Reeves, 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–09, Atlanta, GA 30305, Telephone (404) 842–6596.

For Programmatic/Technical Assistance: Bruce Granoff, Resource Analysis Specialist, Public Health Practice Program Office, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–42, Atlanta, GA 30333, Telephone (404) 639–0425.

Please refer to Announcement Number 703 when requesting information and when submitting your Letter of Intent and application in response to the announcement.

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: April 25, 1996.

Claire V. Broome,

Deputy Director, Centers for Disease Control and Prevention (CDC) and Deputy Administrator, Agency for Toxic Substances and Disease Registry (ATSDR).

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[Announcement 623]

1996 National Breast and Cervical Cancer Early Detection Program

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of funds in fiscal year (FY) 1996 for cooperative agreements to develop State and Tribal comprehensive breast and cervical cancer early detection programs.

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 to improve the quality of life. This announcement is related to the priority area of Cancer. (To order a copy of ''Healthy People 2000,'' see the section ''Where To Obtain Additional Information.'')

Authority

This program is authorized by Sections 1501 and 1507 [42 U.S.C. 300k and 42 U.S.C. 300n–3] of the Public Health Service Act, as amended.

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, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Assistance will be provided only to the official health departments of States or their bona fide agents or instrumentalities and to American Indian Tribes. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments (this includes Indian Tribes, Tribal organizations, and Urban Indian organizations, hereby referred to as Tribes).

1. The following States are excluded:

a. California, Colorado, Maryland, Michigan, Minnesota, Missouri, Nebraska, New Mexico, North Carolina, South Carolina, Texas, and West Virginia, which were funded in 1991, under Program Announcements 121 and 122 entitled Early Detection and Control of Breast and Cervical Cancer.

b. New York, Pennsylvania, Ohio, Wisconsin, Massachusetts, and Washington, which were funded in September 1993, under Program Announcement 321 entitled Early Detection and Control of Breast and Cervical Cancer.

c. Florida, Oklahoma and Utah, which were funded in September 1994, under Program Announcement 321 entitled Early Detection and Control of Breast and Cervical Cancer.

d. Alaska, Georgia, Maine, Oregon, and Rhode Island, which were funded in September 1994, under Program Announcement 474 entitled Early Detection and Control of Breast and Cervical Cancer.

e. Arizona, Arkansas, Connecticut, Iowa, Illinois, Kansas, Louisiana, New Jersey, and Vermont, which were funded in March 1995, under Program Announcement 474 entitled Early Detection and Control of Breast and Cervical Cancer.

2. The following Tribes are excluded: Artic Slope Native Association, Limited, AK; Cherokee Nation, OK; Cheyenne River Sioux Tribe, SD; Eastern Band of Cherokee Indians, NC; Maniilaq Association, AK; Pleasant Point Passamaquoddy, ME; Poarch Band of Creek Indians, AL; South Puget Planning Agency, WA; Southcentral Foundation, AK, which were funded under the American Indian Initiative Program Announcement 442.

States currently receiving CDC funds under Program Announcement 221 and 425, entitled Breast and Cervical Cancer Core Capacity, are eligible to apply for funding under this announcement. However, if funded under this announcement, funding under Program Announcement 221 will cease at the end of the current 12-month budget period. These grantees are currently in a 12-month extension and will not be eligible for an additional extension. Under Program Announcement 425, a no-cost extension may be approved to complete capacity-building activities. If not funded under this announcement, funding will continue as stated in the most recent award.

Availability of Funds

1. Approximately $15 million is available in FY 1996 to fund approximately 19 States/Territories. It is expected that the average award will be $750,000, ranging from $500,000 to $1,500,000.

2. Approximately $1 million is available to fund approximately 5 Tribes. It is expected that the average award will be $200,000 ranging from $150,000 to $350,000.

It is expected that these awards will begin on September 30, 1996, and will be made for 12-month budget periods within a project period of up to five 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 the request of the applicant, Federal personnel may be assigned to a project in lieu of a portion of the financial assistance.

