Centers for Disease Control and Prevention

[30DAY–09]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090.

The following request have been submitted for review since the last publication date on March 21, 1996.

Proposed Project

1. Phase 2, 1996 National Health Interview Survey, Basic Module (0920–0214). The annual National Health Interview Survey (NHIS) is a basic source of general statistics on the health of the U.S. population. Due to the integration of health surveys in the Department of Health and Human Services, the NHIS also has become the sampling frame and first stage of data collection for other major surveys, including the Medical Expenditure Panel Survey, the National Survey of Family Growth, and the National Health and Nutrition Examination Survey. By linking to the NHIS, the analysis potential of these surveys increases. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, AIDS, and childhood immunizations. Journalists use its data to inform the general public. It will continue to be a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2,000.''

Because of survey integration and changes in the health and health care of the U.S. population, demands on the NHIS have changed and increased, leading to a major redesign. Improved information technology is planned, especially computer assisted personal interviewing (CAPI.) This clearance is for a one-time data collection, to introduce, test, and evaluate the redesigned NHIS data system. This data collection, planned for July–December 1996, is also expected to produce data of sufficient quality to allow publication of national estimates and release of public use micro data files. The resulting new NHIS data system is expected to be in the field for at least 10 years, beginning in January, 1997. Separate clearance will be requested for the post-1996 period.

Respondents	Number of respondents	Number of respond-ents/re-spondents	Avg. burden/ responses (in hours)	Total bur-den (in hrs.)
Family	10,500	1	0.5	5,250
Sample Adult	10,500	1	0.5	5,250
Sample child	4,500	1	0.25	1,125
Total	.....	.....	.....	11,625

The total annual burden is 11,625. Send comments to Desk officer, CDC; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

2. Ethnographic Study of Tuberculosis Outreach Worker Activities - New - This data collection will generate descriptive data from those directly involved and responsible for providing outreach to identified TB patients to gain an understanding of outreach activities, how they occur, and their level of effectiveness. Three interview guides have been developed for use with TB outreach workers, their supervisor and a small number of outreach patients. This effort will result in a more comprehensive picture of effective and efficient TB outreach activities. The major product of this effort will be a descriptive analytical report detailing the ''lessons learned''.

Respondents	Number of respondents	Number of responses/ respondents	Avg. Burden (in hrs.)
Outreach Workers	36	1	0.75
Outreach Workers' Supervisor	36	1	0.75
TB Patients	72	1	0.33

The total annual burden is 78.00. Send comments to Desk officer, CDC; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Dated: May 1, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–11446 Filed 5–7–96; 8:45 am]

BILLING CODE 4163–18–P

[Announcement Number 612]

RIN: 0905–ZA97

Academic Medical Center/Community Health Network Childhood Immunization Demonstration Projects; Notice of Availability of Funds for Fiscal Year 1996

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for cooperative agreement demonstration projects to improve the delivery of immunizations to preschool children in urban and rural areas. The purposes of this program are to (1) increase immunization coverage among children receiving care in academic medical centers— networks of primary care providers and/or in community health networks, (2) improve immunization delivery by other providers working in specified Target Communities, and (3) develop innovative methods that increase immunization coverage among difficult-to-reach children without separating immunizations from primary care.

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 Immunization. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under sections 317 (42 U.S.C. 247b) and 311 (42 U.S.C. 243) of the Public Health Service Act as amended, and the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-1, et seq.).

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 Public Law 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.

Definitions

Academic Medical Center (AMC)—A medical school, hospital, or center that is a participating institution in an accredited residency program in pediatrics or family medicine, and that may be part of a managed care organization serving Medicaid- eligible children.

Community Health Network (CHN)—A network of health care providers which provides primary health care services to needy children with low immunization coverage levels, but which does not necessarily include an AMC, as defined above.

Health Professional Shortage Area (HPSA)—HPSAs are urban and rural geographic areas, population groups, and facilities experiencing a shortage of health professionals. The current designated HPSAs of concern to this project are those relating to primary medical care and are identified by the Health Resources and Services Administration, Department of Health and Human Services in the Federal Register of October 2, 1995 (60 FR 51518).

