Bureau's principal source for management and administrative advice and assistance; (19) provides advice, guidance and coordinates personnel activities for the Bureau including EEO, timekeeping, labor relations, ethics; (20) directs and coordinates the allocation of personnel resources; (21) provides organization and management analysis, develops policies and procedures for internal operation and interprets and implements Bureau's management policies, procedures and systems; (22) develops and coordinates Bureau program and administrative delegations of authority activities; (23) provides guidance to the Bureau on financial management activities; (24) provides Bureau-wide support services such as COOP Plans, employee training, contracts, procurement, supply management, equipment utilization, printing, property management, space management, records management, and management reports; and (25) performs a range of functions relating to the awarding of appropriated funds, including Preview development, working with program staff on recommended grant actions, and maintaining commitment levels for Bureau grantees and programs.

Division of Health Center Development (RCH)

Serves as the organizational focus of the competitive grant process for BPHC. Specifically, DHCD: (1) Provides leadership and direction, including tactical planning for the development and expansion of new health centers, health systems infrastructure; (2) provides pre-application assistance to communities and community-based organizations related to health center development, health systems infrastructure development; and (4) provides consultation to and coordinates activities with other components within HRSA, other Federal agencies, consumer and constituency groups, national and state organizations involved in implementation of BPHC's competitive process.

Division of Clinical Quality (RCK)

- (1) Provides clinical and quality leadership for BPHC to meet the President's Initiative to expand health centers; (2) supports BPHC functions to assess the Nation's health care needs of underserved populations and to assist communities in providing primary health care services to the underserved in moving toward eliminating health

disparities; (3) provides leadership for implementing BPHC clinical and quality agenda; (4) serves as the focal point of leadership, coordination, and communication for BPHC clinical and quality activities; (5) provides leadership, direction and coordination for health workforce planning as it supports health center development; (6) supports BPHC through assessments of clinical, quality improvement, risk management, and patient safety activities to improve policies, and programs for primary health care services including clinical information systems; (7) coordinates BPHC clinical and quality liaison with other DHHS organizations, other Federal, State, and private agencies, and organizations for clinical and quality issues for community based primary health care for underserved populations; and (8) coordinates clinical technical assistance program for BPHC health professional and non-health professional staff; (9) carries out data collection and analysis activities that document the clients served and services funded by the Bureau programs; and (10) gathers and evaluates data on costs of publicly financed care and quality of the Bureau's health care programs.

Division of Immigration Health Services (RC9)

Serves as the primary focal point for planning, management, policy formulation, program coordination, direction and liaison for all health matters pertaining to aliens detained by the U.S. Immigrations and Customs Enforcement (ICE), Department of Homeland Security (DHS) and for juvenile aliens through the Office of Refugee Resettlement (ORR). Additionally, DIHS is responsible for provision of direct primary health care at all ICE Service Processing Centers and selected contract detention facilities throughout the Nation. Specifically: (1) Works with ICE to plan, manage, formulate policy, coordinate programs, and provide direction and liaison for health matters pertaining to aliens detained by ICE, (2) manage ICE direct primary care facilities, conduct telehealth services, and assist in oversight of care provided in contract facilities; (3) ensures the efficient operation of a comprehensive health care delivery system by providing direction to a nationwide integrated health care system that includes direct delivery of care as well as managed care services; (4) develops and implements policy and guidelines relating to detained alien health, dental, and mental health screening and care; (5) provides liaison between ICE, DHS,

ORR, other Department of Justice activities and other DHHS components; communicates with members of Congress and their staffs on behalf of ICE, Office of Management and Budget (OMB) staff, and national/international leaders at universities and in the private health care sector for all issues involving health care of detained aliens and as well as for emergency and certain preventive health care for ICE employees; (6) provides medical support including aviation medicine during removal and repatriation of aliens by ICE; (7) provides health care and public health services during deployment for designated special operations; (8) reviews and evaluates all ICE alien health activities in terms of unmet needs, operational improvement, and health and safety of both the health care facilities and detention environments; (9) coordinates payment for all off-site services arranged and authorized by DIHS; and (10) compiles statistical data of the health status of detained alien population and the cost of care within the DIHS and the care purchased outside of the ICE.

Chapter RH—Office of Rural Health Policy

Section RH-30, Functions

Delete the functional statement for the Office of Rural Health Policy (RH) in its entirety and replace with the following:

Office of Rural Health Policy (RH)

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. Specifically, the Office of Rural Health Policy is responsible for the following activities: (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 Center for Medicare and Medicaid Services (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) oversees compliance by CMS with the requirement that 10 percent of its research and demonstration budget is used for rural projects; (11) supports specialized rural programs on minority health, mental health, and agricultural health and safety; (12) plans and manages a nationwide rural health grants program; (13) plans and manages a program of grants to States to initiate and expand offices of rural health; (14) provides leadership and direction to coordinate the Agency's assets in border regions; (15) 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; (16) assures Agency-wide coordination by establishing border health program policies and procedures including tracking mechanisms; (17) conducts management and evaluation studies to improve the health delivery system on the border; (18) serves as the secretariat and chair for the Agency's Border Health Workgroup; (19) plans, directs, and coordinates the Agency's border health activities; and (20) plans, coordinates and facilitates the Agency agreements activities with border health issues.