Purpose

The purpose of this program is to establish a State/Tribal comprehensive public health approach to reduce breast and cervical cancer morbidity and mortality through screening, referral and follow-up, public education and outreach, professional education, quality assurance, surveillance and evaluation. The program will pay for screening of women who are unable to afford these services. Priority for provision of services will be given to women who are low-income, uninsured

and under-insured, racial and ethnic minorities including American Indians, and women who live in hard-to- reach communities in urban and rural America.

Program Requirements

In accordance with Pub. L. 101–354, an award may not be made unless the State/Tribe involved agrees that:

1. Not less than 60 percent of cooperative agreement funds will be expended for screening, appropriate referral for medical treatment, and, to the extent practicable, the provision of appropriate follow-up services. The remaining 40 percent will be expended to support public education, professional education, quality assurance, surveillance, program evaluation, and related program activities. [Section 1503(a) (1) and (4) of the PHS Act, as amended.]

2. States and Tribes are required to implement all program components, i.e., the screening, follow-up and referral services must be initiated by the end of the first budget year, and the remaining activities of a comprehensive breast and cervical cancer early detection program (public education, professional education, quality assurance, surveillance and program evaluation) must be fully operational by the end of the second budget year. [Section 1503 (a) (1) and (3) of the PHS Act, as amended.]

3. Cooperative agreement funds will not be expended to provide inpatient hospital or treatment services. [Section 1504(g) of the PHS Act, as amended.] Treatment is defined as any service recommended by a clinician, including medical and surgical intervention provided in the management of a diagnosed condition. Also, cooperative agreement funds will not be used for the specific diagnostic procedures of breast biopsy and Loop Electrosurgical Excisional Procedure (LEEP).

4. Not more than 10 percent of funds will be expended annually for administrative expenses. These administrative expenses are in lieu of and replace indirect costs. [Section 1504(f) of the PHS Act, as amended.]

5. Matching funds are required from non-Federal sources in an amount not less than $1 for each $3 of Federal funds awarded under this program. [Section 1502 (a) and (b) of the PHS Act, as amended.]

6. Costs used to satisfy matching requirements are subject to the same prior approval requirements and rules of allowability as those which govern project costs supported by Federal funds. (Office of Management and Budget, Circular A–87, ''Cost Principles for State, Local and Indian Tribal Governments'' and PHS Grants Policy Statement, Section 6.)

7. All costs used to satisfy matching requirements must be documented by the applicant and shall be subject to audit.

8. If a new, or improved, and superior screening procedure becomes widely available and is recommended for use, this superior procedure shall be utilized in the program. [Section 1503(b) of the PHS Act, as amended.]

9. An award may not be made unless the State Medicaid Program provides coverage for:

a. In the case of breast cancer, a clinical breast examination and screening mammography.

b. In the case of cervical cancer, both a pelvic examination and Pap test screening. [Section 1502A of the PHS Act, as amended.]

10. In 1993, congressional amendments to the National Breast and Cervical Cancer Early Detection Program included the following changes:

a. States/Tribes may enter into contracts with private for-profit entities to provide screening and diagnostic services only. Contracts for other kinds of services with for-profit agencies are not allowed.

b. The amount paid by a State/Tribe for a screening procedure may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act (Medicare).

c. All facilities conducting mammography screening procedures funded by the Program must meet the regulations for mammography quality assurance developed by the Food and Drug Administration (FDA).

d. For cervical cancer activities, facilities shall meet the standards and regulations developed by the Health Care Financing Administration (HCFA) implementing the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

In accordance with Section 1504 (c)(2) of the PHS Act, as amended, CDC may waive the requirements for specific services/activities if it is determined that compliance by the State/Tribe would result in an inefficient allocation of resources with respect to carrying out a comprehensive breast and cervical cancer early detection program as described in Section 1501(a). A request from the recipient outlining appropriate and detailed justification would be required before the waiver is approved.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for conducting activities under B. (CDC Activities).

A. Recipient Activities

1. Establish a system for screening women for breast and cervical cancer as a preventive health measure. [Section 1501(a)(1) of the PHS Act, as amended.]

This program is to increase the utilization of screening services for breast and cervical cancer among all women in States/Tribes, with priority given to those women who are low-income, uninsured, underinsured, racial and ethnic minorities.

a. Ensure that screening procedures are available for both breast and cervical cancer and provided to women participating in the program, including a clinical breast exam, mammography, pelvic exam, and Pap smear. [Section 1503(a)(2) (A) and (B) of the PHS Act, as amended.]