Immunization Action Plan (IAP)—An initiative first funded in 1992 for communities to develop and implement a broad-based plan to achieve national immunization coverage goals by involving all interested groups concerned with children's health.

Urban Area—For the purposes of this program, one of the 29 cities originally funded, either directly or indirectly, by CDC as an IAP area. Their IAP designation was based on a combination of factors (i.e., magnitude of population, proportion of racial/ethnic minorities, and internal areas or ''pockets'' of chronic low immunization coverage) which most clearly corresponds to the intent of this demonstration program. In alphabetical order, these cities are Atlanta, Georgia; Baltimore, Maryland; Birmingham, Alabama; Boston, Massachusetts; Chicago, Illinois; Cleveland, Ohio; Columbus, Ohio; Dallas, Texas; Detroit, Michigan; El Paso, Texas; Houston, Texas; Indianapolis, Indiana; Jacksonville, Florida; Los Angeles, California; Memphis, Tennessee; Miami, Florida; Nashville, Tennessee; Milwaukee, Wisconsin; Newark, New Jersey; New Orleans, Louisiana; New York, New York; Philadelphia, Pennsylvania; Phoenix, Arizona; San Antonio, Texas; San Diego, California; San Jose, California; San Juan, Puerto Rico; Seattle, Washington; and Washington D.C.

Rural Area—For the purposes of this program, a HPSA nonmetropolitan area, as specified by HRSA in the Federal Register of October 2, 1995. HRSA notes that all HPSA nonmetropolitan areas are beyond the boundary of a Metropolitan Statistical Area as established by the Office of Management and Budget (OMB Bulletin 95–04 dated June 30, 1995).

Target Community—A geographic area (for urban areas having at least 100,000 population) which the applicant defines by census tracts, and which includes a designated HPSA and any contiguous census tract areas to that HPSA in which, as the applicant must establish, a majority of residing children <2 years old are from Medicaid-eligible families.

Project Collaborator—A primary health care provider with clinic facilities serving Target Community children which joins with the applying AMC/CHN at the outset to carry out each task of this demonstration project.

AMC/CHN Primary Care Clinic—A facility managed by, or affiliated with, an AMC/CHN, or which is a Project Collaborator's clinic facility, and which provides comprehensive primary care (immunizations, other preventive care, and acute care) to children in a Target Community.

AMC Network of Children's Primary Care Providers—A collection of geographically disbursed AMC Primary Care Clinics in which all serving health care providers work under the facility's standards of care (and which does not include private physicians with admitting privileges).

Clinic Assessment Software Application (CASA)—A software tool from the National Immunization Program, CDC, for conducting immunization clinic audits. It encompasses a standardized sampling methodology for obtaining medical charts for abstractions. Immunization and utilization ''events'' are recorded in CASA, and CASA calculates various measures of immunization status and practice.

Racial and Ethnic Minority Populations—Groups recognized as racial and ethnic minority populations are: African-Americans, Alaska Natives, American Indians, Asian Americans, Pacific Islanders, and Latinos/Hispanics.

Eligible Applicants

Eligible applicants are Academic Medical Centers/Community Health Networks which:

A. Provide immunization services for children in the context of comprehensive primary care.

B. Have significant experience in delivering health care services to underserved children in urban populations, or rural populations.

C. Are able to effect primary care policy in each of their own AMC/CHN Primary Care Clinics, plus those of their project collaborators, within each designated Target Community.

To be considered eligible applicants, AMCs must have an AMC network of children's primary care providers, as defined in this program announcement. To be considered eligible applicants, Community Health Networks also must provide evidence of linkage to an AMC, as defined in this program announcement, at least to the extent that an AMC agrees to accept responsibility for the clinic-based process and outcome evaluation of the CHN's proposed demonstration program.

Urban area applicants must designate one or more Target Communities wherein collectively lives a minimum current annual birth cohort (all children born in the same calendar year) of 8,000; and from which the applicant currently serves a minimum of 4,000 from that birth cohort in its network of AMC/CHN Primary Care Clinics. (NOTE: The headquarters of the AMC/CHN, its Project Collaborators, or the project's designated AMC/CHN Primary Care Clinics, need not be physically located within the Target Community(ies), but the AMC/CHN Primary Care Clinics, collectively, must be serving the specified minimum birth cohort from the Target Community.)