Establish the Office of Federal Assistance Management as follows:

Chapter RJ—Office of Federal Assistance Management

Section RJ-00, Mission

To provide national leadership, oversight, and financial integrity assurances for the administration of HRSA's Federal assistance programs.

Section RJ–10, Organization

The Office of Federal Assistance Management (OFAM) is headed by the Associate Administrator for Financial Assistance Management who reports directly to the Administrator, Health Resources and Services Administration. The OFAM includes the following components:

- (1) Office of the Associate Administrator (RJ)
- (2) Division of Financial Integrity (RJ1)
- (3) Division of Grants Policy (RJ2)
- (4) Division of Grants Management (RJ3)
- (5) Division of Independent Review (RJ4)

Section RJ–20, Functions*Office of Federal Assistance Management (RJ)*

Provides national leadership in the administration and assurance of the financial integrity of HRSA's programs and provides oversight over all HRSA activities to ensure that HRSA's resources are being properly used and protected. Provides leadership, direction and coordination to all phases of grants policy, administration and independent review. Specifically, (1) serves as the Administrator's principal source for grants policy and financial integrity of HRSA programs; (2) exercises oversight over the Agency's business processes related to assistance programs; (3) facilitates, plans, directs and coordinates the administration of HRSA grant policies and operations; (4) plans, directs and carries out the grants officer functions for all of HRSA's programs; and (5) directs and carries out the independent review of grant applications for all of HRSA's programs.

Division of Financial Integrity (RJ1)

(1) Serves as the Agency's focal point for coordinating financial audits of grantees; (2) coordinates the external financial assessment of HRSA grantees and the resolution of any audit findings; (3) conducts the pre- and post-award review of grant applicants' and grantees' accounting systems; (4) conducts ad hoc studies and reviews related to the financial integrity of the HRSA business processes related to assistance programs; (5) serves as the Agency's liaison with the Office of Inspector General for issues related to grants; (6) manages and maintains the Agency's hot line for reporting fraudulent fiscal activities; and (7) establishes an assessment model for grantee oversight.

Division of Grants Policy (RJ2)

(1) Advises on grants policy issues and assists in the identification and resolution of grants policy issues and problems; (2) analyzes, develops and implements the Agency's grants policy; (3) coordinates the review of departmental grants policies and ensures that Agency policies and procedures are revised to reflect appropriate changes; (4) conducts review of the limited competition process; (5) monitors and reviews the Agency's program application guidance; (6) serves as the grants liaison for the Agency's electronic systems and processes; (7) coordinates the development of standardized documents and processes for the Agency related to grants; (8) reviews Agency programs for proper interpretation and timely implementation and application of grants management policies; and (9) serves as the coordinator for General Accounting Office and OIG studies on HRSA programs.

Division of Grants Management Operations (RJ3)

(1) Exercises the sole responsibility within HRSA for all aspects of grant and cooperative agreement receipt and award processes; (2) participates in the planning, development, and implementation of policies and procedures for grants and other Federal financial assistance mechanisms; (3) provides assistance and technical consultation to program offices in the development and interpretation of laws, regulations, policies and guidelines relative to the Agency's grant and cooperative agreement programs; (4) develops standard operating procedures, methods and materials for the administration of the Agency's grants programs; (5) establishes standards and guides for grants management operations; (6) reviews grantee financial status reports and prepares reports and analyses on the grantee's use of funds; (7) provides technical assistance to applicants and grantees on financial and administrative aspects of grants projects; (8) provides data and analyses as necessary for budget planning, hearings, operational planning and management decisions; and (9) participates in the development of program guidance and instructions for grant competitions.

Division of Independent Review (RJ4)

(1) Plans, directs and carries out HRSA's independent review of applications for grants and cooperative agreement funding, and assures that the process is fair, open and competitive; (2)

develops, implements and maintains policies and procedures necessary to carry out the Agency's independent review/peer review processes; (3) provides technical assistance to independent reviewers ensuring that reviewers are aware of and comply with appropriate administrative policies and regulations; (4) provides technical advice and guidance to the Agency regarding the independent review processes; (5) coordinates and assures the development of program policies and rules relating to HRSA's extramural grant activities; and (6) provides HRSA's Offices and Bureaus with the final disposition of all reviewed applications.

Chapter RM—Maternal and Child Health Bureau**Section RM–10, Organization**

Delete in its entirety and replace with the following:

The Maternal and Child Health Bureau (MCHB) is headed by the Associate Administrator for Maternal and Child Health who reports directly to the Administrator, Health Resources and Services Administration. The MCHB includes the following components:

- (1) Office of the Associate Administrator (RM)
- (2) Office of Operations and Management (RM1)
- (3) Division of Services for Children with Special Health Needs (RM2)
- (4) Division of Child, Adolescent and Family Health (RM3)
- (5) Division of Research, Training and Education (RM4)
- (6) Division of Healthy Start and Perinatal Services (RM5)
- (7) Division of State and Community Health (RM6)
- (8) Office of Data and Program Development (RM7)

Section RM–20, Functions

Delete the functional statements for the Division of Services for Children with Special Health Needs (RM2); the Division of Child, Adolescent and Family Health (RM3); the Division of Perinatal Systems and Women's Health (RM5); and the Office of Data and Information Management (RM7); in their entirety and replace with the following:

Division of Services for Children With Special Health Needs (RM2)