Screening services should be made available according to the following guidelines:

Breast Health: (1) The most important risk factors for breast cancer are being female and older age. Programs should place emphasis on screening women 50 years and older. Specific screening guidelines that outline age eligibility are provided in the Official Program Guidelines Age Eligibility for Mammography Screening (included in the application kit). Eligible women can receive an annual clinical breast examination and screening mammogram.

The following exceptions apply:

(a) Women who have an abnormal clinical breast exam may be referred for a physician consultation, diagnostic mammogram and/or other diagnostic procedures reimbursed by the program (see ''b.'' below).

(b) Among asymptomatic women ages 40–49 who are screened for the first time by the program, priority should be given to those who have a personal history of breast cancer or a first-degree relative with pre-menopausal breast cancer.

(2) For diagnostic services following an abnormal screening result, cooperative agreement funds may be expended for additional mammogram views, fine-needle aspiration, ultrasound, and office visits for evaluation of abnormal clinical breast examinations.

b. Provide priority for screening, referral, tracking, and follow-up services to women who are uninsured or under-insured. [Section 1504(a) of the PHS Act, as amended.]

An award may not be made under this announcement unless the State/Tribe involved agrees to give priority to the

provision of screening, follow-up, and referral services to women who are underserved and low-income.

c. Establish breast and cervical cancer screening services throughout the State/Tribe. [Section 1504(c)(1) of the PHS Act, as amended.]

Funds may not be awarded under this announcement, unless the State/Tribe involved agrees that services and activities will be made available throughout the State/Tribe, including availability to members of any Indian Tribe or tribal organization (as such terms are defined in Section 4 of the Indian Self-Determination and Education Assistance Act).

d. Provide allowances for items and services reimbursed under other programs. [Section 1504(d) (1) and (2) of the PHS Act, as amended.]

Funds may not be awarded under this announcement, unless the State/Tribe involved agrees that funds will not be expended to make payment for any item or service that will be paid or can reasonably be expected to be paid by:

(1) Any State/Tribe compensation program, insurance policy, or Federal or State/Tribe health benefits program.

(2) An entity that provides health services on a prepaid basis.

e. Establish a schedule of fees/charges for services. [Section 1504(b) (1), (2), and (3) of the PHS Act, as amended.]

Funds may not be awarded under this announcement unless the State/Tribe involved agrees that if charges are to be imposed for the provision of services or program activities, the fees/charges for allowable screening and follow-up services will be:

(1) Made according to a schedule of fees that is made available to the public. [Section 1504(b)(1) of the PHS Act, as amended.]

(2) Adjusted to reflect the income of the woman screened. [Section 1504(b)(2) of the PHS Act, as amended.]

(3) Totally waived for any woman with an income of less than 100 percent of the official poverty line as established by the Director of the Office of Management and Budget and revised by the Secretary of the Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981. [Section 1504(b)(3) of the PHS Act, as amended.]

Additionally, the schedule of fees/charges should not exceed the maximum allowable charges established by the Medicare Program administered by the Health Care Financing Administration (HCFA). Fee/charge schedules should be developed in accordance with guidelines described in the interim final rule (42 CFR Parts 405 and 534) which implements Section 4163 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) which provides limited coverage for screening mammography services.

Cervical Health: (1) Women who are 18 years and older, with an intact cervix, are eligible for an annual Pap test and pelvic examination. While the incidence of precancerous lesions and cancer are higher among younger women, older women have higher mortality rates and are less likely to be screened regularly. Hence, programs should provide a balanced distribution in the ages of women receiving Pap tests.

The following exceptions apply:

(a) After a woman has had three consecutive, normal, annual examinations, the Pap test may be performed less frequently at the discretion of her health care provider.

(b) Women who have had a total hysterectomy that was performed for cervical neoplasia are eligible to receive Pap screening.

(2) For diagnostic services following an abnormal screening result, cooperative agreement funds may be expended for colposcopy and colposcopy-directed biopsy.

