

Florida, and thereby indirectly acquire Citizens Bank of Marianna, Marianna, Florida, and Gladsen State Bank, Chattahoochee, Florida.

B. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. *Pilot Grove Savings Bank Employee Stock Ownership Plan*, Pilot Grove, Iowa; to acquire 1.82 percent of the voting shares of Pilot Bancorp, Inc., Pilot Grove, Iowa, and thereby indirectly acquire Pilot Grove Savings Bank, Pilot Grove, Iowa.

Board of Governors of the Federal Reserve System, June 24, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-17252 Filed 6-26-98; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 98-13790) published on pages 28385-28386 of the issue for Friday, May 22, 1998.

Under the Federal Reserve Bank of Richmond heading, the entry for NationsBank Corporation and NationsBank (DE) Corporation, both in Charlotte, North Carolina (collectively NationsBank), is revised to read as follows:

A. Federal Reserve Bank of Richmond (A. Linwood Gill III, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *NationsBank Corporation and NationsBank (DE) Corporation*, both in Charlotte, North Carolina (collectively, NationsBank); to merge with BankAmerica Corporation, San Francisco, California (BankAmerica), and thereby acquire the following bank subsidiaries of BankAmerica: Bank of America National Trust and Savings Association, San Francisco, California; Bank of America Texas, National Association, Dallas, Texas; Bank of America National Association, Phoenix, Arizona; and Bank of America Community Development Bank, Walnut Creek, California. On consummation of the proposed transaction, NationsBank would be renamed BankAmerica Corporation. NationsBank may form one or more intermediate bank holding companies.

In connection with the proposed transaction, NationsBank has provided notice to acquire all of the nonbank subsidiaries of BankAmerica and to

engage, directly or indirectly through such nonbank subsidiaries, in a variety of nonbanking activities that previously have been determined to be permissible for bank holding companies.

NationsBank also would continue to control all of its existing bank and nonbank subsidiaries.

The comment period on this application has been extended. Comments on this application must be received by July 9, 1998.

Board of Governors of the Federal Reserve System, June 24, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98-17253 Filed 6-26-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 98086]

Translational Research Centers for Diabetes Control Within Managed-Care Settings; Availability of Funds for Fiscal Year 1998

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1998 funds, and invites cooperative agreement applications for a multi-center, collaborative, diabetes translational research initiative within managed-care settings to (1) evaluate the extent to which healthcare providers and healthcare delivery systems implement accepted standards of diabetes care (e.g., American Diabetes Association), which can reduce the burden of diabetes and its complications; (2) explore the factors that affect variations in implementing quality diabetes care; and (3) develop and test strategies aimed at closing the gap between existing practice and optimal standards of care.

The collaborative studies will consist of two phases. Phase 1 (12 months)—Planning, collaborative development of the protocol(s), and development of the manual of operations. Phase 2 (48 months)—Conduct of studies selected by the Steering Committee, analysis, and reporting of the results.

Under a Request for Contract, FY 1998 funds will be made available to fund one Data Coordinating Center (DCC). The organization funded for the DCC will not be eligible to receive funds under this Program Announcement. The DCC will collaborate with the recipients

under this announcement in the design and writing of the study protocol(s) and consent forms, creation of the data collection forms, and writing of the manual(s) of operations. In addition, it will assist with the development of the operational plans, develop a system to collect, manage, and store scientific data, management and analysis, and collaborate with the Translational Research Centers in reporting of results.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Diabetes and Chronic Disabling Conditions. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act, as amended (42 U.S.C. 241(a) and 247b (k)(2)). Applicable program regulations are found in 42 CFR Part 51b—Project Grants for Preventive Health Services.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Pub. L. 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, child care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are public and private nonprofit domestic organizations operating within managed-care settings and providing services to a minimum of 5,000 people with diabetes. Thus, managed-care organizations, teaching hospitals, universities, colleges, and research institutions are eligible to apply. Applicants claiming nonprofit status must include evidence of nonprofit status with their application.

Minority individuals and women are encouraged to apply as Principal Investigators. Institutions caring for large numbers of racial and ethnic minority groups with diabetes are especially encouraged to apply.

