

attainment of the goals, objectives, and corresponding performance measures as evidenced by required reports, and based on the availability of funds.

#### *Funding Preferences*

Preference may be given to applicants previously funded under Program Announcement #98086 ("Translational Research Centers for Diabetes Control Within Managed-Care Settings") because these organizations:

1. Are geographically located across the nation with access to diverse diabetic populations in terms of ethnicity/minority, age, and socio-economic factors.
2. Have proven collaboration in conducting multi-center studies using a common protocol with other managed care organizations and academic institutions.
3. Have demonstrated strategies for reaching target diabetic population and attaining a very high response rate (70 to 80 percent).
4. Have established infrastructure, pool of expertise, experienced personnel, and capacity to track and maintain (with retention rates close to 80 percent) a large diabetic cohort within managed care settings.

#### **E. Program Requirements**

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities.

##### **1. Recipient Activities**

Recipients will be responsible for the following activities:

- a. Collaborate with other successful recipients and partners. Participate in the implementation of a multi-center standardized protocol, and in its further development, to include the design of the study, design of instruments, development of methods and procedures for the study, collection of the data, quality control, analysis and interpretation of the data, and dissemination of results.
- b. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project that will include longitudinal ascertainment of serious health conditions. The local IRB will review and approve the protocol on an annual basis.
- c. Assure and maintain the confidentiality of all study data.
- d. Develop standardized and aggregate analytical processes and technical reports or manuscripts for peer-reviewed publications as appropriate.

e. Because the previous program announcement #98086 was designed using a standardized protocol and standardized data collection systems, new applicants must have access to existing data (at baseline, and at least one follow-up data collection within 18 months) collected in a similar standardized and systematic manner on diabetes patients within managed care settings, collected during the previous five years that may be appropriate for inclusion with any of the previously funded centers so that a diabetic cohort may be followed in a uniform manner. Data should have been collected from health plans, provider groups, racial and ethnic minority groups with diabetes, and adults over the age of 18; and may have been assembled through interviews of health plan and provider group leaders, telephone surveys, medical record reviews, and administrative data, and other appropriate sources in order to further the knowledge already gained.

f. Work collaboratively with similar organizations and recipients in a multi-center study using a common protocol to answer the following questions: (1) What is the level of quality of diabetes care and is it changing over time? (2) what is the relationship between structural aspects of care, for example, use of disease management strategies, profit status, management of referral care, guideline implementation (at system, provider, and patient levels) and diabetes quality of care, intermediate outcomes, and long term health (morbidity, mortality, quality of life) and economic outcomes? and (3) what interventions and strategies can improve diabetes quality of care and outcomes?

g. Collaborate in an interactive and ongoing basis with other health organizations, provider groups, community groups, etc., as necessary, to participate in research assessing the existing and changing structures, processes, delivery, and outcomes of care for people with diabetes.

h. Examine the relationship between individual- and area/community-level socioeconomic characteristics of persons with diabetes and their health behaviors, and quality of care (processes and outcomes). These objectives will be accomplished through collaboration with other funded research centers.

i. Identify innovative ways of optimizing the delivery of care and health outcomes; and identify and test strategies to improve care for people with diabetes using rigorous scientific methods and based on knowledge gained from this systematic and collaborative research program.

j. Utilize an existing Steering Committee which will consist of the Principal Investigators of the research study, and who will serve as the governing body for the study.

k. Follow the standardized protocol and manual(s) of operation to be developed by the Steering Committee.

l. Maintain an effective and adequate management and staffing plan with appropriate competencies to gather, analyze, and publish data; and collaborate with other recipients and use standardized systems such as computer assisted telephone systems, hospital record systems, chart review, and administrative data management systems for collecting patient data.

m. Communicate scientifically via publications, abstracts, and presentations, the main and secondary findings pertaining to the goals of the study.

n. Perform joint analysis with aggregate data. Performance will be measured by evidence that the grantee has demonstrated accomplishment of the activities described above in items a through n.

##### **2. CDC Activities**

CDC will be responsible for the following activities:

a. Provide assistance on the design of the multi-center study, to include assisting with the development of sampling procedures, design of the instruments, development of methods and procedures for the study, collection of data, analysis and interpretation of data, resolution of data quality issues and dissemination of results.

b. Assist in the development of a standardized research protocol for IRB review by all cooperating institutions participating in the research project.

c. Obtain and maintain Certificates of Confidentiality in the form of 301(d) and assurance of confidentiality 308(d), as appropriate for the study.

d. Collaborate to produce technical reports or manuscripts for peer-reviewed publications as appropriate. Provide assistance for joint analysis with aggregate data.

e. Serve as consultants to the Steering Committee.

f. Participate in research assessing the existing and changing structures, processes, delivery, and outcomes of care for people with diabetes.

g. Provide consultation to examine the relationship between individual and community socioeconomic characteristics of persons with diabetes and diabetes processes and outcomes of care.

h. Collaborate with research centers to identify and test strategies to improve