2. Provide appropriate referrals for medical treatment of women screened in the program and ensure, to the extent practicable, the provision of appropriate diagnostic and treatment services. [Section 1501(a)(2) of the PHS Act, as amended.]

A system for providing the appropriate diagnostic and treatment services for women whose screening test results are abnormal or suspicious is an essential component of any comprehensive breast and cervical cancer early detection program. Priority for diagnostic services should be given to women participating in the screening program who have abnormal screening results. The operational plan and budget for diagnostic services should reflect the projected number of women to be screened by the program annually and the estimated number of abnormal screening exams expected.

a. Establish and maintain a system for the timely and appropriate referral and follow-up of women with abnormal or suspicious screening tests.

Referral systems should include the regular updating of information on local resources available in the community to which health care providers can refer women for additional diagnostic procedures not paid for by the program, as well as treatment services. Health care providers should assist clients in need of treatment services in obtaining eligibility for public-supported third party reimbursement programs.

b. Develop and implement a tracking system for women screened in the breast and cervical cancer early detection program. [Section 1501(a)(6) of the PHS Act, as amended.]

Tracking the women screened is essential to ensure that those who have abnormal results receive appropriate and timely follow-up for repeat screening, diagnostic procedures, and treatment. Tracking also includes reminders and outreach to women with normal results to return for timely rescreening. A useful tracking system is one that can be effectively integrated into the State/Tribe health care delivery system. The tracking system should provide women with a unique identification number to document the outcome of individual screening tests, regardless of the screening cycle or site. It should also provide information on needed follow-up. Confidentiality must be assured.

To meet the intent of Pub. L. 101–354 in ensuring the appropriate follow-up of women with abnormal screening results, the State/Tribe tracking system must include information on screening location (e.g., county, city), demographic characteristics (e.g., race, date of birth), and screening procedures and results (e.g., mammography, Pap tests) for all women in the program. For women identified with abnormal screening results, information on diagnostic procedures (e.g.,colposcopy) and diagnoses, treatment (e.g., date initiated), and stage of disease must be included.

In collaboration with CDC, States with currently funded comprehensive programs have compiled a list of some of the information necessary to ensure the appropriate follow-up of women. This list is available for the use of States awarded new funding under this announcement.

3. Develop and disseminate public information, education and outreach programs for the early detection and control of breast and cervical cancer. [Section 1501 (a)(3) of the PHS Act, as amended.]

Public information, education, and outreach includes the systematic design and sustained delivery of clear and consistent health messages to women using a variety of methods and strategies that contribute to the early detection of breast and cervical cancer. Successful public education and outreach programs are those that increase women's knowledge, attitudes, and ultimately have an impact on screening behavior.

Public education and outreach activities should increase the number of

women screened especially those who are low-income, uninsured, under-insured, older women of a racial or ethnic minority, and women who reside in hard-to-reach urban or rural communities. State/Tribe and local programs should clearly demonstrate, through evaluation, the relationship of public education and outreach strategies to the number of women screened through the program.

4. Improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer. [Section 1501(a)(4) of the PHS Act, as amended.]

Health care providers (including, but not limited to, primary care physicians, radiologists, cytopathologists, surgeons, gynecologists, nurse practitioners, physician's assistants, registered nurses, radiologic technologists, health educators, and outreach workers) play a key role in assuring that women are screened at appropriate intervals, that screening tests are performed optimally, and that women with abnormal test results receive timely and appropriate diagnostic follow-up and treatment. Professional education strategies can be focused in two directions. One direction could provide direct educational opportunities to those health care professionals who provide breast and cervical cancer screening. A second focus is to develop clinical systems of practice that promote ongoing appropriate screening.

5. Establish mechanisms through which the State/Tribe can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures. [Section 1501(a)(5) of the PHS Act, as amended.]

Cooperative agreement funds may not be awarded under Section 1501 of the PHS Act, as amended, Pub. L. 101–354 unless the State/Tribe involved agrees to assure the implementation of quality assurance procedures for mammography and cervical cytology. [Section 1503(c) and (d) of the PHS Act, as amended.]

a. Develop and implement a quality assurance system for breast cancer screening. The mammography services provided to women screened in the program must be conducted in accordance with the following guidelines issued by the Secretary of the Department of Health and Human Services. [Section 1503(e) of the PHS Act, as amended]:

(1) All facilities conducting mammography screening procedures funded by the program must meet the requirements for mammography quality assurance developed by the Food and Drug Administration (FDA).

