comprised of two existing organizations that will otherwise remain unchanged—the Office of Regulatory Affairs and the Office of International Programs. In addition to exercising direct line authority over those two existing Offices, this new Deputy Commissioner will provide executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities.

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm*

Dated: July 25, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19111 Filed 7–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Review and Qualification of Clinical Outcome Assessments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss measurement principles for clinical outcome assessments (COAs) for use in clinical trials for new drugs. COAs include patient-reported outcome (PRO) measures, clinician-reported outcome (ClinRO) measures, and observer-reported outcome (ObsRO) measures. This public workshop is intended to provide information for and gain perspectives from patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons on various aspects of the development and implementation of COAs in the evaluation of treatment benefit. Regulatory review issues regarding context of use and documentation of the measurement properties of a COA will be covered during panel discussions. The input from this public workshop will be published in the form of a white paper or a series of manuscripts.

DATES: *Date and Time:* The public workshop will be held on October 19, 2011, from 8:30 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and routine security check before the workshop.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Attendees are responsible for their own accommodations.

The public workshop will also be available to be viewed online via Web cast at *https://collaboration.fda.gov/coaworkshop/.* Persons interested in participating by Web cast must register online by October 17, 2011.

Contact Person: Shauna Shupe, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6417, Silver Spring, MD 20993–0002, 301–796–0900, *e-mail: Shauna.Shupe@fda.hhs.gov.*

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited to 150 attendees. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m.

To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and FAX number) to *COAworkshop@fda.hhs.gov.* For those without Internet access, please call Shauna Shupe (see *Contact Person)* to register.

If you need special accommodations due to a disability, please contact Shauna Shupe at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The Center for Drug Evaluation and Research (CDER) reviews COAs including PRO measures, (ClinRO) measures, and ObsRO measures when submitted with an investigational new drug application, a new drug application, or a biologics licensing application. The FDA guidance for industry entitled ''Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims,'' available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf,* explains how FDA reviews PRO measures.

CDER also reviews a COA when submitted for qualification as a drug development tool (DDT). Qualification of a COA is a regulatory determination that the COA is well-suited for a specific context of use in drug development. Following a public announcement of the qualification decision by FDA, the COA will be publicly available for use in any appropriate drug development program. Because the qualification process is separate from the drug marketing application process, qualification is conducive to public-private partnerships engaging in this COA development effort. Such collaborative approaches may increase the efficiency of COA development when more than one entity is interested in the use of a COA for a specific context of use. The FDA draft guidance for industry entitled ''Qualification Process for Drug Development Tools,'' available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf,* provides the draft process for CDER participation in the consultation, advice, and qualification review for COAs and other DDTs.

This workshop will focus on FDA review principles specific to all type of COAs, *i.e.,* PRO, ClinRO, and ObsRO measures. More specifically, the workshop will provide researchers involved in the drug development process with information on the following topics concerning FDA review of COAs for treatment benefit evaluation:

- COA measurement principles;
- COA nomenclature;

• Determination of COA context of use;

• Practical considerations to develop and implement COAs to document treatment benefit; and

• Description of interagency collaborations and public-private partnerships for COA development.

The Agency encourages patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm206132.htm* approximately 45 days after the workshop.

The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government Agencies to small businesses.

Dated: July 20, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19140 Filed 7–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes Funding Opportunity

Announcement Type: Limited Competition.

Funding Announcement Number: HHS–2011–IHS–NIHOE–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates:

Application Deadline Date: August 2, 2011.

Review Date: August 8, 2011.

Earliest Anticipated Start Date: August 15, 2011.

I. Funding Opportunity Description

Statutory Authority: The Indian Health Service (IHS) is accepting applications for two limited competition cooperative agreements.

The IHS award includes the following three components, as described in this announcement: ''Retained Tribal Shares of Line Item 128 of the IHS Tribal Shares Table'' (Tribal Shares), ''Health Care Policy Analysis and Review'' and ''Tribal Leaders Diabetes Committee'' (TLDC). The IHS award is authorized under the Snyder Act, codified at 25 U.S.C. 13.

The CMS award, through IHS, includes the following component, as described in this announcement: ''CMS''. The CMS award is authorized under section 1110 of the Social Security Act, codified at 42 U.S.C. 1310, via an Intra-Departmental Delegation of Authority from CMS to IHS dated April 15, 2011 (IDDA–11–92), to permit obligation of funding for CMS for analyses, research and studies to address the potential and actual impact of CMS programs on American Indian/Alaska Native (AI/AN) beneficiaries and the health care system serving these beneficiaries.

IHS will be administering the CMS award pursuant to the Economy Act, codified at 31 U.S.C. 1535. It is the intention of IHS and CMS that one entity will receive both awards. CMS and IHS will concur on the final decision as to who will receive the CMS award. Each award is funded by each respective agency's appropriation. The awardee is responsible for accounting for each of the two awards separately and must provide two separate financial reports (one for each award), as indicated in Section VI. Award Administration Information, Number 4. Reporting Requirements, Item A. Progress Reports and Item B. Financial Reports of this announcement.

This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA).

Background: Outreach and education programs (program) carry out health program objectives in the AI/AN community in the interest of improving Indian health care for all 565 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health programs issues and disseminates educational information to all AI/AN Tribes and villages. These awards require that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. These awards also require that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS and CMS based on Tribal input through a broad based consumer network.

Purpose: The purpose of these awards is to further IHS and CMS missions and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. The following health services components will be awarded:

IHS Cooperative Agreement Components

1. Tribal Shares
2. Health Care Policy Analysis and Review
3. TLDC

CMS Cooperative Agreement Component

1. CMS

II. Award Information

Type of Award: Cooperative Agreements.

Estimated Funds Available: The total amount of funding identified for fiscal year (FY) 2011 is approximately $1,250,000 to fund the two cooperative agreements for one year. $300,000 is estimated for outreach, education, and support to Tribes who have elected to leave their Tribal Shares with the IHS (this amount could vary based on Tribal Share assumptions; Tribal Shares funding will be awarded in partial increments based on availability and amount of funding); $100,000 for the Health Care Policy Analysis and Review; $250,000 associated with providing legislative education, outreach and communications support to the IHS TLDC and to facilitate Tribal consultation on the Special Diabetes Program for Indians (SDPI); and $600,000 for CMS. The awards under this announcement *are subject to the availability of funds.*

Anticipated Number of Awards: Two awards are anticipated as follows: One IHS award comprised of the following three components: Tribal Shares; Health