Funding Preference: A funding preference will be given to applications under the following conditions: Women, racial, and ethnic minority populations to be accessed by the applicant—to ensure that the selected Diabetes

Translational Research Centers will together have a good balance of racial and ethnic minority groups.

Applicants must have direct access to a population of at least 5,000 people with diabetes or access through a partnership, operating within a managed-care setting.

Institutions may apply as a single entity or in a collaborative partnership. In this regard, applicants are encouraged to form collaborative arrangements with investigators at minority institutions or minority investigators at other institutions. However, only one institution will be named as the recipient of grant funds in a partnership.

The expertise appropriate for the Translational Research Center applications includes a knowledge of the clinical, epidemiological, and health services research aspects of diabetes. All eligible applicants must have diabetes-related research capacity within a managed-care setting, i.e., access to large numbers of patients with diabetes (minimum of 5,000); strong multi disciplinary research groups, access to good data systems, access to academic skills in health services research, epidemiology, survey design, behavioral sciences, and health economics.

Eligibility characteristics must be clearly specified with appropriate documentation in the Application Requirements section of your application (see Application Content).

Note: Effective January 1, 1996, Pub. L. 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in Lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

Approximately \$800,000 is available in FY 1998 to fund up to four Translational Research Centers. It is expected that the average award during the planning phase (Year 1) of this project will be \$200,000 (including direct and indirect costs), ranging from \$150,000 to \$250,000. However, it is anticipated that additional funds may be available in FY 1999 to increase the average award for Year 01 to approximately \$500,000, ranging from \$300,000 to \$700,000.

Please plan your project in anticipation of these additional funds. It is expected that awards will begin on or before September 30, 1998, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds. At this time, CDC anticipates that there will not be a renewed competition after five years.

Use of Funds

Allowable Uses: Funds are awarded for a specifically defined purpose and must be targeted for implementation and management of the project. Funds can support personnel, services directly related to the project, and the purchase of hardware and software for data collection, analysis, and project management and evaluation purposes.

Prohibited Uses: Cooperative agreement funds under this program announcement cannot be used for (1) construction, (2) renovation, (3) the purchase or lease of passenger vehicles or vans, (4) to supplant non-federal funds that would otherwise be made available for this purpose, or (5) cost of regular patient care.

Restrictions on Lobbying: Applicants should be aware of restrictions on the use of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants and cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1998 Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, (Pub. L. 105-78) states in section 503(a) and (b) that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relations, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agency acting

for such recipient, related to any activity designed to influence legislation or appropriations pending before Congress or any State legislature.

Background

A considerable body of evidence exists for the efficacy of interventions (e.g., glycemic control, cardiovascular disease (CVD) risks reduction, screening for diabetes complications) to reduce the avoidable burden of diabetes. Nevertheless, the effectiveness, generalizability, feasibility, and sustainability of several of these interventions in real-life settings are less than clear. Furthermore, several reports suggest that considerable gaps exist between existing practice and recommended standards of diabetes care for people with diabetes. For example, the American Diabetes Association has recommended standards of care for several aspects of diabetes management (American Diabetes Association, Clinical Practice Recommendations 1998, Diabetes Care 1998;21 (Suppl.1). However, national estimates from the Behavioral Risk Factor Surveillance System indicate that the population of Americans receiving appropriate diabetes care practices such as foot and eye examinations, glycosylated hemoglobin, and other preventive care evaluations fall short of the recommended standards.

Managed care represents a revolution in the way health care is funded, organized, and delivered in the United States, and has affected the way in which diabetes treatment and control are conducted in both the private and public sectors. In the public sector, many health departments are in some stage of transition from directly delivering clinical services to using other delivery models that involve managed care. Thus, managed-care providers play a key role in the way people with diabetes are diagnosed and managed for increasing numbers of Americans. With more diagnostic and treatment services for diabetes being conducted in managed care, new partnerships are needed between managed-care health plans and public health agencies to design and implement essential and innovative diabetes-related services. Furthermore, managed-care (by virtue of coordinating all care for persons with diabetes) is probably the closest approximation to population medicine currently available in the United States. Managed-care, therefore, offers significant opportunities to understand and test intervention effectiveness and cost-effectiveness within a real-life context,

as well as the public health impact of system wide interventions.