(2) Radiologists participating in the program shall record their findings using the second edition American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI–RADS). The BI–RADS' reporting categories are as follows: (1) Negative; (2) Benign finding; (3) Probably benign finding—short interval follow-up suggested; (4) Suspicious finding; (5) Highly suggestive of malignancy; (6) Assessment incomplete.

(3) A report of the results of a mammogram performed through this program shall be placed in a woman's permanent medical records that are maintained by her health care provider.

b. Develop and implement a quality assurance system for cervical cancer screening. The laboratory services provided to women for cytological screening must be conducted in accordance with the following guidelines issued by the Secretary of the Department of Health and Human Services. [Section 1503(e) of the PHS Act, as amended]:

(1) Facilities shall meet the standards and regulations promulgated by the Health Care Financing Administration (HCFA) under the Clinical Laboratory Improvement Act (CLIA) of 1988.

(2) All cervical cytology interpretation is required to be done on the premises of a qualified laboratory.

(3) A report of the results of a Pap test performed through this program shall be placed in the woman's permanent medical records that are maintained by her health care provider.

(4) Pathologists participating in the program shall record their Pap test findings using the Bethesda System which specifies specimen adequacy and incorporates these categories: (1) Within Normal Limits; (2) Infection/ Inflammation/Reactive Changes; (3) Atypical squamous cells; (4) Low Grade Squamous Intra epithelial Neoplasia (SIL); (5) High Grade SIL; (6) Squamous Cell Carcinoma; (7) Other.

6. Establish mechanisms which enhance the State/Tribe cancer surveillance system (i.e., the Statewide Central Cancer Registry and other databases) and facilitate program planning and evaluation. [Section 1501(a)(5) of the PHS Act, as amended.]

Monitoring the distribution and determinants of breast and cervical cancer incidence and mortality is necessary to effectively plan, implement, and evaluate a comprehensive early detection program. Linkages with, and in some cases enhancements of, State/Tribe vital statistics, the Central Cancer Registry, the Behavioral Risk Factor Surveillance System and other State/Tribe and local surveys are needed to evaluate the status of program process (i.e., management, professional education, public education and outreach), impact (i.e., changes in participant screening behavior or screening practices of providers) and outcome (i.e., State/Tribe program screening data, cancer staging, morbidity, mortality).

a. To do this, surveillance systems should be established or enhanced which will:

(1) Collect Statewide/Tribe population-based information on the demographics, incidence, staging at diagnosis, and mortality from breast and cervical cancer.

(2) Identify segments of the population at higher risk for disease and for the failure to be screened.

(3) Identify factors contributing to the disease burden, such as behavioral risk factors and limited or inequitable access to early detection and treatment services.

(4) Monitor the number and characteristics of women screened in the program and the outcome of screening by analyzing data from the State/Tribe tracking system.

(5) Monitor screening resources, including the number of available mammography facilities, cytology laboratories, and providers of cervical cancer screening.

(6) When appropriate, develop linkages between the above-mentioned data bases.

b. Measuring the effectiveness of program activities to modify the screening behavior of women (impact evaluation) and on morbidity and mortality (outcome evaluation) is important for the identification of successful intervention strategies for the early detection of breast and cervical cancer. Equally important is process evaluation or the assessment of factors that contributed to the successful or unsuccessful establishment and implementation of program activities.