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease among children with special health care needs (CSHCN) and their families, with

special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such populations. Specifically, the Division carries out the following activities: (1) Administers a program that supports the development of systems of care and services for CSHCN and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for CSHCN and their families; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) provides consultation and technical assistance to State programs for CSHCN and to local communities, consistent with a Bureau wide technical assistance consultation plan and in concert with other agencies and organizations; (6) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for CSHCN and their families; (7) develops and implements a national program for those at risk or living with genetic diseases, including a national program for persons with hemophilia, implementing a system of demonstration projects related to early identification, referral, treatment, education, and counseling information; (8) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act, Supplemental Security Income, Individuals with Disabilities Education Act, and others) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for CSHCN, including those with genetic disorders, and their families; (9) promotes the dissemination of information on preventive health services and advances in the care and treatment of CSHCN, including those with genetic disorders, and their families; (10) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for CSHCN, including those with genetic disorders, and their families; (11) provides a focus for international health activities of the Bureau for services for CSHCN and their families; (12) participates in the development of interagency agreements concerning Federal assignees to State MCH

programs; (13) carries out a national program on traumatic brain injury, and (14) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Child, Adolescent, and Family Health (RM3)

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease and injury among children, adolescents, and their families with special emphasis on the development and implementation of family-centered, comprehensive, coordinated, community-based and culturally competent systems of care for such populations. Specifically, the Division carries out the following activities: (1) Administers a program that supports the development of systems of care and services for children, adolescents, and their families; (2) develops policies and guidelines and promulgates standards for professional services, effective organization and administration of health programs for children, adolescents, and their families; (3) accounts for the administration of funds and other resources for grants, contracts, and programmatic consultation and assistance; (4) coordinates with MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) serves as the focal point within the Bureau in implementing programmatic statutory requirements for State programs for children, adolescents, and their families; (6) provides consultation and technical assistance to State programs for children, adolescents, and their families and to local communities, consistent with a Bureau-wide technical assistance consultation plan, working with other agencies and organizations; (7) carries out a national program designed to improve the provision of emergency medical services for children; (8) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for children, adolescents, and their families; (9) serves as the national focus for improving the health and well-being of adolescents; (10) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for children, adolescents, and their families; (11) disseminates information on preventive health services and advances in the care

and treatment of children, adolescents, and their families; (12) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children, adolescents, and their families; (13) provides a focus for international health activities for the Bureau for services for children, adolescents, and their families; and (14) administers funds and other resources for grants, contracts, and cooperative agreements.

Division of Healthy Start and Perinatal Services (RM5)

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on perinatal, infant and women's health to improve and strengthen the access, delivery, quality, coordination and information for services for the targeted populations, especially for the vulnerable and high-risk. Specifically, the Division is responsible for the following activities: (1) Administers national programs on perinatal and women's health with an emphasis on infant mortality reduction and prevention; (2) provides policy direction, technical assistance, and professional consultation on Division programs; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other Maternal and Child Health Bureau Divisions and Offices in promoting Division programs' objectives and the mission of the Bureau; (5) serves as the focal point within the Bureau in implementing programmatic requirements for the Division's programs; (6) coordinates Division programs within the Agency and with other Federal programs; (7) provides liaison with public, private, professional and voluntary organizations for Division programs; (8) disseminates information on Division programs; (9) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to Division programs; (10) provides a focus for international health activities of the Bureau for Division programs; and (11) administers funds and other resources for grants, contracts, and cooperative agreements.

Office of Data and Program Development (RM7)

Provides leadership by carrying out the following two activities: (1) Identifies and analyzes data needs and

utilizes and implements a data strategy and program focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such populations; and (2) serves as the Bureau focal point for the management of the planning, evaluation, legislation, and legislative implementation activities, including the development, coordination, and dissemination of program objectives, policy positions, reports and strategic plans. Specifically, the Office carries out the following data functions: (1) Develops, coordinates, and maintains a data and information system designed to improve implementation of Title V and other Bureau programs; (2) develops, coordinates, and implements systematic technical assistance and consultation on data and information systems and evaluation approaches to State and local agencies and organizations or groups concerned with infants, children, adolescents, and children with special health care needs (CSHCN); (3) through grants and contracts, provides support for a broad range of data collection, analyses and projects designed to improve the health status of infants, children, adolescents, and CSHCN; (4) coordinates and provides professional consultation and technical assistance to State and local agencies and organizations; (5) develops, coordinates and disseminates data; (6) plans, implements and monitors a system of placement of Federal employees assigned to State health agencies; (7) coordinates and monitors the placement of Centers for Disease Control and Prevention sponsored epidemiologists in State agencies; and (8) provides for data program coordination at all levels of Bureau program operations through analyses of program data, trends and other issues concerning scientific and policy matters, the provision of health services and data and information related to the promotion of health and prevention of disease among infants, children, adolescents, and CSHCN. In addition, the Office carries out the following program development functions: (1) Advises and assists the Associate Administrator for Maternal and Child Health and other Bureau staff in the development, coordination and management of strategic planning and policy documents, responses to departmental and HRSA initiatives, and information papers to support Bureau

and Administration goals; (2) interprets evaluation requirements and develops, coordinates, and manages the preparation of the annual evaluation plans and activities, and conducts or contracts for specific evaluation projects related to the performance of MCHB programs; (3) develops, coordinates, and manages Bureau activities related to the development, clearance, and dissemination of **Federal Register** notices, guidelines, final grant reports, and periodic and annual reports to other Federal and non-Federal agencies; (4) participates in the development of budget submissions including the Government Performance Review Act annual performance plan and the Office of Management and Budget Program Assessment Review Tool; (5) coordinates activities closely and continuously with the Office of Planning and Evaluation, and the MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (6) provides liaison with public, private, professional, and voluntary organizations on programs related to MCHB planning and legislative issues; and (7) participates in international health activities of the Bureau.