Separate applications from an eligible applicant may be accepted for review if aspects of one application do not depend on CDC supporting any other application. Dependent applications will be returned to the applicant without further consideration because CDC intends to make only one award to any eligible applicant.

Availability of Funds

Approximately $5,400,000 is available in FY 1996 to fund approximately four cooperative agreements, three in urban areas and one in a rural area. Only one urban area award will be made in a State, but this will not affect the award of the single rural area cooperative agreement. It is expected that the average award will be $1,350,000 per year (including direct and indirect costs), ranging from $1,000,000 to $1,500,000, with awards being made on or before September 30, 1996. The awards will be made for 12-month budget periods within a project period of up to 5 years. Funding estimates may vary and are subject to change based on the availability of funds.

Cooperative agreement applications which exceed the $1,500,000 (including direct and indirect costs) per year will be returned to the applicant as non-responsive.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

At the request of the applicant, Federal personnel with skills in immunization program operations may be assigned to a project in lieu of a portion of the financial assistance provided for the initial budget period(s) of this project.

Use of Funds

Allowable Uses

Funds should be targeted for implementation, management, and evaluation of the project. Funds can support personnel and the purchase of modest amounts of hardware and software to (1) create and operate systems that track and improve the immunization status of children, (2) link with the USDA Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and (3) conduct clinic assessments of immunization coverage levels with feedback to the providers. Funds may be used to support direct medical care, e.g., new or expanded primary care services designed to increase immunization coverage levels, but it is expected that this will be limited to the final task of the project. Applicants may enter into contractual arrangements for goods or services, or to support collaborative activities, but must retain direct control of all tasks of the project.

Prohibited Uses

Cooperative agreement funds through this project cannot be used for (1) construction, (2) renovation, (3) the purchase or lease of passenger vehicles or vans, or (4) hiring or contracting personnel to conduct interventions such as special remote vaccination clinics or other vaccination-only activities that promote vaccination outside the context of delivering primary medical care, or (5) supplanting any current applicant expenditures.

Purpose

The purpose of these projects is for AMCs/CHNs to demonstrate increases in immunization coverage levels (above the baseline percent) of at least 25 percentage points in the AMC's/CHN's network of Primary Care Clinics, at least 20 percentage points among other Target Community health care providers, and at least 15 percentage points in the overall population of each Target Community (attainment of the latter to be determined by an independent evaluator under contract to CDC), over a 5-year period through the use of conventional and innovative practices. (A paper summarizing methods for improving immunization practices in primary care settings is provided with each application kit.) The projects have three specific tasks:

Task I—the AMC/CHN is to increase immunization coverage among children already receiving care in the AMC's/CHN's network of Primary Care Clinics. Concurrently, the AMC/CHN is asked to perform a community needs assessment to adjust approaches to achieving Task I and to prepare for carrying out Tasks II and III.

Task II—The AMC/CHN is to translate its experience with the successful methods used to carry out Task I to other providers of children's primary care within the Target Community(ies), resulting in measurable changes in immunization practices and measurable improvements in the immunization coverage among the children served by the other providers.

Task III—The AMC/CHN is to use innovative or experimental methodologies to improve immunization coverage levels in the Target Community(ies). Task I focuses on children who receive care in the AMC/CHN Primary Care Clinics. Task II focuses on children who receive care from other Target Community health care providers. Task III requires that the successful parts of Tasks I and II, along with any other population-based strategies used, have an overall impact on immunization coverage for the Target Community(ies).

Most AMCs/CHNs will initiate these three tasks in sequence, but some AMCs/CHNs may be sufficiently advanced to initiate Tasks I and II simultaneously. By midway into the project period, most AMCs/CHNs probably will be conducting these three tasks concurrently.

Program Requirements

The following are application requirements:

A. Is your organization an Academic Medical Center or a Community Health Network, as each is defined in this program announcement (if so, please specify which)?

B. Does your AMC/CHN provide comprehensive primary care and immunization services?

C. Does your AMC/CHN have experience in delivering services to underserved child populations in the setting (urban area or rural area) for which you intend to apply?

D. Have your AMC/CHN and each of your Project Collaborators been providing primary medical care to infants and children for at least the past 12 months?