The design of each program component should ensure that there can be meaningful process, impact, and outcome evaluation. The evaluation plan should assess the implementation and effectiveness of each program component. At a minimum, the evaluation plan should identify those program activities that will be evaluated, the process, impact, and outcome indicators to be measured, how they will be measured, the proposed program time-lines, and resources needed. Activities could include:

(1) An inventory of specific services provided and a systematic description

of the infrastructure developed with cooperative agreement funds;

(2) A description of the women who received services, including the number of women and demographic information such as age, race and ethnicity;

(3) An assessment of the referral system including the number of women referred for diagnostic and treatment services, number who received these services, and the capacity of the system to identify community resources to assist women in obtaining access to available services;

(4) An assessment of the availability and accessibility of breast and cervical cancer screening services and an estimation of the number of uninsured women by age and racial/ethnic distribution in the State/Tribe to be served by the program;

(5) An assessment of the planning, development, implementation, and accomplishment of program activities (e.g., goals, objectives, time lines, recruiting, hiring, and retaining staff; training staff; establishing and maintaining contracts with provider agencies, and assuring the quality of contractor performance);

(6) An assessment of changes in participant and provider knowledge, attitudes, behaviors, and practices related to screening for breast and cervical cancer;

(7) And an assessment of the quality of screening tests provided by the program.

7. Ensure the coordination of services and program activities with other similar programs and establish a broad-based council to advise and support the program. [Section 1504(e) of the PHS Act, as amended.] Coordination with other similar programs maximizes the availability of services and program activities, promotes consistency in screening procedures and educational messages, and reduces duplication. An award may not be made under this program announcement unless the State/Tribe agrees that the services and activities provided in this program are coordinated with other Federal, State/Tribe, and local breast and cervical cancer early detection programs through the development of collaborative partnerships. [Section 1504(e) of the PHS Act, as amended.]

The success of a comprehensive breast and cervical cancer early detection program is improved by broad-based support in the community and active public and private sector involvement. Partnership development with a broad range of stakeholders, including consumers, brings valuable knowledge, skills, and financial resources to the program, and provides access to, and information about, populations of women who have been missed by traditional screening systems.

Linkages should be established with federally funded programs such as the Regional Offices of the National Cancer Institute/Cancer Information Service (NCI/CIS), the Health Resources and Services Administration (HRSA) community/migrant health centers, Title X Family Planning programs, State Offices for Aging and Minority Health, the Indian Health Service (IHS) and the Medicare Program of the Health Care Financing Administration (HCFA). Linkages and active collaboration are strongly encouraged with private sector organizations such as the American Cancer Society (ACS), the Young Women's Christian Association (YWCA), the Susan G. Komen Breast Cancer Foundation, the National Breast Cancer Coalition (NBCC), the National Alliance of Breast Cancer Organizations (NABCO), the American Association of Retired Persons (AARP), professional organizations, private physicians, survivors of breast and cervical cancer, local women's support groups, community leaders, managed care organizations, and other agencies and businesses in the community that provide health care and related support services to women.

8. Develop and implement a breast and cervical cancer control plan for program management and operations.

The success of a comprehensive breast and cervical cancer early detection program is increased by the existence of a comprehensive, integrated, and realistic plan to address these diseases among all women, with priority to uninsured and underinsured women and racial and ethnic minorities. All program components of the comprehensive program should be addressed.

A comprehensive breast and cervical cancer screening operational plan should relate to the State/Tribe Year 2000 Objectives and to the State/Tribe Cancer Control Plan. The operational and management plan should also reflect the development of qualified and diverse technical, program, and administrative staff, appropriate organizational relationships including lines of authority, adequate internal and external communication systems, and a system for sound fiscal management.

B. CDC Activities

1. Convene a workshop of the funded States/Tribes every one to two years for information-sharing and problem-solving and hold a Program Director's meeting twice a year.

2. Provide funded States/Tribes with ongoing consultation and technical assistance to plan, implement, and evaluate each component of the comprehensive program as described under Recipient Activities above. Consultation and technical assistance will be provided in the following areas:

a. Interpretation of current scientific literature related to the early detection of breast and cervical cancer;

b. Practical application of Pub. L. 101–354, including amendments to the law;

c. Nationally recognized clinical and quality assurance guidelines for the assessment and diagnosis of breast and cervical cancer;

d. Design and implementation of each program component (screening, referral, tracking, and follow-up; public education and outreach; professional education; collaborative partnerships; quality assurance; surveillance; and evaluation);

e. Evaluation of each program component (process, impact, and outcome) through the analysis and interpretation of program outcomes, screening data, and surveillance data;

f. Overall operational planning and program management.

