

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
Total					441

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
800.55(k)	1	1	1	20	20

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 3, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0439]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Food and Drug Administration Recall Regulations” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, ila.mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On November 28, 2011, the Agency submitted a proposed collection of information entitled “Food and Drug Administration Recall Regulations” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a

currently valid OMB control number.

OMB has now approved the information collection and has assigned OMB control number 0910–0249. The approval expires on March 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 3, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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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 77 FR 13613–13616 dated March 7, 2012).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the HIV/AIDS Bureau (RV): (1) Rename the Division of Science and Policy (RVA) to the Division of Policy and Data (RVA) and update the functional statement; (2) rename the Office of Program Support (RV2) to the Office of Operations and Management (RV2); (3) rename the Division of Service Systems (RV5) to the Division of Metropolitan HIV/AIDS Programs (RV5)

and update the function statement; (4) establish the Division of State HIV/AIDS Programs (RVD); (5) rename the Division of Community Based Programs (RV6) to the Division of Community HIV/AIDS Programs (RV6); and rename the Division of Training and Technical Assistance (RV7) to the Division of HIV/AIDS Training and Capacity Development (RV7) and update the functional statement.

Chapter RV—HIV/AIDS Bureau

Section RV–10, Organization

Delete in its entirety and replace with the following:

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

- (1) Office of the Associate Administrator (RV);
- (2) Office of Operations and Management (RV2);
- (3) Division of Policy and Data (RVA);
- (4) Division of Metropolitan HIV/AIDS Programs (RV5);
- (5) Division of State HIV/AIDS Programs (RVD);
- (6) Division of Community HIV/AIDS Programs (RV6); and
- (7) Division of HIV/AIDS Training and Capacity Development (RV7).

Section RV–20, Functions

(1) Delete the functional statement for the HIV/AIDS Bureau (RV) and replace in its entirety.

Office of the Associate Administrator (RV)

The Office of the Associate Administrator provides leadership and direction for the HIV/AIDS programs and activities of the Bureau and

oversees its relationship with other national health programs. Specifically: (1) Promotes the implementation of the National HIV/AIDS Strategy within the Agency and among Agency-funded programs; (2) coordinates the formulation of an overall strategy and policy for programs established by Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111-87; (3) coordinates the internal functions of the Bureau and its relationships with other Agency Bureaus and Offices; (4) establishes HIV/AIDS program objectives, alternatives, and policy positions consistent with broad Administration guidelines; (5) provides leadership for and oversight of the Bureau's budgetary development and implementation processes; (6) provides clinical leadership to Ryan White-funded programs and global HIV/AIDS programs; (7) oversees the implementation of the Global HIV/AIDS Program as part of the President's Emergency Plan for AIDS Relief; (8) serves as a principal contact and advisor to the Department and other parties on matters pertaining to the planning and development of HIV/AIDS-related health delivery systems; (9) reviews HIV/AIDS-related program activities to determine their consistency with established policies; (10) develops and oversees operating policies and procedures for the Bureau; (11) oversees and directs the planning, implementation, and evaluation of special studies related to HIV/AIDS and public health within the Bureau; (12) prioritizes Technical Assistance needs in consultation with each Division/Office; (13) plans, develops, implements and evaluates the Bureau's organizational and staff development, and staff training activities inclusive of guiding action steps addressing annual Employee Viewpoint Survey results; (14) plans, implements, and evaluates the Bureau's national Technical Assistance conference calls, TARGET Web site, Webex trainings and other distance learning modalities; (15) represents the Agency in HIV/AIDS-related conferences, consultations, and meetings with other Operating Divisions, Office of the Assistance Secretary for Health, the Department of State, and the White House; (16) coordinates the development and distribution of all Bureau communication activities, materials and products internally and externally; (17) provides leadership for and oversees Bureau's grants processes; and (18) oversees Bureau Executive Secretariat

functions and coordinates HRSA responses and comments on HIV/AIDS-related reports, position papers, guidance documents, correspondence, and related issues, including Freedom of Information Act requests.