E. Does your AMC/CHN have the ability to effect primary care policy in each of the AMC/CHN Primary care

clinics in the Target Communities you would propose for this project?

F. If you are an AMC, does your institution have a network of primary care providers for children, as defined in this program announcement?

G. If you are a CHN, do you have linkages with an AMC, as defined in this program announcement, at least to the extent that an AMC has agreed to accept responsibility for the clinic-based process and outcome evaluation of the CHN's proposed demonstration program?

H.1. If you are applying for an urban area award, do you have at least one AMC/CHN Primary Care Clinic serving at least one urban Target Community with ≥100,000 population, as those terms are defined in this program announcement?

H.2. If you are applying for an urban area award, do you have a collective current annual birth cohort of at least 8,000 residing in your proposed Target Community(ies)?

H.3. If you are applying for an urban area award, do your AMC/CHN Primary Care Clinics serving the population from your proposed Target Community(ies) collectively serve a current annual birth cohort of at least 4,000?

H.4. If you are applying for a rural area award, do you have at least one AMC/CHN Primary Care Clinic in at least one rural Target Community, as those terms are defined in this program announcement?

I. Do each of the Target Communities you would select for this project have at least one additional primary care provider, other than an AMC/CHN Primary Care Clinic participating in this project, serving children from the Target Community population?

J. Is there a commitment at the *highest levels of your AMC/CHN* that the project manager, within reasonable limits, will be given sufficient direct authority and institutional backing to make those decisions necessary to ensure success of the project, even if those decisions may affect other domains, such as clinic/provider policies and practices?

K. Do each of your AMC/CHN Primary Care Clinics in the Target Community(ies) have an existing and proven patient information system (automated or manual) capable of recording demographic information about your enrolled population, and utilization information about patient encounters and immunizations administered?

L. Are you able to identify a populations, preferably within your MSA (if applying for an urban area award) or your State (if applying for a rural area award), to serve as a control for CDC's population-based evaluation of your project? (i.e., a population from an area which includes a HPSA and which has a racial/ethnic composition and Medicaid proportion which approximates (±15 percent for each population group and for the Medicaid proportion) their distribution when the selected Target Communities are taken as a collective).

Provide a succinct but informative response to each application requirement. Respond with ''N/A'' whenever a requirement does not relate to your type of eligible applicant organization (AMC or CHN) or the type of award (urban area or rural area) for which you are applying. Your response must not exceed 4 pages or have independent attachments, although you are encouraged to reference appropriate text in, or attachments to, the application. Your response must appear as the first 1–4 pages of the text of your application and be titled, ''Program Requirements.'' An affirmative response to each applicable question (A-L) is required to qualify for further review. All responses should provide adequate explanation and clarification of any exceptions.

Cooperative Activities

In conducting activities of this program, the recipient shall be responsible for the activities under A., below and CDC shall be responsible for conducting activities under B., below.

A. Recipient Activities

1. Task I activities include:

a. A Target Community needs assessment—To ensure effective program planning, a recipient is expected to conduct a community needs assessment in collaboration with the organizations/agencies serving the Target Community populations. The intent is for recipients to obtain information about these populations and to involve their representatives actively in the development of the program plan. Recipients are expected to: (1) use a participatory process that includes relevant community organizations, State and local health departments, and other local agencies; (2) identify and assess the unmet immunization and primary care needs of the targeted population(s); and, (3) document the available resources for supporting an effort to raise immunization coverage levels in the Target Community. Based on the results of the needs assessment, and in coordination with CDC, a recipient is expected to develop a program and community-specific plan for Task II and Task III. The needs assessment should determine, describe, and document:

(1) Access to, and availability of, immunization and primary care services for the population(s) of the Target Community(ies), barriers to obtaining services, and specific unmet primary care needs; and;

(2) Technical assistance needs of providers and organizations serving, or proposing to serve, Target Community populations.