Chapter RP—Bureau of Health Professions

Section RP–10, Organization

Delete in its entirety and replace with the following:

The Bureau of Health Professions (BHP) is headed by the Associate Administrator for Health Professions who reports directly to the Administrator, Health Resources and Services Administration. The BHP includes the following components:

- (1) Office of the Associate Administrator (RP)
- (2) Office of Workforce Evaluation and Quality Assurance (RPM)
- (3) Division of Medicine and Dentistry (RPC)
- (4) Division of State, Community and Public Health (RPE)
- (5) Division of Nursing (RP5)
- (6) Division of Health Careers Diversity and Development (RPD)
- (7) Division of National Health Services Corps (RPH)

Section RP–20, Functions

Delete the functional statements for the Bureau of Health Professions (RP); the Office of Program Support (RP1); the Office of Planning and Policy (RPA); the Division of Practitioner Databanks (RPB); Division of Medicine and Dentistry (RPC); and the National Center for Health Workforce Analysis (RPL) in

their entirety and replace with the following:

Bureau of Health Professions (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 Workforce Evaluation and Quality Assurance (RPM)

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) monitors obligatory service requirements and conditions of deferment for compliance; (6) coordinates with other Divisions within the Bureau to develop policy and program guidance to monitor obligatory

service requirements and conditions of deferment; (7) develops and provides program data and reports regarding service requirements and conditions of deferment; (8) provides departmental, Agency and Bureau leadership for a National Health Workforce and Analysis Program; (9) 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; (10) provides technical assistance to States, educational institutions, professional associations and other Federal agencies relative to health personnel analytical information and analysis; (11) 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); (12) provides national leadership and management of the designation of health professional shortage areas and medically-underserved populations; (13) 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; (14) 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; (15) approves designation requests and finalizes designation policies and procedures for both current and proposed designation criteria; (16) negotiates and approves State designation agreements (e.g., use of databases, population estimates, Statewide Rational Service Areas); (17) 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; (18)

maintains active consultative relations with professional organizations, societies, and Federal agencies involved in the NPDB and HIPDB; (19) 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 quality review of specified medical events in the health care system including quality assurance, and (c) risk management and utilization reviews; (20) encourages and supports evaluation and demonstration projects and research concerning quality assurance, medical liability and malpractice; (21) conducts and supports research based on NPDB and HIPDB information; (22) works with the Secretary's office to provide technical assistance to States undertaking malpractice reform; and (23) maintains liaison with the Office of the General Counsel and the Office of the Inspector General, HHS for Bureau programs.

Division of Medicine and Dentistry (RPC)

Serves as the principal focus with regard to education, practice, and research of medical 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.

Chapter RR—Healthcare Systems Bureau

Rename the Special Programs Bureau (RR) as the Healthcare Systems Bureau and amend the organization and

functional statements to include functions related to the Ricky Ray Program, the 340B Drug Pricing Program, and Poison Control Centers Program.

Section RR-10, Organization

Delete in its entirety and replace with the following:

The Healthcare Systems Bureau (HSB) is headed by the Associate Administrator for Healthcare Systems who reports directly to the Administrator, Health Resources and Services Administration. The HSB includes the following components:

- (1) Office of the Associate Administrator (RR)
- (2) Division of Transplantation (RR1)
- (3) Division of Facilities Compliance and Recovery (RR2)
- (4) Division of Facilities and Loans (RR3)
- (5) Division of Vaccine Injury Compensation (RR4)
- (6) Division of Healthcare Emergency Preparedness (RR5)
- (7) Smallpox Vaccine Injury Compensation and Ricky Ray Hemophilia Relief Program Office (RR6)
- (8) Office of Pharmacy Affairs (RR7)
- (9) Division of Engineering Services (RR8)

Section RR-20, Functions

Delete the functional statements for the former Special Programs Bureau in their entities and replace with the following:

Healthcare Systems Bureau (RR)

(1) Administers the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients; (2) administers the National Marrow Donor Program in matching volunteer unrelated marrow donors for transplants and studying the effectiveness of unrelated marrow donors for transplants and related treatment; (3) administers the National Cord Blood Stem Cell Bank (NCBSCB); (4) develops and maintains a national program of grants and contracts to organ procurement organization and other entities to increase the availability of various organs to transplant candidates; (5) manages the national program for compliance with the Hill-Burton uncompensated care requirement and other assurances; (6) directs and administers the Section 242 hospital mortgage insurance program (through inter-agency agreement with HUD) and HHS direct and guaranteed construction loan repayment program; (7) directs and administers an earmarked grant program for the construction/renovation/equipping of health care and other

facilities; (8) directs and administers the National Vaccine Injury Compensation Program; (9) directs and administers the Smallpox Emergency Personnel Protection Act Program; (10) 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; (11) directs and administers the National Hospital Bioterrorism Preparedness Program; (12) directs and administers the Trauma-Emergency Medical Services Program; (13) directs and administers the Poison Control Center Enhancement and Awareness Act; (14) directs and administers the Ricky Ray Hemophilia Relief Fund Act of 1998; (15) manages and promotes the 340B Drug Pricing Program; and (16) provides policy input and operational direction for the facilities engineering and construction management system.