Purpose

The purpose of this diabetes translational research initiative is to initiate a multicenter, collaborative program of applied population-based research related to diabetes, and to develop a knowledge base through published research in scientific literature and handbooks for professional associations that will improve the process, delivery, and outcome of diabetes services within managed-care settings. The knowledge base to be developed will address methods for and assessment of effectiveness, cost-effectiveness, generalizability, feasibility, and sustainability of interventions. Such a knowledge base may include a variety of activities covering the range of diabetes interventions, including diabetes screening and diagnosis; treatment approaches, glycemic control, CVD risk reduction, and screening for diabetes complications.

This program will improve the availability, accessibility, quality of process, effectiveness, cost-effectiveness, and health outcomes of diabetes-related services provided by managed-care health plans. The benefit of this program will be the establishment of new partnerships and relationships among managed-care health plans and between managed-care health plans and public health agencies. Thus, the challenges of improving diabetes control services may be collaboratively assessed in a manner to have a national public health impact. The other goals of this program will include provision of data for policy development, assessment, and capacity-building at the State and local levels with respect to managed care and the CDC Diabetes Control Program's ability to develop appropriate diabetes control policies and to conduct diabetes surveillance in a changing health environment.

Program Requirements

Work performed under this cooperative agreement will be the result of collaborative efforts among the funded Translational Research Centers and the Data Coordinating Center. Recipients will be responsible for implementing research methods and study design, analysis, use of data, and dissemination of results via peer-reviewed scientific publications or other related material.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities

under A., below, and CDC will be responsible for carrying out the activities described under B., below.

A. Recipient Activities

1. Participate in the protocol development, data collection, quality control, final data analysis and interpretation, the preparation of publications, and presentation of findings.

2. Establish a Steering Committee that will be the primary governing body of the study and will be comprised of each of the Principal Investigators from the Translational Research Centers and the Data Coordinating Center. The Steering Committee will have primary responsibility for developing common study protocols, facilitating the conduct and monitoring of the studies, and reporting the study results.

3. Work cooperatively with the other Translational Centers, the Data Coordinating Center, and agree to follow the common protocol(s) and manual(s) of operations developed in Phase 1 of the study by the Steering Committee.

4. Transmit all relevant study data to a central Data Coordinating Center for data editing, formatting, combination, and primary analysis.

5. Collaborate with other health organizations, community groups, etc., as necessary to accomplish program activities.

6. Maintain an effective and adequate management and staffing plan. The success of the program will depend on recruiting and hiring staff in a timely manner. Staff should have the education, background, and experience to successfully conduct the activities proposed in this application.

B. CDC Activities

1. Support and stimulate the recipients' activities by collaborating and providing scientific and public health consultation and assistance in the development of activities related to the cooperative agreement. Consistent with this concept, the tasks and activities in carrying out the studies will be shared among the recipients and the CDC.

2. Establish a Data Coordinating Center that will serve as a resource for standardized assessment, analysis, reporting, and that will assist in the design and writing of study protocol(s) in collaboration with the Research Centers.

3. Assist in the coordination of activities between the Diabetes Translational Research Centers and the Data Coordinating Center.

4. Facilitate communication among recipients and assist in quality control,

interim data monitoring, final data analysis and interpretation, and coordination and performance monitoring.

5. Serve as a consultant to the Steering Committee.

Technical Reporting Requirements

An original and two copies of the following reports must be submitted to the Grants Management Branch, CDC.

A. Semiannual progress reports are required of all cooperative agreement recipients. The first semiannual report is required with each year's noncompeting continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project). The second semiannual report is due 30 days after the end of each budget period and should cover activities from the date of the previous report. Progress reports should address the status of all recipient activities above, including:

1. A comparison of actual accomplishments to the objectives established for the period.

2. The reasons for slippage if established goals were not met.

3. Other pertinent information essential to evaluating progress.

4. Data pertaining to various project activities.

B. A financial status report (FSR) is required no later than 90 days after the end of each budget period. The final financial status report is required no later than 90 days after the end of the project period. Please submit the original and two (2) copies of all reports to the Grants Management Branch, CDC.