Office of Operations and Management (RV2)

The Office of Operations and Management headed by the Director and the Bureau's Executive Officer provides administrative and fiscal guidance and support for HAB and is responsible for all budgetary, administrative, human resources, operations, facility management and contracting functions. The Office also oversees and coordinates all Bureau program integrity activities. Specifically, the Office: (1) Assists in the development and administration of budgetary policies and procedures with government funding recommendations to the Associate Administrator; (2) provides guidance to the Bureau on all financial management activities; (3) develops the Bureau's Operating Budget and guides the formulation process; (4) develops budget and procurement plans; (5) provides guidance to Division leadership in the development and formulation of program budgets; (6) participates in the implementation of the formula based awards process; (7) reviews and approves funding memos and grant notices; (8) tracks Bureau budget expenditures for grants, contracts, cooperative agreements, and programmatic expenses; (9) collaborates with other office staff in the processing of contracts, cooperative agreements, and Inter/Intra Agency Agreements; (10) coordinates human resources activities for the Bureau and advises on the allocation of the Bureau's human resources; (11) develops policies and procedures for internal Bureau requirements, and interprets and implements the Agency's management policies and procedures; (12) coordinates the Bureau's delegations of authority activities; (13) manages travel related activities for the Bureau and, advises on Federal and Agency travel regulations; (14) manages the Bureau's performance management systems; (15) 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; (16) provides support in the implementation of staff development and training activities; (17) provides oversight to Bureau Contracting Officers Representative (COR) training

requirements; (18) manages the Bureau's Inter/Intra Agency Agreement processes; (19) provides direction regarding technological developments in office management activities; (20) develops policies and procedures for internal Bureau requirements in areas of contracting; (21) interprets and implements the Agency's contracting policies and procedures; (22) coordinates the Bureau's delegations of authority activities; (23) manages all COR functions for contracts within the Bureau; and (24) provides oversight to Bureau CORs.

Division of Policy and Data (RVA)

The Division of Policy and Data serves as the Bureau's principal source of program data collection and evaluation and the focal point for coordination of program performance activities, policy analysis and development of policy guidance. The Division coordinates all technical assistance activities for the Bureau in collaboration with each Division. Specifically: (1) Plans, coordinates and administers the Bureau's annual program evaluation strategy; (2) conducts analysis and reports on Ryan White HIV/AIDS Program data to support public health decisionmaking for statutory programs; (3) designs, conducts, and/or administers health services research to evaluate grantee delivery of services to clients served by all HRSA HIV/AIDS programs including underserved and vulnerable populations; (4) designs and implements special scientific studies on the impact and outcomes of Bureau health care programs; (5) implements 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; (6) collects and analyzes Ryan White health data and information; (7) manages Bureau-sponsored, health data collection systems; (8) collects, compiles, cross tabulates, and disseminates full and complete statistics internally and externally on the condition and progress of the Ryan White HIV/AIDS Program; (9) determines methodology by which the Bureau and program grantees may accurately measure public health indicators supporting the National HIV/AIDS Strategy; (10) conducts data cleaning activities that document the clients served and services funded by the Bureau programs; (11) coordinates the HAB-wide implementation of the National HIV/AIDS Strategy; (12) 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; (13) provides program policy interpretation and guidance to the Bureau, Agency, Department, grantees, and other governmental and private organizations and institutions on matters related to the Ryan White HIV/AIDS Program and HIV-related areas; and (14) coordinates activities pertaining to policy and position papers to ensure the fullest possible consideration of programmatic requirements that meet departmental and Agency goals, policies, procedures and Federal statute.

Division of Metropolitan HIV/AIDS Programs (RV5)

The Division of Metropolitan HIV/AIDS Programs, within the HIV/AIDS Bureau, administers programs and activities and manages funds and other resources related to the provision of coordinated comprehensive HIV health care and support services for persons with HIV/AIDS. The Division manages the portfolio of grantees and programs funded under Part A of the Ryan White HIV/AIDS Program. Specifically, the Division: (1) Directs and manages the implementation of Emergency Relief Grants (Part A) of Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111–87 (the Ryan White HIV/AIDS Program); (2) promotes the implementation of the National HIV/AIDS Strategy among Part A programs; (3) provides program implementation proposals and plans, and the interpretation of legislation and regulations; (4) monitors HIV services planning and delivery programs in cities and metropolitan areas and provides administrative, strategic, and programmatic direction to grantees to encourage efficient, coordinated treatment of persons with HIV infection; (5) provides Technical Assistance, assesses effectiveness of Technical Assistance efforts/initiatives, identifies new Technical Assistance needs and priority areas, in collaboration with the Division of Policy and Data, and participates in the Bureau-wide Technical Assistance workgroup; (6) develops Program Application and Funding Opportunity documents; (7) develops requirements, guidance and monitors cities and metropolitan areas that promote early identification of people living with HIV, linking them to care and retaining them in care for their HIV disease; (8) formulates and interprets program related policies; and (9) coordinates and consults with state

and local health departments, other components of the Department, other Federal agencies and/or outside groups on the implementation of the Part A program.