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 National Bone Marrow Donor Registry and the Cord Blood Bank programs. 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 in 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; and (10) mechanisms to evaluate the long-term effects of living organ donation.

The Division: (1) Administers the two national programs to facilitate blood and marrow transplantation with donors unrelated to the patients: the National Bone Marrow Donor Registry (NBMDR) and the National Cord Blood Stem Cell Bank (NCBSCB); (2) stays informed of the medical, scientific, research, and financial environment for blood and marrow transplantation; (3) Develops policy in the area of blood and marrow transplantation, in coordination with the NBMDR and NCBSCB contractors, other DHHS agencies, and the U.S. Navy; (4) administers and oversees the contracts for the operation of the NBMDR and NCBSCB, advising on contractor projects and participating in contractor committees; (5) 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 NBMDR and NCBSCB contractors and transplant centers and other organizations outside the U.S.; and (6) 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)

Substantiates health facilities compliance with the reasonable volume of uncompensated services assurance and administers the Health Care and Other Facilities program. Specifically, (1) establishes, develops, monitors, and enforces the implementation of 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; and (3) coordinates its activities with other components of the Bureau, HRSA, other HHS agencies, and other department components.

Division of Facilities and Loans (RR3)

On behalf of the Secretary of Health and Human Services (HHS) and in coordination with the U.S. Department of Housing and Urban Development (HUD), with which there is a Memorandum of Agreement, the Division of Facilities and Loans (DFL) administers the Section 242 Hospital Mortgage Insurance Program, monitors the financial condition of Hill-Burton and other HHS loan recipients, and generally assists other agencies both

within and outside HHS in both loan and construction activities. DFL accomplishes these tasks by the (1) review and evaluation of the financial and programmatic portions of new applications; (2) monitoring of the financial and physical condition of loans in the portfolio; (3) assistance to those clients in the accomplishment of loan modifications and during times of financial difficulty; (4) site and/or program assessment on behalf of clients contemplating the purchase, rehabilitation, or new construction of Head Start facilities, post-secondary educational facilities, general healthcare facilities and other facilities related to the local infrastructure such as hospitals and public health buildings, and other government buildings for nations in the Pacific Rim; (5) maintenance of automated information systems necessary for program implementation; (6) provision and dissemination of program information; and (7) development of legislative amendments, regulations, and policies related to both HUD and HHS programs. DFL maintains a working relationship with other Federal and private sector partners in the administration and operation of the loan and construction activities. The organizational structure of DFL shall be comprised of two Branches under the Office of the Director.

Division of Vaccine Injury Compensation (RR4)

On behalf of the Secretary of Health and Human Services (HHS), 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. Maintains a working relationship with other Federal and private sector partners in the administration and operation of the VICP. The organizational structure of DVIC shall be comprised of two Branches under the Office of the Director.

Division of Healthcare Preparedness (RR5)

Facilitates the development of State, territorial, and municipal preparedness programs, via grants, cooperative agreements, and contracts, to enhance the capacity of the Nation's hospitals and other healthcare entities to respond to mass casualty incidents caused by terrorism and other public health emergencies. Specifically, the Division, together with other components of the Agency: (1) Serves as the national focus for leadership in and coordination of Federal, State, local and non-governmental efforts to define the readiness needs for hospitals and other healthcare entities to respond to terrorism or other public health emergencies and to assist in the development of programs that address identified problems; (2) analyzes regional or national issues and problems and recommends responses to those problems through research, training, or other actions, as indicated; (3) develops, interprets, and disseminates policies, regulations, standards, guidelines, new knowledge, and program information for the various programs and services relevant to healthcare terrorism and public health emergency preparedness; (4) provides technical assistance and professional consultation to field and headquarters staffs, State and local health personnel, other Federal agencies, hospitals, hospital associations, and professional organizations on all aspects of healthcare terrorism and public health emergency preparedness planning efforts; (5) establishes and maintains cooperative working relationships with professional organizations and other relevant entities and serves as a focal point for communications to improve healthcare terrorism and public health emergency preparedness; (6) works collaboratively with the Centers for Disease Control and Prevention and the Department's Office of the Assistant Secretary for Public Health Emergency Preparedness in administering the National Bioterrorism Hospital Preparedness Program; (7) promotes coordination of healthcare terrorism and public health emergency preparedness under Public Law 107-188, the Public Health Security and Bioterrorism Preparedness Act of 2002 (Section 319 of the Public Health Service Act, 42 U.S.C. 201 *et seq.*), while supporting activities related to countering potential terrorist threats to civilian populations; (8) administers the Poison Control Program within the authority of Public Law 108-194, the Poison Control Center Enhancement and Awareness Act

Amendments of 2003, to ensure the availability of the Nation's poison control centers as a source of public information and public education regarding potential biological, chemical, and nuclear domestic terrorism; (9) administers the Emergency System for Advance Registration of Volunteer Healthcare Personnel Program within the authority of Section 107 of the Public Health Security and Bioterrorism Preparedness Act of 2002, to identify qualified healthcare personnel to respond to emergency and mass casualty events and ensure the qualifications of these identified individuals; and (10) administers the Trauma—Emergency Medical Services Systems Program, within the authority of Title XII of the Public Health Service Act, to facilitate the development of effective, comprehensive, and inclusive Statewide trauma systems that are prepared and responsive to emergency and mass casualty events.