Notification of Intent To Apply (Preapplication Letter)

To assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement (98086), a nonbinding letter of intent-to-apply is requested from potential applicants. Although not a prerequisite of the application, the letter should be submitted to Bernice A. Moore, Epidemiology and Statistics Branch, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), Mailstop K-10, 4770 Buford Highway NE., Atlanta, GA 30341-3717, telephone (770) 488-5855; fax (770) 488-5966; or Internet or CDC WONDER E-mail at bamo@cdc.gov. It should be postmarked no later than one month before the planned submission deadline (due not later than July 15, 1998). The letter should identify the Program Announcement number, the

name and address of the applicant's institution, and telephone number of a contact person. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently.

Application Content

It is anticipated that applications for Diabetes Translational Research Centers within this initiative will focus on important aspects of the process and outcome of care for people with diabetes. Process of care may include diabetes screening and diagnosis; treatment approaches; glycemic control; cardiovascular disease (CVD) risks reduction; screening for diabetes complications; and outcome of care may include quality of life and avoidable morbidity and death among people with diabetes. In addition, the extent and causes of variation in implementation of accepted standards of diabetes care may be explored at three levels—individuals, healthcare providers, and health care delivery systems. Emphasis should be on identifying important and potentially modifiable factors that contribute to the failure to use recommended standards of diabetes care, and on designing and testing (using rigorous scientific approaches) cost-effective strategies aimed at achieving optimal care. Furthermore, in keeping with the philosophy of Translational Research, designs should emphasize intervention effectiveness which span diverse populations and a variety of healthcare approaches (e.g., type of managed care), leading to findings with high generalizability. Thus, good translational research will require multicenter participation and represent populations of diverse age, ethnicity, socioeconomic status, and severity of diabetes. Furthermore, strategies aimed at achieving optimal diabetes care should aim for generalizability, sustainability and cost-effectiveness.

Each applicant must propose the research questions and study designs that best address the objectives of this initiative and are most appropriate for their patient population. The outcome of this initiative should result in the following questions:

1. What are the current levels of care provided to people with diabetes, and how does it compare with the recommended standards of diabetes care (e.g., American Diabetes Association)?
2. What is the health-related quality of life for people with diabetes and what factors influence patient satisfaction and quality of life?
3. What are the major factors that influence the process, delivery, effectiveness, costs, and sustainability of

interventions aimed at glycemic control, and conventional CVD risk factor (elevated blood pressure, dyslipidemia, smoking, overweight, physical inactivity) reduction among people with diabetes?

4. What are the major factors that influence the process, delivery, effectiveness, costs, and sustainability of interventions aimed at the early detection of microvascular complications of diabetes (e.g., retinopathy, nephropathy)?

Collaborative protocols to study the above questions will be developed by a Steering Committee composed of the recipients and the Principal Investigator of a Data Coordinating Center selected under a separate Request for Contract. The collaborative study protocol(s) will move into the implementation stage with the concurrence of the Steering Committee.

It is not the intent of this Program Announcement to solicit elaborately detailed research plans for the above proposed collaborative studies because the final protocols will be collaboratively developed by the investigators during the planning phase (Phase 1).

Specific Instructions

All applicants must develop their applications in accordance with PHS Form 5161-1 (Revised 5/96), information contained in this Program Announcement, and the format and page limitations that follow. Provide a clear and succinct description and supportive references regarding how each of the statements apply in your application:

1. Experience in one or more of the following areas: Health economics research, health services research, epidemiological research, or health information systems research.
2. Employs or can engage investigators in the fields of economics, health services research, or information systems research who have direct experience at establishing, working with, and researching diabetes-related topics, and with a corresponding record of substantial publication in the peer-reviewed scientific literature.
3. Ability and willingness to designate one experienced and published investigator as the project's principal investigator.
4. The principal investigator for this project has access to a population of at least 5,000 people with diabetes who are cared for within a managed-care setting, and has access to research infrastructure and to basic data necessary to carry out this project.