3. Provide two training opportunities and a video teleconference with self-study educational packets on selected topics to State and Tribal program staff through the National Center for Chronic Disease and Prevention, Division of Cancer Prevention and Control's (DCPC) National Training Center.

4. Conduct site visits to assess program progress and mutually resolve problems, as needed, and/or coordinate reverse site visits to CDC in Atlanta, GA.

5. At the request of the applicant, and if available, assign Federal personnel to a project in lieu of a portion of the financial assistance. [Section 1507(b) of the PHS Act, as amended.]

Evaluation Criteria (Total 100 Points)

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

1. Background and Need (5 Points)

The extent of the disease burden and the need among the priority populations as measured by:

a. The State/Tribal breast and cervical cancer age-adjusted mortality rates averaged over five years and ranking nationally;

b. The disease burden, including the incidence rates of breast and cervical cancer by age, race and ethnicity (where available);

c. The number of uninsured women by race/ethnicity who are 18–49 years,

50–64 years, and the number of women eligible for Medicare;

d. The unmet screening needs of uninsured women;

e. Existing access and barriers to early detection services, (e.g., social, financial, geographic).

2. Operational Plan (60 Points)

The degree of comprehensiveness and quality of the Operational Plan in relation to:

a. The number of women projected for screening, quality of screening, re-screening, and surveillance programs, and compliance with Federal requirements (i.e., screening guidelines, FDA mammography certification requirements, BI–RAD reporting, and CLIA requlations.) (20 Points)

b. The extent in which proposed public education activities appear likely to increase the number of women screened, especially those women identified as a priority for services. (15 Points)

c. The extent in which proposed professional education activities provide training options and educational opportunities to improve the quality of care of women. (15 Points)

d. The extent to which proposed surveillance and evaluation appears to use reliable data and program results to measure program effectiveness and to facilitate program planning, development, and implementation, and to enhance program goals and objectives. (10 Points)

3. Collaborative Partnerships and Community Involvement (15 Points)

The feasibility and extent of the applicant's proposal to develop collaborative partnerships with other Federal, State and local programs, Tribes, and voluntary, professional, and private-sector agencies, and to establish and maintain a broad-based council of partners at State, Tribe, and local levels.

4. Breast and Cervical Cancer Control Plan (10 Points)

The feasibility and appropriateness of the applicant's management plan that describes the development of qualified and diverse technical, program, and administrative staff, organizational relationships including lines of authority, internal and external communication systems, and a system for sound fiscal management.

5. Capability for Program Implementation (10 points)

The extent to which the applicant appears likely to be successful in implementing the proposed activities as measured by:

a. Accomplishments by capacity-funded States in establishing a comprehensive public health infrastructure to support a breast and cervical cancer early detection.

b. Relevant past experiences of unfunded applicants in conducting breast and cervical cancer early detection programs.

6. Budget and Justification (Not Weighted)

The extent to which the proposed budget is adequately justified, reasonable, and consistent with this program announcement.

7. Human Subject (Not Weighted)

Whether or not exempt from the DHHS regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (1) protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (4) 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.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order 12372. This order sets up a system for State/Tribe and local review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to expected announcements of cooperative agreement funds 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 of each State. A current list of SPOCs is included in the application kit. Indian Tribes are strongly encouraged to request tribal government review of the proposed application. If Tribal governments have any Tribal process recommendations or if 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), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–09, Atlanta, GA 30305, no later than 60 days after the application deadline date. The granting agency does not guarantee to ''accommodate or explain'' the State or Tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.919.

Other Requirements

Paperwork Reduction Act

Projects which involve the collection of information from ten or more individuals and funded by 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. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its Tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Application Submission and Deadline

The original and two copies of the completed application Form PHS–5161–1 (OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management branch, Procurement and Grants Office, Centers for Disease control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–09, Atlanta, GA 30305, on or before July 1, 1996.

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

a. Received on or before the stated 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 the U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailing.)

2. Late Applications:

Applications which do not meet the criteria in 1.a. or 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, information on application procedures, an application package, and business management technical assistance may be obtained from Nealean K. Austin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, telephone (404) 842–6508; by fax (404) 842–6513; by Internet or CDC WONDER electronic mail at nea1@opspgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from Kevin Brady, MPH, Acting Assistant Branch Chief for Management and Operations, Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–57, Atlanta, GA 30341–3724, telephone (404) 488–4880 and by fax (404) 488–4727; by Internet or CDC WONDER electronic mail at KBB2@ccdpcp1.em.cdc.gov.