Division of State HIV/AIDS Programs (RVD)

The Division of State HIV/AIDS Programs, within the HIV/AIDS Bureau, administers programs and activities and manages funds and other resources related to the provision of coordinated comprehensive HIV health care and support services, including reimbursement for treatment with life-prolonging drugs, for persons with HIV/AIDS. The Division manages the portfolio of grantees and programs funded under Part B of the Ryan White HIV/AIDS Program. Specifically, the Division: (1) Directs and manages the implementation of HIV CARE Grants (Part B) of Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111–87 (the Ryan White HIV/AIDS Program) including the AIDS Drug Assistance programs; (2) promotes the implementation of the National HIV/AIDS Strategy among Part B programs; (3) provides program implementation proposals and plans, and the interpretation of legislation and regulations; (4) monitors HIV services planning and delivery programs in states and territories and provides administrative, strategic, and programmatic direction to grantees to encourage efficient, coordinated treatment of persons with HIV infection; (5) in collaboration with the Division of Policy and Data, assesses effectiveness of Technical Assistance efforts/initiatives, identifies new Technical Assistance needs and priority areas, and participates in the Bureau-wide Technical Assistance workgroup; (6) develops Program Application and Guidance documents; (7) develops requirements, guidance and monitors state and territorial programs for medical therapies established to ensure that these treatments are integrated into the system of health care services; (8) promotes the development of state treatment program formularies that include classes of drugs necessary for the proper treatment of people with HIV infection; (9) formulates and interprets program related policies; and (10) coordinates and consults with state and local health departments, other components of the Department, other Federal agencies and/or outside groups on the implementation of Division programs.

Division of Community HIV/AIDS Programs (RV6)

The Division of Community HIV/AIDS Programs within the HIV/AIDS Bureau, provides national leadership and manages the implementation of Parts C, D and F under Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111–87 (the Ryan White HIV/AIDS Program) including, Planning and Capacity Development programs (Part C), HIV Early Intervention Services program (Part C), Grants for Coordination Services and Access to Research for Women, Infants, Children, and Youth program (Part D), and the Dental Reimbursement and Community Based Dental Partnership programs (Part F). The Division promotes the implementation of the National HIV/AIDS Strategy among Part C, D, and F/Dental programs and administers programs and activities related to: (1) Providing comprehensive health services to persons infected with HIV in medically underserved areas; (2) demonstrating strategies and innovative models for the development and provision of HIV primary care services; (3) coordinating services for women of child-bearing age with HIV/AIDS, infants, children, and youth; (4) assisting dental schools and other eligible institutions with respect to oral health care to patients with HIV; and (5) in collaboration with the Division of Policy and Data, the Division assesses effectiveness of Technical Assistance efforts/initiatives, identifies new Technical Assistance needs and priority areas, and participates in the Bureau-wide Technical Assistance workgroup. The Division manages the portfolio of grantees and programs who provide comprehensive HIV primary care, treatment, and HIV-related support services.

Division of HIV/AIDS Training and Capacity Development (RV7)

The Division of HIV/AIDS Training and Capacity Development within the HIV/AIDS Bureau, provides national leadership and manages the implementation of Part F under Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111–87 (the Ryan White HIV/AIDS Program), including the Special Projects of National Significance and the AIDS Education and Training Centers Programs. The Special Projects of National Significance Program develops innovative models of HIV care and the AIDS Education and Training Centers Program increases the number of health

care providers who are educated and motivated to counsel, diagnose, treat, and medically manage people with HIV disease and to help prevent high-risk behaviors that lead to HIV transmission. The Division also implements the Global HIV/AIDS Program as part of the President's Emergency Plan for AIDS Relief (PEPFAR) to manage international programs designed to provide direct care and treatment for people living with HIV/AIDS and to strengthen health systems for delivery of prevention, care and treatment services for people living with HIV/AIDS in PEPFAR funded countries. The Division will translate lessons learned from both the Global HIV/AIDS Programs and Special Projects of National Significance projects to the Part A, B, C, D, and F grantee community. In collaboration with the Division of Policy and Data, the Division assesses effectiveness of Technical Assistance efforts/initiatives, identifies new Technical Assistance needs and priority areas, and participates in the Bureau-wide Technical Assistance workgroup.