5. Describe the composition of the proposed study population (for example, addressing the inclusion of women and members of minority groups and their subpopulations in the section that will describe the research design). A copy of the CDC policy on Women, Racial and Ethnic Minorities is enclosed with the application kit for guidance.

6. Nonprofit organizations must document their status on application PHS Form 5161-1 (Revised 5/96), Part D of the Checklist.

Responses to the above may follow the Table of Contents in your application, but must appear as the first page(s) of the text of your application and be titled, Application Requirements. Eligibility characteristics must be clearly specified with appropriate documentation in the Application Requirements section of your application.

The application narrative must include the following sections in the order presented below:

A. Rationale for the research question(s) chosen to be addressed (not to exceed 1 page):

Describe the research question(s) chosen to be addressed and the rationale for this selection. Include an explanation of why this question is a priority for the investigator(s) and what types of interest, experience, or expertise the investigator(s) brings to the particular problem inherent in the chosen research question(s).

The extent to which the rationale for the chosen research question (1) is based on public health importance, (2) is based on the experience and expertise of the investigator(s), and (3) clearly communicates the anticipated value to the purpose of the Diabetes Translational Research Initiative.

B. Objectives of the research (not to exceed 4 pages):

Itemize the objectives and timelines of the research in relation to the chosen research question(s), and describe: (1) The extent to which the objectives of the chosen research question(s) are numerically measurable, specific, realistic, time-phased, and suitable for development into a collaborative, multicenter study protocol; the extent to which applicant presents a detailed operational plan for initiating and conducting the project that clearly and appropriately addresses all Recipient Activities; (2) the extent to which the applicant clearly identifies specific assigned responsibilities and time commitment of all key professional personnel; (3) the extent to which the plan clearly describes applicant's technical approach and methods for conducting the proposed studies and

extent to which the approach and methods are appropriate and adequate to accomplish the objectives; (4) the extent to which applicant describes collaboration with CDC and others during the various phases of the project and shows commitment to a multicenter, collaborative approach.

C. Design of the research (not to exceed 3 pages):

The extent to which the proposed methodology of the research is scientifically sound, realistic, appears likely to answer the chosen research question(s), and will produce generalizable findings; and, if appropriate, the degree to which the applicant has included women, racial and ethnic minority populations in the proposed research to include:

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representations.

2. The proposed justification when representation is limited or absent.

3. A statement whether the design of the study is adequate to measure differences when warranted.

4. A statement whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

D. Background and experience of the principal investigator, coinvestigators, and the applying institution, organization, or agency (not to exceed 3 pages):

Describe the educational and professional background of the principal investigator, and document the relevant experience of the principal investigator and qualifications of the applying institution, organization, or agency for carrying out health economics, health services, or information systems research. Specifically, emphasize the experience of the principal investigator in participating in collaborative, multicenter research projects, and describe the data sources that are available to the investigator. Describe the population and number of people with diabetes within the managed-care health plan, and provide details of the managed-care structure, organization, financing, and percentage of the Medicaid population under contract. Provide a brief description of how the project will be organized, and indicate the proposed staffing plan.

E. Access to a large number of people with diabetes (≤ 5000) cared for within managed care (not to exceed 2 pages):

Describe the extent to which (1) the population used in carrying out this research project is sufficiently typical of

people with diabetes around the country or accurately represents special groups of people with the disease—so that a solution to the collaborative research question(s) will have the broadest possible application; (2) the principal investigators have sufficient access to well developed data sources and ability to use it for the purposes of carrying out this research project; and (3) if applicable, attach evidence of collaboration specifying the commitment of the parties involved and provide details, including the terms of access to data and to populations and any specified limits to collaboration for the purposes of this project.

F. Budget and budget justification (not to exceed 5 pages):

Provide a detailed, line-item budget with justification that demonstrates the request is consistent with the purpose and objectives of this program. The budget for Phase I of the study should be clearly delineated. Budgets should allow for approximately three persons, including the Principal Investigator, to attend Steering Committee and Subcommittee meetings. The detailed budget for Phase I should be estimated on the basis of monthly meetings during Phase 1.

G. Human Subjects:

Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, describe (in an appendix) adequate procedures for the protection of human subjects. Also, ensure that women, and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects.