Please refer to Program Announcement Number 623 when requesting information and submitting an application.

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.

There may be delays in mail delivery and difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics. Therefore, CDC suggests using Internet, following all instructions in this announcement and leaving messages on the contact person's voice mail for more timely responses to any questions.

Dated: April 24, 1996.

Joseph R. Carter,

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

[FR Doc. 96–10778 Filed 4–30–96; 8:45 am]

BILLING CODE 4163–18–P

Public Health Service

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of t-Butyl Alcohol

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of t-butyl alcohol. t-Butyl alcohol is widely used in the manufacture of perfumes and a variety of cosmetics.

Toxicology and carcinogenicity studies were conducted by administration of t-butyl alcohol, in drinking water to groups of 60 F344/N rats of each sex at doses of 0, 1.25, 2.5, or 5 mg/mL for males and 0, 2.5, 5, or 10 mg/mL for females. Groups of 60 $B_6C_3F_1$ mice of each sex received t-butyl alcohol in drinking water at does of 0, 5, 10, or 20 mg/mL.

Under the conditions of these 2-year drinking water studies, there was some evidence of carcinogenic activity [1] of t-butyl alcohol in male F344/N rats based on increased incidences of renal tubule adenoma or carcinoma (combined). There was no evidence of carcinogenic activity of t-butyl alcohol in female F344/N rats receiving 2.5, 5 or 10 mg/mL. There was equivocal evidence of carcinogenic activity in male $B_6C_3F_1$ mice based on marginally increased incidences of follicular cell adenoma or carcinoma (combined) of the thyroid gland. There was some evidence of carcinogenic activity of t-butyl alcohol in female $B_6C_3F_1$ mice based on increased incidences of follicular cell adenoma of the thyroid gland.

Questions or comments about the Technical Report should be directed to Central Data Management at P.O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541–3419.

Copies of *Toxicology and Carcinogenesis Studies of t-Butyl Alcohol (CAS No. 75–65–0)* (TR–436) are available without charge from Central Data Management, NIEHS, MD E1–02, P.O. Box 12233, Research Triangle Park, NC 27709; telephone (919) 541–3419.

[1] The NTP uses five categories of evidence of carcinogenic activity observed in each animal study: two categories for positive results (''clear evidence'' and ''some evidence''), one category for uncertain findings (''equivocal evidence''), one category for no observable effect (''no evidence'') and one category for studies that cannot be evaluated because of major flaws (''inadequate study'').

Dated: April 27, 1996.

Kenneth Olden,

Director, National Toxicology Program.

[FR Doc. 96–10832 Filed 4–30–96; 8:45 am]

BILLING CODE 4140–01–M

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of Diethylphthalate with Dermal Initiation/Promotion Study of Diethylphthalate and Dimethylphthalate

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of Diethylphthalate. Diethylphthalate and Dimethylphthalate are used as phthalte plasticizers in an extensive array of products.

Toxicology and carcinogenicity studies were conducted by dermal administration of diethylphthalate to groups of 60 F344/N rats of each sex at doses of 0, 100, or 300 µL and to groups of 60 $B_6C_3F_1$ mice of each sex at doses of 0, 7.5, 15, or 30 µL. Neat chemical was applied to rats for 5 days per week for 103 weeks and up to 10 animals per group were evaluated after 15 months. Mice received doses in 100 µL of acetone for 5 days per week for 103 weeks with a 1 week recovery period, and up to 10 animals per group were evaluated after 15 months.

An additional group of 50 male Swiss (CD–1®) mice were dosed dermally with diethylphthalate of dimethylphthalate to study their effect as initiators and promoters. They were tested as initiators with and without 12–*O*tetradecanoylphorbol and they were tested as promoters with and without the known skin tumor initiator 7,12-dimethylbenzanthrancene.

Under the conditions of these 2-year dermal studies, there was no evidence of carcinogenic activity [1] of