

www.aoa.gov/AoARoot/Grants/Reporting_Requirements/docs/FinalReportHandbook.doc. ACL estimates the burden of this collection of information as follows: *Frequency:* Semi-annually with the Final report taking the place of the semi-annual report at the end of the final year of the grant. *Respondents:* States, public agencies, private nonprofit agencies, institutions of higher education, and organizations including tribal organizations. *Estimated Number of Responses:* 600. *Total Estimated Burden Hours:* 12,000.

Dated: August 3, 2012.

Kathy Greenlee,
Administrator and Assistant Secretary for Aging.

[FR Doc. 2012-19453 Filed 8-7-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0608]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "MedWatch: The Food and Drug Administration Medical Products Reporting Program" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, Jonnalynn.Capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On June 28, 2012, the Agency submitted a proposed collection of information entitled "MedWatch: The Food and Drug Administration Medical Products Reporting Program" 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 0910-0291. The approval expires on June 30, 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: August 3, 2012.

David Dorsey,
Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012-19377 Filed 8-7-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0793]

Request for Nominations of Specific Drug/Biologic Product(s) That Could Be Brought Before the Food and Drug Administration's Pediatric Subcommittee of the Oncologic Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for product nominations.

SUMMARY: The Food and Drug Administration's (FDA) Office of Hematology and Oncology Products invites the public to suggest one or more specific drug or biologic products that could be brought before the December 4, 2012, Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC). The number of drugs studied for use in pediatric patients is growing, and we see a reduction in off-label use. However, we would like to improve current and future pediatric product development by focusing on products whose development would benefit the most from the attention of an advisory committee. The company developing a product that is brought before the committee will be given the unique opportunity to present proposed pediatric studies in the United States, share their plans for global pediatric development, and hear discussions by the Pediatric Subcommittee on possible directions for their current or future pediatric oncology product development.

DATES: Nominations must be received by September 4, 2012, to receive consideration for inclusion. Nominations received after this date will receive consideration for future meetings of the Pediatric Subcommittee of the ODAC.

ADDRESSES: Email nominations to Christine.Lincoln@fda.hhs.gov, and please include the subject line "Suggested Product for 2012 Pediatric Oncology Subcommittee of ODAC."

FOR FURTHER INFORMATION CONTACT: Christine Lincoln, RN, MS, MBA, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2206, Silver Spring, MD 20993, 301-796-4117, Christine.Lincoln@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) Advisory Committees are an important, transparent interface that allows the Agency to include the public in its decision-making processes. Significant public health and safety issues are brought before these committees for deliberation, and the meetings bring together both experts with state-of-the-art knowledge and members of the public with relevant personal experiences. This broad participation gives FDA a unique perspective as it seeks to assure the safety, efficacy, and security of FDA-regulated products.

Additional information about the prior November 2, 2011, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee may be found on FDA's Web site at: <http://www.fda.gov/AdvisoryCommittees/Calendar/ucm274396.htm>.

Dated: August 2, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2012-19330 Filed 8-7-12; 8:45 am]

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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 46098-46099 dated August 2, 2012).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA). Specifically, this notice updates the functional statement for both the Office of Operations (RB) and the Office of Management (RB4) to include the human resources function for HRSA;

transfers the records management function from the Division of Policy and Information Coordination (RB41) to the Immediate Office of the Director, Office of Management (RB4); transfers the personnel security function from the Division of Workforce Management (RB42) to the Division of Management Services (RB43); transfers the workforce planning function from the Division of Workforce Management (RB42) to the Division of Workforce Development (RB44); and renames the Division of Workforce Management (RB42) to the Division of Human Resources Management (RB42).

Chapter RB—Office of Operations

Section RB–20, Functions

(1) Delete the functional statement for the Office of Operations in its entirety and replace with the following:

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

Chapter RB4—Office of Management

Section RB4–10, Organization

Delete in its entirety and replace with the following:

The Office of Management (RB4) is headed by the Director, Office of Management within the Office of Operations, Health Resources and Services Administration, who reports directly to the Chief Operating Officer.