Typing and Mailing

All pages must be clearly numbered and a complete index to the application and its appendixes must be included. Do not bind, staple, or paper clip any pages of any copy of the application, including appendixes. Do not include any bound documents (e.g., pamphlets or other publications) in the appendixes. Do not include cardboard, plastic, or other page separators between the sections. The entire application must be typewritten, single-spaced, and in unredacted type (12-point fonts) on 8½" by 11" white paper, with at least 1" margins, including headers and footers, and printed on one side only.

Evaluation Criteria (Total 100 Points)

Applications will be reviewed and evaluated according to the following criteria:

A. Rationale for the Research Question(s) Chosen to be Addressed (15 points)

Describe the research question(s) chosen to be addressed and the rationale for this selection. Included in this should be an explanation of why this question is a priority for the investigator(s) and what types of interest, experience, or expertise the investigator(s) brings to the particular problem inherent in the chosen research question(s).

The extent to which the rationale for the chosen research question (1) is based on public health importance, (2) is based on the experience and expertise of the investigator(s), and (3) clearly communicates the anticipated value to the purpose of the Diabetes Translational Research Initiative.

B. Objectives of the Research (20 points).

(1) The extent to which the objectives of the chosen research question(s) are numerically measurable, specific, realistic, and time-phased, and suitable for development into a collaborative, multicenter study protocol. The extent to which the applicant presents a detailed operational plan for initiating and conducting the project that clearly and appropriately addresses all Recipient Activities; (2) the extent to which the applicant clearly identifies specific assigned responsibilities and time commitment of all key professional personnel; (3) the extent to which the plan clearly describes applicant's technical approach and methods for conducting the proposed studies and the extent to which the approach and methods are appropriate and adequate to accomplish the objectives; and (4) the extent to which applicant describes collaboration with other translation centers during the various phases of the project, and shows commitment to a multicenter, collaborative approach.

C. Design of the Research (20 points).

The extent to which the proposed methodology of the research is scientifically sound, realistic, appears likely to answer the chosen research question(s), and will produce generalizable findings; and, if appropriate, the degree to which the applicant has included women, racial and ethnic minority populations in the proposed research to include:

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representations.

2. The proposed justification when representation is limited or absent.

3. A statement whether the design of the study is adequate to measure differences when warranted.

4. A statement whether the plans for recruitment and outreach for study participants include the process of

establishing partnerships with community(ies) and recognition of mutual benefits.

D. Background and Experience of the Principal Investigator and of the Applying Institution, Organization, or Agency (20 points).

Describe the educational and professional background of the principal investigator, and document the relevant experience of the principal investigator and qualifications of the applying institution, organization, or agency for carrying out health economics, health services, or information systems research. Specifically, emphasize the experience of the principal investigator in participating in collaborative, multicenter research projects, and describe the data sources that are available to the investigator. Describe the population and number of people with diabetes within the managed-care health plan, and provide details of the managed-care structure, organization, financing, and percentage of Medicaid population under contract. Provide a brief description of how the project will be organized and indicate the proposed staffing plan.

E. Access to a large Number of people with diabetes (≤5000) cared for within managed care (25 points).

Describe the extent to which (1) the population used in carrying out this research project is sufficiently typical of people with diabetes around the country or accurately represents special groups of people with the disease—so that a solution to the collaborative research question(s) will have the broadest possible application; (2) the principal investigator has sufficient access to well developed data sources and ability to use it for the purposes of carrying out this research project; and (3) if applicable, attach evidence of collaboration specifying the commitment of the parties involved and provide, including the terms of access to data and to populations any specified limits to collaboration for the purposes of this project.

F. Budget and Budget Justification (Not Weighted).

The extent to which the budget is reasonable and consistent with the purpose and objectives of this program.

G. Human Subjects (Not Weighted).

If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHSS) regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Panel recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no

comments to make or concerns to raise; (2) protections appear inadequate and the Review Panel has concerns related to human subjects; (3) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable, and (4) protections appear adequate that women, racial and ethnic minority populations are appropriately represented in applications involving human research.

Content of Noncompeting Continuation Applications

Submitted within the project period need only include:

A. A brief progress report that describes the accomplishments of the previous semi-annual period. This report will be in lieu of the semi-annual progress report.