Section RV-30, Delegations of Authority

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

This reorganization is effective upon date of signature.

Dated: April 4, 2012.

Mary K. Wakefield,
Administrator.

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BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Health Professions Preparatory, Indian Health Professions Pregraduate and Indian Health Professions Scholarship Programs

Overview Information: Indian Health Professions Preparatory, Indian Health Professions Pregraduate and Indian Health Professions Scholarship Programs.

Announcement Type: Initial.

CFDA Numbers: 93.971, 93.123, and 93.972.

Key Dates:

Application Deadline: May 7, 2012, for continuing students.

Application Deadline: May 7, 2012, for new students.

Application Review: May 21–25, 2012.

Application Notification: First week of July, 2012.

Award Start Date: August 1, 2012.

I. Funding Opportunity Description

The Indian Health Service (IHS) is committed to encouraging American Indians and Alaska Natives to enter the health professions and to assuring the availability of Indian health professionals to provide health care services to Indians. The IHS is committed to the recruitment of students for the following programs:

- *The Indian Health Professions Preparatory Scholarship* authorized by section 103 of the Indian Health Care Improvement Act (IHCA), Public Law 94-437 (1976).
 - *The Indian Health Professions Pre-graduate Scholarship* authorized by section 103 of the IHCA, Public Law 94-437 (1976).
 - *The Indian Health Professions Scholarship* authorized by section 104 of the IHCA, Public Law 94-437 (1976).
- Full-time and part-time scholarships will be funded for each of the three scholarship programs.

The scholarship award selections and funding are subject to availability of funds appropriated for the Scholarship Program.

II. Award Information

Awards under this initiative will be administered using the grant mechanism of the IHS.

Estimated Funds Available: An estimated \$14.0 million will be available for FY 2012 awards. Of this estimated \$14.0 million in funding, no more than \$1.0 million will be set aside for Preparatory and Pre-graduate Scholarships, with the remaining balance to be used toward Health Professions Scholarships. The IHS program anticipates, but cannot guarantee, due to possible funding changes, student scholarship selections from any or all of the following disciplines in the 103, 103P and 104 Programs for the Scholarship Period 2012–2013. Due to the rising cost of education and the decreasing number of scholars who can be funded by the IHS Scholarship Program (IHSSP), the IHSSP has changed the funding policy for Preparatory and Pre-graduate scholarship awards and reallocated a greater percentage of its funding in an effort to increase the number of Health Professions scholarships, and inherently the number of service obligated scholars, to better meet the health care provider needs of the IHS and its Tribal and Urban Indian health care system partners.

Anticipated Number of Awards: Approximately 25 awards will be made under the Health Professions Preparatory and Pre-graduate Scholarship Programs for Indians. The awards are for tuition and fees only and the average award to a full-time student is approximately \$10,701.35. An estimated 280 awards will be made under the Indian Health Professions Scholarship Program. The awards are for 12 months in duration, and will cover both tuition and fees and Other Related Costs (ORC). The average award to a full-time student is approximately \$48,056.05. In FY 2012, an estimated \$9,500,000 is available for continuation awards, and an estimated \$3,500,000 is available for new awards.

Project Period—The project period for the IHS Health Professions Preparatory Scholarship support, tuition and fees only, is limited to two years for full-time students and the part-time equivalent of two years, not to exceed four years for part-time students. The project period for the Health Professions Pre-graduate Scholarship support, tuition and fees only, is limited to four years for full-time students and the part-time equivalent of four years, not to exceed eight years for part-time students.

The IHS Indian Health Professions Scholarship support, tuition, fees and Other Related Costs (ORC) is limited to four years for full-time students and the part-time equivalent of four years, not to exceed eight years for part-time students.

III. Eligibility Information

This announcement is a limited competition for awards made to American Indians (Federally recognized Tribal members, state recognized Tribal members, and first and second degree descendants of Federal or state recognized Tribal members), or Alaska Natives only. Continuation awards are non-competitive.

1. Eligible Applicants

The Health Professions Preparatory Scholarship awards are made to American Indians (Federally recognized Tribal members, first and second degree descendants of Tribal members, and state recognized Tribal members, first and second degree descendants of Tribal members), or Alaska Natives who:

- Have successfully completed high school education or high school equivalency; and
- Have been accepted for enrollment in a compensatory, pre-professional general education course or curriculum; and

The Health Professions Pre-graduate Scholarship awards are made to