The Office of Management includes the following components:

- (1) Immediate Office of the Director (RB4);
- (2) Division of Policy and Information Coordination (RB41);
- (3) Division of Human Resources Management (RB42);
- (4) Division of Management Services (RB43); and
- (5) Division of Workforce Development (RB44).

Section RB4–20, Functions

(1) Delete the functional statement for the Office of Management (RB4) and replace in its entirety; (2) transfer the records management function from the Division of Policy and Information Coordination (RB41) to the Immediate Office of the Director (RB4); transfer the personnel security function from the Division of Workforce Management (RB42) to the Division of Management Services (RB43); transfer the workforce planning function from the Division of Workforce Management (RB42) to the Division of Workforce Development (RB44); and rename the Division of Workforce Management (RB42) to the Division of Human Resources Management (RB42).

Office of Management (RB4)

Provides HRSA-wide leadership, program direction, and coordination of all phases of administrative management. Specifically, the Office of Management: (1) Provides management expertise, staff advice, and support to the Administrator in program and policy formulation and execution; (2) provides administrative management services including human resources, property management, space planning, safety, physical security, and general administrative services; (3) conducts HRSA-wide workforce analysis studies and surveys; (4) plans, directs, and coordinates HRSA's activities in the areas of human resources management, including labor relations, personnel security, and performance; (5) coordinates the development of administrative policies and regulations; (6) oversees the development of annual operating objectives and coordinates HRSA work planning and appraisals; (7) directs and coordinates HRSA's organizations, functions and delegations of authority programs; (8) administers the Agency's Executive Secretariat and committee management functions; (9) provides staff support to the Agency Chief Travel Official; (10) provides staff support to the Deputy Ethics Counselor; (11) directs, coordinates, and conducts workforce development activities for HRSA; and (12) manages and maintains

a records management program for the Agency.

Division of Policy and Information Coordination (RB41)

(1) Advises the Administrator and other key Agency officials on cross-cutting policy issues and assists in the identification and resolution of cross-cutting policy issues and problems; (2) establishes and maintains tracking systems that provide HRSA-wide coordination and clearance of policies, regulations and guidelines; (3) plans, organizes and directs the Executive Secretariat with primary responsibility for preparation and management of written correspondence; (4) arranges briefings for Department officials on critical policy issues and oversees the development of necessary briefing documents; (5) coordinates the preparation of proposed rules and regulations relating to HRSA programs and coordinates review and comment on other Department regulations and policy directives that may affect HRSA programs; (6) oversees and coordinates the committee management activities; and (7) coordinates the review and publication of **Federal Register** notices.

Division of Human Resources Management (RB42)

(1) Provides advice and guidance on all aspects of the HRSA human resources management program; (2) provides the full range of human resources operations including: employment; staffing and recruitment; compensation; classification; executive resources; labor and employee relations; employee benefits; and retirement; (3) develops and coordinates the implementation of human resources policies and procedures for HRSA's human resources activities; (4) monitors, evaluates, and reports on the effectiveness, efficiency and compliance with HR laws, rules, and regulations; (5) provides advice and guidance for the establishment or modification of organization structures, functions, and delegations of authority; (6) manages the ethics program; (7) administers the performance management programs, including the SES Performance Review Board; (8) manages the incentive and honor awards programs; (9) represents HRSA in human resources matters both within and outside of the Department; and (10) oversees the commissioned corps liaison activities including the day-to-day operations of workforce management.