The needs assessment should include the procedures used to identify and assess immunization and primary care needs, the actual unmet immunization and primary care needs, and any recent, current, or proposed actions to be taken within the Target Community(ies) to address them. This documentation also should include lessons learned through the needs assessment process and the technical assistance services planned (for Task II and Task III), so this information can be shared with other organizations, agencies, and recipients.

b. Application of interventions in the AMC's/CHN's network of primary care providers in the Target Community(ies)—In each AMC/CHN Primary Care Clinic that operates in each Target Community selected for this demonstration project, a recipient is expected to apply practices that have been shown to improve and sustain immunization coverage. A recipient is expected to document the efforts made, including successes and failures and outcomes resulting from these activities. At a minimum, these practices must be consistent with the Standards for Pediatric Immunization Practices, with particular emphasis on the following interventions:

(1) Reminder/recall systems—Each AMC/CHN Primary Care Clinic or network of Primary Care Clinics should establish a reminder/recall system conditioned on the immunization status of the enrolled patients.

(2) Provider immunization record assessment and feedback—The recipient must ensure that a semiannual immunization record assessment is conducted using software approved by CDC (such as CASA) for each provider within each AMC/CHN Primary Care Clinic. The recipient may perform CASA-type assessments of Task I, either through its own resources or by engaging other expertise, such as the State or local health department. (A paper on the supportive potential of public health departments for this project is provided with each application kit.) Depending on the expertise residing at the AMC chosen to take responsibility for the clinic-based process and outcome evaluation of its

program, a CHN may want to insist that the AMC engage the State or local health department, or another expert entity, to assist in conducting its CASA-type clinic assessment. The data obtained through these assessments should be used by the recipient in conjunction with CDC to identify problems in immunization service delivery and to formulate and implement solutions.

(3) Administration of vaccines—Target Community AMC/CHN Primary Care Clinics should ensure that all providers administer all appropriate vaccines at the appropriate time.

(4) Observance of the most current Recommended Immunization Schedule, approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), or accelerated schedule, as appropriate to an individual child.

(5) Observance of true immunization contraindications—AMC/CHN Primary Care Clinics should practice only true contraindications to vaccination, as stated in the most current ACIP recommendations.

c. Task I clinic-based process evaluation—A recipient is expected to ensure the ongoing process evaluation of various Task I activities to identify delivery problems. At a minimum, the quarterly process indicators for each Target Community AMC/CHN Primary Care Clinic should include:

(1) CASA-type utilization indicators.

(2) Enrollment status for each Target Community AMC/CHN Primary Care Clinic.

(3) Appointment and reminder/recall process data.

d. Task I clinic-based outcome evaluation—On a semiannual basis, a recipient is expected to ensure the gathering, analysis, and reporting of immunization outcome indicators for each Target Community AMC/CHN Primary Care Clinic relating to two age groups of children: 12–15 and 24–27 months of age. A recipient is expected to ensure that a baseline CASA-type assessment is performed for each Target Community AMC/CHN Primary Care Clinic and is repeated at 6-month intervals. Sampling should be consistent with the CASA methodology.

2. Task II activities—The purpose of Task II is to improve the immunization practices of other Target Community primary medical care providers. This includes:

a. Continuing Task I activities in each AMC/CHN Primary Care Clinic;

b. Exporting successful Task I activities to other AMC/CHN Primary Care Clinic(s) serving the Target Community(ies); and,

c. Exporting successful Task I activities to other primary health care providers serving the Target Community(ies).

d. Clinic-based process and outcome evaluations—As with Task I, the recipient is responsible in performing Task II for ensuring that a CASA-type assessment is periodically performed for each participating primary health care provider in the Target Community(ies). Also, as with Task I, the recipient may discharge this responsibility by using its own resources or by engaging other expertise, such as the State or local health department.

3. Task III activities—The purpose of Task III is to design and test creative approaches to raising the immunization coverage level of remaining Target Community children. Task III includes:

a. Continuing all Task I and Task II activities in the Target Community(ies);

b. Developing creative, practical strategies for bringing all infants into the primary health care delivery system for the earliest recommended well-child-care visit, and retaining them in the system; and developing protocols based on conventional scientific methods for rigorously evaluating the feasibility of these strategies;

c. Developing creative, practical strategies for returning and retaining children who have dropped out of the health delivery system, and develop protocols based on conventional scientific methods for rigorously evaluating the feasibility of these strategies;

d. Collaborating with CDC on the design of all Task III investigations;

e. Implementing investigations to test Task III strategies.

f. Task III Evaluation—Procedures and parameters for the evaluation of Task III activities will be described as part of the individual protocols approved and implemented and on the schedule specified in those protocols.

