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 workshop will focus on FDA review principles specific to all types 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;
- Qualification process for COAs and other DDTs.
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 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.