Division of Management Services (RB43)

Plans, directs and coordinates Agency administrative activities. Specifically:

(1) Provides administrative management services including property, space planning, safety, physical security, and general administrative services; (2) ensures implementation of statutes, Executive Orders, and regulations related to official travel, transportation, and relocation; (3) provides oversight for the HRSA travel management program involving use of travel management systems, passenger transportation, and travel charge cards; (4) provides planning, management and oversight of all space planning projects, move services and furniture requirements; (5) develops space and furniture standards and related policies; (6) provides analysis of office space requirements required in supporting decisions relating to the acquisition of commercial leases; (7) provides advice, counsel, direction, and support to employees to fulfill the Agency's primary safety responsibility of providing a workplace free from recognizable safety and health concerns; (8) manages, controls, and/or coordinates all matters relating to mail management within HRSA, including developing and implementing procedures for the receipt, delivery, collection, and dispatch of mail; (9) maintains overall responsibility for the HRSA Forms Management Program; and (10) manages the personnel security, badging, Transhare and quality of work life programs.

Division of Workforce Development (RB44)

(1) Plans, directs, and manages HRSA-wide training programs, intern, professional and leadership development programs, the long-term training program, and the mentoring program; (2) develops, designs, and implements a comprehensive strategic human resource leadership development and career management program for all occupational series throughout HRSA; (3) provides technical assistance in organizational development, career management, employee development, and training; (4) maximizes economies of scale through systematic planning and evaluation of Agency-wide training initiatives to assist HRSA employees in achieving required competencies; (5) identifies relevant scanning/benchmarking on workforce and career development processes, services, and products; (6) establishes policies governing major learning initiatives and new learning activities, and works collaboratively with other components of HRSA in planning, developing, and implementing policies related to training initiatives; (7) plans, directs,

and manages HRSA-wide training and service programs for fellowships and internships sponsored by other partner organizations and implemented within HRSA; (8) conducts Agency-wide workforce analysis studies and surveys; (9) develops comprehensive workforce strategies that meet the requirements of the Office of Personnel Management and the Department of Health and Human Services, programmatic needs of HRSA, and the governance and management needs of HRSA leadership; and (10) evaluates employee development practices to develop and enhance strategies to ensure HRSA retains a cadre of public health professionals and reduces risks associated with turnover in mission critical positions.

Section RB4-30, 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: July 26, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012-19421 Filed 8-7-12; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number HHS-2012-IHS-TSGP-0001]

Funding Opportunity: Tribal Self-Governance Program; Planning Cooperative Agreement

Catalog of Federal Domestic Assistance Number: 93.444.

Announcement Type: New—Limited Competition.

Key Dates

Application Deadline Date: September 9, 2012.

Review Date: September 12, 2012.

Earliest Anticipated Start Date: September 30, 2012.

Signed Tribal Resolutions Due Date: September 11, 2012.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting limited competition

Planning Cooperative Agreement applications for the Tribal Self-Governance Program (TSGP). This program is authorized under Public Law (Pub. L.) 106-260, the Tribal Self-Governance Amendments of 2000; Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), Public Law 93-638, as amended; and the Snyder Act, Public Law 67-85 (25 U.S.C. 13). This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the government-to-government relationship between the United States and each Indian Tribe. Through the TSGP, Tribes negotiate with the IHS to assume IHS programs, services, functions, and activities (PSFAs), or portions thereof, to manage them to best fit their Tribal communities. Participation in the TSGP is one of three ways that Tribes can choose to obtain health care from the Federal Government for their members. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting), and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive; Tribes may choose to combine them based on their individual needs and circumstances. Participation in the TSGP affords Tribes the most flexibility to tailor health care services to the needs of their communities. The TSGP is and always has been a Tribally driven initiative, and strong Federal-Tribal partnerships have been critical to the program's success. The OTSG serves as the primary liaison and advocate for Tribes participating in the TSGP and was established to implement Tribal Self-Governance legislation and authorities within the IHS. The OTSG develops, directs, and implements Tribal Self-Governance policies and procedures; provides information and technical assistance to Self-Governance Tribes; and advises the IHS Director on Agency compliance with TSGP policies, regulations and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN) that negotiates Self-Governance instruments (Compacts and Funding Agreements) on behalf of the IHS Director. To begin the Self-Governance planning process, a Tribe should contact the ALN. The ALN will provide an