B. Any new or significantly revised items or information (objectives, scope of activities, operational methods, evaluation, key personnel, work plans, etc.) not included in year 01 or subsequent continuation applications.

C. An annual budget and justification. Existing budget items that are unchanged from the previous budget period do not need rejustification. Simply list the items in the budget and indicate that they are continuation items.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372, which sets up a system for State and local government review of proposed Federal assistance applications. Applicants should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. The application kit includes a current list of SPOCs. If the SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E-18, Room 305, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, no later than 30 days after the application due date (a waiver has been requested). Please include the Program Announcement Number and Program

Title on the letter. The granting agency does not guarantee to "accommodate or explain" for State or tribal process recommendations it receives after that date.

Public Health System Reporting Requirement

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF 424).

B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not to exceed one page, and should include the following:

1. A description of the population to be served.

2. A summary of the services to be provided.

3. A description of the coordination plans with the appropriate State or local health agencies.

If the State and/or local health official desires a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.988.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by this cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review

committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit. Should human subjects reviews be required, the proposed word play should incorporate timelines for such development and review activities.

Women, Racial, and Ethnic Minorities Policy

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino. Applicants shall ensure that women and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951.

Confidentiality

Any personal identifying information obtained in connection with the delivery of services provided to any individual under any program that is being carried out with a cooperative agreement made under this Program Announcement shall not be disclosed unless required by a law of a State or political subdivision or unless such an individual provides written, voluntary informed consent.

Application Submission and Deadline

The application must be carefully completed, following the directions provided in this Program Announcement. An original and two copies of the application PHS Form 5161-1 (Revised 5/96) must be submitted to Sharron P. Orum, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, (CDC), 255 East Paces Ferry Road, NE., Mailstop E-18,

Atlanta, GA 30305-2209, on or before August 14, 1998.

1. **Deadline:** Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. **Late Applications:** Applications that do not meet the criteria in 1.a. and 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-18, Atlanta, GA 30305-2209, telephone (404) 842-6595; fax (404) 842-6513; or Internet or CDC WONDER E-mail at <lxt1@cdc.gov>. Programmatic technical assistance may be obtained from Bernice A. Moore, Epidemiology and Statistics Branch, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), Mailstop K-10, 4770 Buford Highway NE., Atlanta, GA 30341-3701, telephone (770) 488-5855; fax (770) 488-5966; or Internet or CDC WONDER E-mail at <bamo@cdc.gov>.

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

Please refer to Announcement Number 98086 when requesting information and submitting an application.

You may obtain this and other CDC Announcements from one of two Internet sites on the actual publication date: CDC's homepage at <http://www.cdc.gov> or at the Government

Printing Office homepage (including free on-line access to the **Federal Register** at <http://www.access.gpo.gov>).

Potential applicants may obtain a copy of *Healthy People 2000* (Full Report, Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report, Stock No. 017-001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325; telephone 202-512-1800.

Dated: June 22, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-17202 Filed 6-26-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Infectious Diseases (NCID), Hepatitis Branch of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Consultants Meeting on the Prevention and Control of Hepatitis C Virus (HCV) Infection.

Times and Dates: 6 p.m.-9:30 p.m., July 15, 1998. 8 a.m.-5 p.m., July 16, 1998. 8 a.m.-12 p.m., July 17, 1998.

Place: Atlanta Marriott Marquis Hotel, 265 Peachtree Center Avenue, Atlanta, Georgia 30303.

Status: Open to the public, limited only by the space available. Registration is required.

Purpose: The purpose of this working meeting is to review and discuss draft recommendations that will serve as a resource to individuals and organizations involved in evaluating persons for HCV infection, and are based on currently available knowledge.

Matters To Be Discussed: Participants will discuss recommendations for identifying persons at risk for HCV infection and the appropriate counseling and testing of these persons. Participants will also discuss recommendations to guide appropriate medical referral of HCV infected persons. The agenda will include an overview of HCV public health strategies; and sessions on (a) screening; (b) counseling and referral; and (c) implementation.

The participants will include representatives from public, private, voluntary and non-governmental organizations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.