Although the projects resulting from this announcement are demonstrations rather than research studies, valuable new knowledge will be gained that can help other areas improve the immunization status of children. It is expected that the recipients will publish their methods and results. Data from individual projects belong to the recipients but must be shared with the CDC, and CDC reserves the right to publish scientific papers from data that are aggregated across projects. Publication of individual project data in the same manuscript with these aggregate data will be a shared responsibility with the standard rules of authorship applying. Thus, all authors must have participated in the creation, conduct, analysis, and interpretation of results.

B. CDC Activities

1. Provide medical, epidemiologic, programmatic, and educational consultation and technical assistance in planning, operating, improving, and evaluating the demonstration project.

2. Provide technical assistance in community coalition development to increase the potential for achieving Task II and Task III.

3. Provide oversight for the rigorous scientific approach to be taken in Task III to increase the use of primary care by underserved families of underimmunized children.

4. Ensure that recipients are provided population-based immunization coverage data for their respective urban area or rural area Target Community(ies) as such data become available from the independent evaluation contractor.

5. Coordinate the dissemination of findings from the demonstration project and collaborate with recipients on specific publications involving data collected.

Evaluation Criteria

Upon receipt, applications will be screened by CDC staff for completeness and responsiveness as outlined under the previous heading, ''Program Requirements'' (A–L). Incomplete applications and applications which are not responsive will be returned to the applicant without further consideration. Applications which are complete and responsive may be subjected to a preliminary evaluation by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review (triage); the CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization.

Applications accepted for full review will be reviewed and evaluated according to the following criteria:

A.1. *For Urban Area Applicants*—The extent to which need for the program is justified by the applicant's documentation of: (1) the magnitude of unmet primary care needs and underimmunization (if available) of urban inner city and other underserved populations in the proposed Target Community(ies); and (2) the existence of the current annual birth cohort residing in the proposed Target Community(ies)—10 Points.

A.2. *For Rural Area Applicants*—The extent to which need for the program is justified by the applicant's documentation of the magnitude of unmet primary care needs and underimmunization (if available) of the underserved populations living in the proposed Target Community(ies)—10 Points.

B. The extent to which the applicant's documentation establishes: (1) experience in delivering children's primary care and immunization services to underserved child populations in the Target Community(ies); (2) knowledge of the population in the Target Community(ies), as reflected by the cultural appropriateness of services that the applicant is providing; and (3) existence of the current annual birth cohort collectively served by AMC/CHN Primary Care Clinics participating as part of the proposed Target Community(ies)—10 Points.

C. The extent to which the proposed program framework is comprehensive, specific, reasonable, and realistic—20 Points.

D. The quality and feasibility of a narrative program proposal that includes: (1) detailed plans for: (a) implementing all Task I and Task II activities and general preparations for Task III; (b) program management; (c) documenting the process, including successes and failures, of implementing the activities of the three tasks; (d) resolving problems that might be encountered in designing and implementing program activities, (e.g., problems in recruiting, hiring, or retaining staff; training of staff; monitoring and ensuring staff performance; and monitoring and ensuring provider performance in Task II and Task III); and (e) completing and submitting progress reports; and (2) the extent to which: (a) the applicant's proposed Target Community(ies) are visually represented on a census tract map; (b) data regarding the applicant's proposed Target Community(ies) and AMC/CHN Primary Care Clinics appear to document the infrastructure needed to successfully conduct and evaluate this demonstration project; (c) the plan to ensure the sustainability of the results of carrying out the project's tasks is realistic; and (d) the plan is feasible in relation to the size of the current annual birth cohort, both residing in the Target Community(ies) and being served by AMC/CHN Primary Care Clinics in the selected Target Community(ies)—20 Points.

E. The extent to which: (1) the evaluation plan, either of an applying AMC or of a CHN through the AMC which will be responsible for the clinic-based process and outcome evaluation for the CHN's project, will measure the achievement of the applicant's stated goals and objectives, quality assure services, and support the ongoing management of the project; (2) the evaluation capability of an applying AMC, or of a CHN through the AMC which will be responsible for clinic-based process and outcome evaluation of the CHN's proposed demonstration program; and (3) the proposed control population is visually represented on a census tract map and meets the specifications for HPSA inclusion, racial/ethnic group composition, and Medicaid proportion set forth in subsection E. Evaluation Plan of the Application Contents section—20 Points.