Smallpox Vaccine Injury Compensation and Ricky Ray Hemophilia Relief Fund Program Office (RR6)

Responsible for implementing and administering, on behalf of the Secretary of Health and Human Services (HHS), the Smallpox Emergency Personnel Protection Act of 2003 and the Ricky Ray Hemophilia Relief Fund Act of 1998. Specifically, the Smallpox Vaccine Injury Compensation Program: (1) Develops regulations which describe program administrative operational policies and procedures; (2) evaluates petitions for compensation filed under the Act through medical review and assessment of compensability for all completed request for benefits; (3) processes benefits for payments made under the Act; (4) promulgates regulations to revise the Smallpox Vaccine Injury Table; (5) develops and maintains all automated information systems necessary for program implementation; (6) provides and disseminates program information; (7) establishes Memorandums of Understanding and Inter-Agency Agreements with other Federal Agencies and Departments which contribute to program operations; and (8) maintains a working relationship with other Federal and private sector partners in the administration and operation of the Smallpox Emergency Personnel Protection Act of 2003. Specifically, the Ricky Ray Hemophilia Relief Program (RRHRFP): (1) Develops and maintains information systems necessary for the program implementation; (2) develops and implements program operation plans, policies and procedures; (3) develops regulations which describe the

program's criteria, guidelines, and operating procedures; (4) develops program data needs, formats, and reporting requirements, including collection, collation, analysis, and dissemination of data; (5) evaluates petitions for a compassionate payment under the RRHRFP through a medical review and an assessment of all complete petition files; (6) tracks compassionate payments made by the program; (7) reports to the Secretary and the Congress when warranted; (8) proposes revisions to the Act when warranted; (9) provides information to the general public and others on the program; (10) maintains liaison with the Office of General Counsel and other agencies concerning the program; (11) serves as the principle point of contact for inquiries and information from individuals on matters relating to the program operations, the petition process, payment and reconsideration process; (12) receives, reviews and makes recommendations concerning litigation requests; and (13) provides program budget estimates and justifications, and long-range and annual program plans.

Office of Pharmacy Affairs (RR7)

Promotes access to clinically and cost effective pharmacy services by: (1) Maximizing the value of 340B Drug Pricing Program for entities eligible to participate by (a) managing the PHS Pharmaceutical Pricing Agreements with pharmaceutical manufacturers who participate in the Medicaid program, (b) 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, (c) 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, (d) implementing and overseeing the 340B Prime Vendor Program that provides drug distribution and price negotiation services for participating covered entities, (e) 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, (f) providing a full range of technical assistance to eligible and participating entities, (g) 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 (h) maintaining liaison with grantee associations, professional organizations, the pharmaceutical industry, and trade associations concerning drug pricing and pharmacy issues; (2) supporting HRSA health centers, States, and other delivery systems as they develop quality programs for affordable drug benefits through (a) managing clinical pharmacy demonstration projects, (b) assisting health centers and other grantees to make optimum use of resources available for pharmacy services, (c) demonstrating innovative methods of delivering pharmacy services, and (d) providing technical assistance to grantees, States, local governments, and other health care delivery systems to plan and implement pharmacy benefits; (3) serving as a Federal Government resource for pharmacy practice through (a) developing and maintaining cooperative relationships with national pharmacy and governmental organizations to share information and build infrastructure for safety-net providers, (b) providing technical assistance for pharmacy practice, and (c) providing model pharmacy products (such as sample contracts and business plans) for safety-net health care providers; and (4) carrying out special projects as assigned by the Administrator.

Division of Engineering Services (RR8)

(1) Provides policy input and operational direction for the Agency's facilities engineering and construction management system; (2) provides input into the intra and the interagency reimbursement agreements for the DES services with the Administration on Children and Families, the Office of Minority Health, the Office of Rural Health, the Department of Housing and Urban Development (Section 242 Hospital Mortgage Insurance), and the National Cancer Institute (NCI); (3) assures the delivery of comprehensive architectural and engineering services in support of federally assisted and direct Federal construction services; (4) administers property management activities related to PHS owned or utilized facilities; (5) serves as a source of expertise and provides technical assistance on architecture and engineering activities to field offices; (6) develops, implements, and monitors the annual work plan related to assigned program areas in response to national and regional priorities; (7) coordinates the development of regional objectives which cross program and organizational

lines; advises the Bureau Director's office and others on Agency architectural engineering activities, representing the Agency on committees and work groups; (9) performs assigned work tasks when called upon; (10) develops guidance materials and technical publications to enhance efficiency and economy in the design, construction, modernization, and conversion activities, and (11) jointly develops pertinent programmatic materials with components of the Bureau, HRSA, DHHS, and other concerned Federal agencies.

Chapter RS—Office of Administration and Financial Management

Rename the Office of Management and Program Support (RS) as the Office of Administration and Financial Management and amend the organization and functional statements to reflect: (1) the realignment of the Office of Human Resources and Development (RS7) to the Office of the Assistant Secretary for Administration and Management; and (2) the realignment of the Division of Grants Management Operations' (RSA) functions to the newly established Office of Federal Assistance Management (RJ).

Section RS-20, Organization

Delete in its entirety and replace with the following:

The Office of Administration and Financial Management (OAFM) is headed by the Associate Administrator for Administration and Financial Management who reports directly to the Administrator, Health Resources and Services Administration. The OAFM includes the following components:

- (1) Office of the Associate Administrator (RS)
- (2) Division of Management Services (RS1)
- (3) Division of Financial Management (RS2)
- (4) Division of Procurement Management (RS4)
- (5) Division of Policy Review and Coordination (RS7)

Section RS-30, Functions

(1) Delete the functional statements for the Division of Grants Management Operations (RSA) and the Division of Independent Review (RS9) and move the functions to the newly established Office of Federal Assistance Management (RJ); and (2) Delete the functional statements for the Office of Management and Program Support (RS); the Division of Management Services (RS1); and the Division of Policy Review and Coordination (RS7) in their

entireties and replace with the following:

Office of Administration and Financial Management (RS)

Provides Agency-wide leadership, program direction, and coordination to all phases of management. Specifically, the Office of Administration and Financial Management: (1) Provides management expertise and staff advice and support to the Administrator in program and policy formulation and execution; (2) manages the Agency-wide Contingency of Operations (COOP) program; (3) plans, directs, and coordinates the Agency's activities in the areas of administrative management, financial management, human resources management, including labor relations, debt management, procurement management, real and personal property accountability and management, alternative dispute resolution and administrative services; (4) directs and coordinates the development of policy and regulations; (5) oversees the development of annual operating objectives and coordinates HRSA work planning and appraisals; (6) directs and coordinates the Agency's organization, functions and delegations of authority programs; and (7) administers the Agency's Executive Secretariat and committee management functions.

Division of Management Services (RS1)

Provides Agency-wide leadership and direction in the areas of management policies and procedures and property management, and serves as the Executive Officer for the Office of the Administrator (OA), Office of Administration and Financial Management (OAFM), and the Office of Federal Assistance Management (OFAM). Specifically: (1) Provides advice and guidance for the establishment or modification of organization structures, functions, and delegations of authority; (2) conducts and coordinates the Agency's issuances, reports and mail management programs; (3) conducts Agency-wide management, improvement and information studies and survey; (4) oversees and coordinates the implementation of directives and policies relating to the Privacy Act; (5) plans, directs, and coordinates administrative management activities and services including human resources, financial, material management, and general administrative services for OA, OAFM, and OFAM; (6) acts for the Associate Administrator for Administration and Financial Management concerning space planning, parking and communications management for headquarters and

represents him/her in matters relating to the management of the Parklawn Building Complex; (7) advises on and coordinates Agency-wide policies and procedures required to implement General Services Administration and departmental regulations government material management, including travel transportation, motor vehicle and utilization and disposal of property; (8) coordinates the Agency's Alternative Dispute Resolution (ADR) Program; (9) manages the Agency's ethics and security programs; (10) administers the Agency's performance management, quality of work life, customer service and awards programs; (11) ensures that management practices and policies related to the Commissioned Corps are coordinated throughout the Agency; (12) coordinates with the service provider the provision of human resources management, working with the service provider to monitor their performance; and (13) coordinates and serves as a focal point for the Agency's intern programs;

Division of Policy Review and Coordination (RS7)

(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) contributes to the analysis, development and implementation of Agency-wide policies through coordination with relevant Agency program components and other related sources; (4) plans, organizes and directs the Agency's Executive Secretariat with primary responsibility for preparation and management of written correspondence; (5) arranges briefings for Department officials on critical policy issues and oversees the development of necessary briefing documents; (6) administers administrative early alert system for the Agency to assure senior Agency officials are informed about administrative actions and opportunities; (7) 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; (8) manages and maintains a records management program for the Agency; (9) manages the intra- and interagency agreements process; (11) oversees and coordinates the Agency's committee management activities; and

(12) coordinates the review and publication of Federal Register Notices.

Chapter RV—HIV/AIDS Bureau

Section RV-10, Organization

Delete in its entirety and replace with the following:

The HIV/AIDS Bureau (HAB) is headed by the Associate Administrator for HIV/AIDS who reports directly to the Administrator, Health Resources and Services Administration. The HAB includes the following components:

- (1) Office of the Associate Administrator (RV)
- (2) Office of Program Support (RV2)
- (3) Division of Science and Policy (RVA)
- (4) Division of Service Systems (RV5)
- (5) Division of Community Based Programs (RV6)
- (6) Division of Training and Technical Assistance (RV7)
- (7) Office for the Advancement of Telehealth (RV9)

Section RV-20, Functions

Delete the functional statements for the Office of Program Support (RV2); the Office of Policy and Program Development (RV3); and the Office of Science and Epidemiology (RV4) in their entireties and replace with the following:

Office of Program Support (RV2)

Plans, directs, coordinates and evaluates Bureau-wide administrative management support activities. Specifically, OPS: (1) Serves as the Bureau's principal source for management and administrative advice and assistance; (2) assists in the development and administration of policies and procedures which govern funding recommendations to the Associate Administrator; (3) provides guidance to the Bureau on financial management activities; (4) coordinates personnel activities for the Bureau and advises on the allocation of the Bureau's personnel resources; (5) provides organization and management analysis for the Bureau, develops policies and procedures for internal Bureau requirements, and interprets and implements the Administration's management policies and procedures; (6) coordinates the Bureau's delegations of authority activities; (7) manages the Bureau's performance management systems; (8) provides or arranges for the provision of support services such as procurement, safety and security, property management, supply management, space management, manual issuances, forms, records, reports, and supports civil rights compliance activities; (9) provides

direction regarding technological developments in office management activities; and (10) manages the Bureau's executive secretariat function.

Division of Science and Policy (RVA)

Serves as the Bureau's principal source of program data collection and evaluation, the development of innovative models of HIV care, and the focal point for coordination of program performance activities and development of policy guidance. The Division will advise the Associate Administrator and collaborate with Division Directors in plans for and the development of both science and policy proposals to support the mission of the Bureau. The Division coordinates and develops collaborative efforts with other HHS components and all HRSA Bureaus, including the Office of Planning and Evaluation, in the preparation of HIV/AIDS-related program policies. Specifically; Science: (1) Coordinates the documentation of all HIV/AIDS science, evaluation, and innovative models of care within HRSA programs; (2) organizes, guides, and coordinates the Bureau's scientific planning and development activities in epidemiology, health services research, and demonstration projects; (3) studies and analyzes trends in health care, including availability, access distribution, organization, and financing, to determine if the Bureau's activities address HIV/AIDS issues in an effective, efficient manner; (4) designs and implements special scientific studies on the impact and outcomes of Bureau health care programs; (5) carries out data collection and analysis activities that document the clients served and services funded by the Bureau programs; (6) gathers and evaluates data on costs of publicly financed care and quality of the Bureau's health care programs; (7) plans, directs, coordinates, and administers the Bureau's annual program evaluation strategy; and (8) directs and manages the implementation and evaluation of priority models of care through the Special Programs of National Significance (Title XXVI, Part F of the PHS Act), including developing Program Application and Guidance documents. Specifically, Policy: (1) Participates in the development and coordination of program policies and implementation plans, including the development, clearance, and dissemination of regulations, criteria, guidelines, and operating procedures; (2) provides program policy interpretation and guidance to the Bureau, Agency, Department, grantees, and other governmental and private organizations and institutions; (3)

coordinates activities pertaining to policy and position papers to assure the fullest possible consideration of programmatic requirements that meet departmental and Agency goals, policies, and procedures and Federal statute; (4) monitors and analyzes HIV/AIDS-related policy developments, both within and outside the Department, for their potential impact on HIV/AIDS activities, and develops recommendations for the Bureau's response; (5) serves as the liaison to HRSA's Office of Planning and Evaluation and other appropriate offices to respond to and prepare HIV/AIDS related program policies, including testimony and related information; (6) serves as the liaison for all legislatively-related matters and activities; (7) directs and coordinates performance review and monitoring activities related to: a) GPRA, OMB, PART and Healthy People 2010 activities; b) GAO, OIG, and IOM reports; c) Agency, Department, Administration or other congressionally mandated initiatives; and d) other issues requiring performance review by the Bureau; (8) develops the Bureau's strategic planning agenda, providing guidance and coordination for the Bureau's program planning and development activities; (9) coordinates Bureau and HRSA responses and comments on HIV/AIDS-related reports, position papers, guidance documents, correspondence, and related issues, including Freedom of Information Act requests; (10) coordinates and serves as the external liaison with governmental and private-sector advisory groups that have a policy and/or performance impact on the Bureau; and (11) maintains a current Resource Library containing significant and relevant Bureau and HIV/AIDS-related materials, documents, and publications.

Section RA-30, Health Resources and Services Administration, Delegations of Authority

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

This reorganization is effective upon the date of signature.

Dated: September 13, 2004.

Elizabeth M. Duke,
Administrator.

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BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2004-19106]

National Preparedness for Response Exercise Program (PREP)

AGENCY: Coast Guard, DHS.

ACTION: Notice; request for public comments on PREP triennial exercise schedule for 2005, 2006, and 2007, and PREP Guidelines.

SUMMARY: The Coast Guard, the Research and Special Programs Administration, the Environmental Protection Agency and the Minerals Management Service, in concert with representatives from various State governments, industry, environmental interest groups, and the general public, developed the Preparedness for Response Exercise Program (PREP) Guidelines to reflect the consensus agreement of the entire oil spill response community. This notice announces the PREP triennial cycle, 2005 through 2007, requests comments from the public, and requests industry participants to volunteer for scheduled PREP Area exercises. Additionally, this notice requests comments on issues or concerns related to the PREP.

DATES: Comments and related material must reach the Docket Management Facility on or before November 22, 2004.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG-2004-19106 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Web site: <http://dms.dot.gov>.

(2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590-0001.

(3) Fax: 202-493-2251.

(4) Delivery: Room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, or need general information regarding the PREP Program and the schedule, contact Lieutenant Commander Mark Cunningham, Office of Response, Plans and Preparedness Division (G-MOR-2), U.S. Coast Guard Headquarters, telephone 202-267-2877, fax 202-267-