F. The extent to which the applicant's description of a patient information system indicates a conclusion that the system is adequate to support an effective program—10 Points.

G. The extent to which the applicant proposes and properly documents potentially effective coordination, collaboration, and working relationships with State/local health departments—5 Points.

H. The extent to which the applicant documents effective prior working relationships with project collaborators, and the extent to which the applicant will coordinate and collaborate with providers (private and public), relevant community organizations, coalitions, and other agencies serving the populations in the Target Community(ies). For applying CHNs, the extent to which there is documentation showing the details of an formal agreement whereby a collaborating AMC agrees to assume responsibility for the clinic-based process and outcome evaluation of the CHN's project activities—5 Points.

Funding Priorities

During the selection process of urban area demonstration projects, CDC will make every effort to ensure that funded applications reflect a geographic distribution, as well as racial/ethnic diversity of the target populations; however, consistent with consideration of technical merit, at least one urban area award will be made to an applicant serving a predominantly African-American population, and at least one award will be made to an applicant serving a predominantly Hispanic population. No more than one urban area project will be funded in a State. The award of a rural area project will not be affected by the geographic distribution or ethnic/racial diversity of urban area projects. Therefore, it is possible that an urban area project and the single rural area project could be awarded in the same State, but not to the same recipient.

Interested persons are invited to comment on the proposed funding priority. All comments received on or before June 7, 1996 will be considered before the final funding priority is established. If the funding priority should change as a result of any comments received, a revised announcement will be published in the Federal Register prior to the final selection of awards. Written comments should be addressed to: Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, Room 321, Atlanta, Georgia 30305.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 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. A current list of SPOCs is included in the application kit. If the SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Atlanta, Georgia 30305, no later than 60 days after the application due date. Please include the Program Announcement Number and Program Title on the letter.

Public Health System Reporting Requirement

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental applicants must prepare and submit the items identified below to the head of the appropriate State and/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 and/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 include the following:

1. A description of the population to be served;

2. A summary of the services to be provided; and

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

If the State and/or local health official should desire 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 93.268.

Other Requirements

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.

Application Submission and Deadline

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Specialist (whose address is reflected in section B, ''Applications''). It should be postmarked no later than one month prior to the planned submission deadline, (e.g., June 12 for a July 12 submission). The letter should identify the announcement number, the name of the applicant AMC or CHN and its Project Collaborators, as defined in this announcement, and the geographic type (urban or rural) of program which the intended application will address. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently and thereby potentially benefit all applicants.

B. Application

The application should be carefully completed, following the directions provided in this program announcement. The original and two copies of the application PHS Form 5161–1 must be submitted to Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, Room 300, Mailstop E–13, Atlanta, Georgia 30305, on or before July 12, 1996.

1. Deadline

Applications will 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 triage process, if it is employed, or the objective review process if it is not. (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. or 1.b. above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement #612. You will receive a complete program description. The program announcement is also available on through the CDC homepage on the Internet. The address for the CDC homepage is http://www.cdc.gov. CDC will not send program announcements by facsimile or express mail. If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Lisa Tamaroff, 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–13, Atlanta, Georgia 30305, telephone (404) 842–6796, Internet address: lgt1@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from Russ Havlak, Immunization Services Division, National Immunization Program, Centers for Disease Control and Prevention (CDC), Building 12, Corporate Square Boulevard, Mailstop E–52, Atlanta, Georgia 30329, telephone (404) 639–8569, Internet address: grh1@cpstb1.em.cdc.gov.

Please refer to Announcement Number 612 when requesting information and submitting an application.

There may be delays in mail delivery as well as difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics (July 19–August 4). Therefore, CDC suggests the following to get more timely responses to any questions: using internet/email, following all instructions in this announcement, and leaving messages on the contact person's voice mail.

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, D.C. 20402–9325, telephone: 202–512–1800.

Dated: May 2, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–11443 Filed 5–7–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates,