

owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 29, 1999.

A. Federal Reserve Bank of Cleveland (Paul Kaboth, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. *Minster Financial Corp.*, Minster, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of Minster Bank, Minster, Ohio.

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

1. *Van Orin Bancorp, Inc.*, Van Orin, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of First State Bank of Van Orin, Van Orin, Illinois.

Board of Governors of the Federal Reserve System, March 30, 1999.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 99-8210 Filed 4-2-99; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices

also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 19, 1999.

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

1. *James V. Antonacci*, Richard K. McCord, Charles E. Robbins, and Richard H. Levi, all of Springfield, Illinois to acquire, as a group acting in concert, the voting shares of Fairmount Bancorp, Inc., and The First National Bank of Fairmount, both of Fairmount, Illinois.

Board of Governors of the Federal Reserve System, March 30, 1999.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 99-8212 Filed 4-2-99; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 19, 1999.

A. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer)

230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. *Bank of Montreal*, Toronto, Canada; and Bankmont Financial Corp., Chicago Illinois; to engage *de novo* through their subsidiary, Nesbitt Burns Securities, Inc., Chicago, Illinois in investing and trading activities pursuant to § 225.28(b)(8)(ii) of Regulation Y; and buying and selling bullion, and related activities pursuant to § 225.28(b)(8)(iii) of Regulation Y.

Board of Governors of the Federal Reserve System, March 30, 1999.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 99-8211 Filed 4-2-99; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99052]

Cooperative Agreement for 1999 National Breast and Cervical Cancer Early Detection Program; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for the National Breast and Cervical Cancer Early Detection Program. This program addresses the "Healthy People 2000" priority area(s) related to cancer.

The purpose of this program is to establish a State/territorial/tribal comprehensive public health approach to reduce breast and cervical cancer morbidity and mortality through screening, tracking, follow-up and case management, public education, information, and outreach, professional education, quality assurance and improvement, surveillance, evaluation, partnership development and community involvement. The program is established to eliminate disparity and provide comprehensive breast and cervical cancer screening services for all women at or below 250 percent of the official poverty line as established by the Director of the Office of Management and Budget (OMB) and revised by the Secretary of DHHS in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1991 (Section 1504(b)(3) of the PHS Act, as amended). Criteria for priority populations are uninsured or under-insured older women who are racial,

ethnic and cultural minorities, such as American Indians, Alaska Natives, African-Americans, Hispanics, Asian/Pacific Islanders; Lesbians; women with disabilities; and for women who live in hard-to-reach communities in urban and rural areas. Priority populations, as defined above, will be used throughout this document.

B. Eligible Applicants

Assistance will be provided only to the official health departments of States and Territories or their bona fide agents or instrumentalities and to Indian Tribal governments (including Indian Tribes, Tribal organizations, Alaska Natives and Urban Indian organizations, hereafter referred to as Tribes). This includes the Commonwealth of Puerto Rico, the Federated States of Micronesia, Guam, and the Republic of the Marshall Islands, and federally recognized tribes.

1. The following States and territories are excluded:

a. American Samoa, California, Colorado, Maryland, Michigan, Minnesota, Missouri, New Mexico, North Carolina, South Carolina, Texas, and West Virginia, which were funded in August 1997, under Program Announcement 718 entitled National Breast and Cervical Cancer Early Detection Program.

b. Alabama, Commonwealth of the Northern Mariana Islands, Delaware, Hawaii, Idaho, Indiana, Kentucky, Mississippi, Montana, Nevada, New Hampshire, North Dakota, Republic of Palau, South Dakota, Tennessee, Virgin Islands, Virginia, Washington, DC, and Wyoming, which were funded in September of 1996, under Program Announcement 623 entitled 1996 National Breast and Cervical Cancer Early Detection Program.

2. The following Tribes are excluded:

a. Consolidated Tribal Health Project, Inc., CA, and Southeast Regional Health Consortium, AK, which were funded August 1997, under Program Announcement 718 entitled National Breast and Cervical Cancer Early Detection Program.

b. Hopi tribe, AZ; Native American Rehabilitation Association of the NW, OR; Indian Community Health Service, AZ; and the Navajo Division of Health, AZ, which were funded in September of 1996, under Program Announcement 623 entitled 1996 National Breast and Cervical Cancer Early Detection Program.

States currently receiving CDC funds under Program Announcement 321 and 474, entitled Early Detection and Control of Breast and Cervical Cancer, are eligible to apply for funding under this announcement. Tribes currently

receiving CDC funds under Program Announcement 442, entitled Early Detection Program American Indian Initiative, are eligible to apply for funding under this announcement.

Additionally, Puerto Rico, currently funded under Program Announcement 425, entitled Capacity Building for Core Components of Breast and Cervical Cancer Prevention and Control, is eligible to apply under this announcement.

C. Availability of Funds

1. Approximately \$53,000,000 is available in FY 1999 to fund approximately 23 States. It is expected that the average award will be \$2,100,000, ranging from \$1,000,000 to \$4,500,000.

2. Approximately \$3,500,000 is available in FY 1999 to fund approximately 12 Tribes/Territories. It is expected that the average award will be \$300,000, ranging from \$200,000 to \$500,000.

It is expected that the awards will begin on September 30, 1999, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

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

Direct Assistance

You may request Federal personnel, equipment, or supplies as direct assistance, in lieu of a portion of financial assistance.

Use of Funds

1. Not less than 60 percent of cooperative agreement funds will be expended for screening, tracking, follow-up, and the provision of appropriate support services such as case management. The remaining 40 percent will be expended to support public education, information, and outreach; professional education; quality assurance and improvement; surveillance; program evaluation; partnership development and community involvement. (Section 1503(a)(1) and (4) of the PHS Act, as amended.)

2. Cooperative agreement funds will not be expended to provide inpatient hospital or treatment services. (Section 1504(g) of the PHS Act, as amended.) Also, cooperative agreement funds will not be used for the specific diagnostic procedure of Loop Electro surgical Excisional Procedure (LEEP).

3. 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.)

Note: Treatment is defined as any medical or surgical intervention recommended by a clinician, and provided for the management of a diagnosed condition.

4. 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.)

5. 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. (OMB Circular A-87 "Cost Principles for State, Local and Indian Tribal Governments" and PHS Grants Policy Statement, Section 6).

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

Recipient Financial Participation

Recipient financial participation is required for this program in accordance with the authorizing legislation. Section 1502(a) and (b)(1), (2), and (3) of the PHS Act, as amended, requires matching funds from non-Federal sources in an amount not less than \$1 for each \$3 of Federal funds awarded under this program. However, The Omnibus Territories Act requires DHHS to waive matching fund requirements for Guam, U.S. Virgin Islands, American Samoa and the Commonwealth of the Northern Mariana Islands.

The matching funds may be in cash or its equivalent in-kind or donated services, including equipment, fairly evaluated. The contributions may be made directly or through donations from public or private entities. Pub. L. 93-638 authorizes tribal organizations contracting under the authority of Title I and compacting under the authority of Title III to use funds received under the Indian Self-Determination Act as matching funds.

In States/territories/tribes, non-Federal funds from a variety of sources may presently be used to support one or more of the breast and cervical cancer early detection activities described in this program announcement. Maintenance of Effort (MOE)—The average amount of non-Federal dollars expended for breast and cervical cancer programs and activities made by a State/territory/tribe for the two year period preceding the first Federal fiscal year of the program funding for breast and

cervical cancer early detection activities. Supplantation of existing program efforts funded through other Federal or non-Federal sources is not allowable. Applicants may also include, as State/territory/tribe matching funds, any non-Federal amounts expended pursuant to Title XIX of the Social Security Act for the screening, tracking, follow-up and case management of women for breast and cervical cancer.

Matching funds may not include: (1) the payment for treatment services or the donation of treatment services; (2) services assisted or subsidized by the Federal government; or (3) the indirect or overhead costs of an organization.

D. Program Requirements

In accordance with Public Law 101-354:

1. States, territories and tribes are required to implement all the following program components:

a. States and tribes presently receiving comprehensive funding: All program components should be operational at this time.

b. Territory presently receiving capacity funding: Comprehensive breast and cervical cancer screening, follow-up, tracking services and other support services such as a case management should be initiated within the first twelve months of the first budget year. The capacity building program components (not the screening, tracking, follow-up and case management systems) should be fully operational at this time.

c. Territories/tribes not presently receiving capacity funds and applying for comprehensive funding: The application should outline plans for the operation of all program components. The screening, tracking, follow-up and case management systems should be initiated within twelve months of the award date. (Section 1503 (a)(1) and (3) of the PHS Act, as amended.)

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

3. An award may not be made unless the State/Territorial 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)

For those Territorial Departments of Health not receiving Medicaid, this

program requirement would be non-applicable.

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

a. The amount paid by a State/territory/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) (Section 1501(b)(3) of the PHS Act, as amended).

b. 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), most recently reauthorized and finalized October 31, 1998.

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

5. In 1998, Reauthorization language for the National Breast and Cervical Cancer Early Detection Program included the following change:

a. States/territories/tribes may enter into contracts with public and non-profit private entities and through contracts with public and private entities to provide screening, tracking, follow-up, and case management services, as well as for public education, information, and outreach activities, professional education activities, establish mechanisms to monitor quality of screening procedures, and to evaluate such activities. If a non-profit private entity and a private entity that is not a non-profit entity both submit applications to a State/tribe/territory, the State/tribe/territory may give priority, based on a competitive review process, to the application submitted by the non-profit private entity in any case in which the State/tribe/territory determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity (Section 1501(b) of the PHS Act, as amended).

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/territory/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 "Recipient Activities", and CDC will be responsible for conducting activities under "CDC Activities".

Recipient Activities

1. Establish a system for screening and rescanning 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 access to and use of screening services for breast and cervical cancer among all women with emphasis being given to identified priority populations as described under the "Purpose" section.

a. Ensure that screening and rescanning 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).)

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

(1) Provide priority for screening, tracking, follow-up and other support services such as case management to women who are low-income and 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/territory/tribe involved agrees to give priority to the provision of screening, tracking, follow-up, and other support services such as case management to low-income women who are underserved or uninsured.

Note: Low income is defined as at or below 250 percent of the official poverty line. The official poverty line is established by the Director of the OMB and revised by the Secretary of the DHHS in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1991 (Section 1504(b)(3) of the PHS Act, as amended.)

(2) Establish breast and cervical cancer screening services throughout the State/territory/tribe. (Section 1504(c)(1) of the PHS Act, as amended.) Funds may not be awarded under this announcement, unless the State/territory/tribe involved agrees that services and activities will be made available throughout the State, territory, or 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).

(3) 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/territory/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:

(a) Any State/territory/tribe compensation program, insurance policy, or Federal or State/territory/tribe health benefits program.

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

(4) 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/territory/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 diagnostic evaluation will be:

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

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

(c) Totally waived for any woman with an income of less than 100 percent of the official poverty line.

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.

Breast Health: The most important risk factors for breast cancer are being female and older age. Priority for mammograms should be given to eligible women 50 years and older not enrolled in Medicare Part B previously screened in the NBCCEDP. Specific policies that outline eligibility criteria and authorize screening and diagnostic services are provided in the NBCCEDP PPM.

Cervical Health: 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 are higher

among younger women, older women have higher rates of invasive cancer and cervical cancer mortality and are less likely to be screened regularly. Hence, programs should provide a balanced distribution in the ages of women receiving Pap tests. Women who have had a total hysterectomy that was performed for cervical neoplasia are eligible to receive Pap screening. Priority for Pap tests should be given to eligible women previously screened in the NBCCEDP. The following exception applies: 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.

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

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

A system for providing the appropriate and timely 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 provided a screening procedure by the program who have abnormal screening results. The implementation 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. Programs are encouraged to use the Screening and Diagnostic Worksheet included in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Policies and Procedures Manual (PPM) to report their projections.

3. Develop, implement and maintain a proactive system for the timely and appropriate tracking, follow-up, and case management of women with abnormal or suspicious screening tests (Section 1501(a)(6) of the PHS Act, as amended.)

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, as well as treatment services. Clients in need of treatment services should be assisted with obtaining eligibility for public-

supported third party reimbursement programs or private donated services.

Tracking the women screened is essential to identify those women who have abnormal results and ensure they receive appropriate and timely follow-up for short-interval rescreening, diagnostic procedures, and treatment. Tracking also includes reminders and outreach to women with normal or benign results to return for timely rescreening. A proactive tracking system is one that can be effectively integrated into the State/territory/tribe health care delivery system. The tracking system should provide women with a unique identification number and to document the outcome of individual screening tests, regardless of the screening cycle or site. It should also provide information on needed diagnostic follow-up. Confidentiality of a woman's clinical procedure results 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/territory/tribe tracking and follow-up 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 final diagnoses, treatment (e.g., date initiated), and stages of cancer must be included.

4. 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 include 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, and ultimately have an impact on attitudes and screening behavior.

Public information, education, and outreach activities should increase the number of women screened especially those who are identified as priority populations as defined in the "Purpose" section. State/territory/tribe and local programs should clearly demonstrate, through evaluation, the relationship of public information, education, and outreach strategies to the number of women screened through the program. The program should develop a plan that

defines the scope (content, priority populations, methods, strategies outcomes, resources) of the public information, education, and outreach efforts.

5. 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.)

The purpose of professional education activities is to affect health care providers' knowledge, attitudes, and behaviors to ultimately result in more women, who are identified as priority populations as defined in the "Purpose" section, in the intended audience being screened appropriately.

Professional education refers to the education of physicians, nurses, case managers, cytotechnologists, radiologists, radiologic technologists, health educators, outreach workers, support staff members, and other health professionals. It includes preprofessional, postgraduate, and continuing education. Professional education includes developing knowledge, attitudes, and skills to enable professionals to perform their jobs more effectively. It involves the identification of resources and needs and planning, implementing, and evaluating training for the health care provider. Professional education includes promoting the development and implementation of systems of health care delivery that provide positive clinical outcomes for patients, as well as the development and dissemination of clear recommendations and guidelines.

A plan should be developed that defines the scope (i.e., content, provider populations, strategies, methods, outcomes, resources) of professional education, including a prioritized list of professional groups to be trained.

Training should be based on adult learning principles with a focus on skill-based training.

6. Establish mechanisms through which the State/territory/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/territory/tribe involved agrees to assure that the State/territory/tribe will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to section 1503(c) of the PHS Act, as amended.

a. Develop and implement a quality assurance and improvement 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.

(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), most recently Reauthorized and finalized October 31, 1998.

(2) Radiologists participating in the program will 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—additional imaging evaluation needed.

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

b. Develop and implement a quality assurance and improvement 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.

(1) All facilities providing laboratory services will 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 will be placed in the woman's permanent medical records that are maintained by her health care provider.

(4) Pathologists participating in the program will 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) Atypical glandular cells; (8) Other.

In addition to using only MQSA and CLIA certified providers, quality assurance and improvement efforts should include use of:

(1) An active medical advisory group;
(2) Established clinical guidelines;
and,

(3) A system that assures that abnormal screening results are followed-up and that rescreening occurs.

7. Establish mechanisms which enhance the State/territory/tribe cancer surveillance system (i.e., linkage to the 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 and coordination with State/territory/tribe vital statistics, the Central Cancer Registry, the Behavioral Risk Factor Surveillance System and other State/territory/tribe and local surveys are needed to evaluate the status of a program's goals and objectives.

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

(1) Collect Statewide/territory/tribal 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/territory/tribe tracking and follow-up 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 and the effect on morbidity and mortality is important for the identification of successful intervention strategies for the early detection of breast and cervical

cancer. Equally important is the 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 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 objectives to be measured, how they will be measured, the proposed program time-lines, and resources needed. In addition to evaluating progress in meeting goals and objectives, the program should develop performance indicators to use as a measure of program improvement and resource management and allocation.

Note: Indicator is defined as a performance measure used to track critical processes over time to signify progress toward a particular goal or outcome of the program.

8. Ensure the coordination of services and program activities with other similar programs and establish a broad-based coalition 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/territory/tribe agrees that the services and activities provided in this program are coordinated with other Federal, State/territory/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 health service 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), local medical and nursing societies 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.

9. Develop a work and management plan for the implementation of a comprehensive breast and cervical cancer screening.

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 emphasis given to women identified as priority populations under the "Purpose" section. All program components of the comprehensive program should be addressed.

A work plan should include goals, measurable objectives, strategies proposed to attain the goals and performance indicators (if applicable). The goals in the work plan should relate to the State, territory, or tribe Year 2000 Objectives and to the State, territory, and tribe Cancer Control Plan.

The management plan should reflect the development of qualified and diverse technical, program, and program/administrative staff, appropriate organizational relationships including lines of authority, adequate internal and external communication systems, and a system for sound fiscal management.

10. Representation or attendance at CDC sponsored training, meetings, site visits, and conferences.

CDC Activities

1. Convene a workshop of the funded Programs every one to two years for information-sharing and problem-solving and hold a Program Director's meeting at least once a year.

2. Provide consultation and technical assistance to plan, implement, and evaluate each component as described under Recipient Activities above, to include:

a. Practical application of Pub. L. 101-354, including amendments to the law;

b. Design and implementation of each program component (screening, tracking, follow-up and support services such as case management; public education and outreach; professional education; partnership development and community involvement; quality assurance and improvement; surveillance; and evaluation);

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

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

e. Evaluation of each program component through the analysis and interpretation of program outcomes, screening data, and surveillance data;

f. Overall operational planning and program management.

3. Provide training opportunities on selected topics to State, territorial and tribal program staff through the National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control's 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, Georgia.

C. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The application, including budget, justification and appendices, should be no more than 125 double-spaced unbound pages, printed on one-side of 8½ x 11" paper, suitable for photocopying, with one inch margins, and 12 point font.

1. Executive Summary

The applicant should provide a clear, concise one or two page written summary to include: (1) The need for the program; (2) The goals, objectives and activities of the proposed comprehensive breast and cervical cancer early detection program; (3) the requested amount of Federal funding;

and (4) capability to implement the program.

2. Background and Need

The applicant should describe:

a. The disease burden by age and race/ethnicity;

(1) The State/territory/tribe breast and cervical cancer age-adjusted mortality rates averaged over five years and their ranking nationally,

(2) The incidence rates for these diseases (where available) from central cancer registries;

b. Total number of women in the State/territory/tribe;

c. The number of low income women who are uninsured, by age (18–39; 40–49; 50–64; 65+) and racial/ethnic distribution;

d. Unmet screening and rescreening needs of uninsured and underinsured women (where available);

e. Barriers to early detection screening services.

3. Implementation Plan

The applicant should develop a Work plan that describes the:

a. Proposed goals, performance indicators related to goals, measurable, time-phased, and realistic objectives, and strategies to attain the goals for: (1) The overall program and (2) specific program components as described under the Recipient Activities. Project the number of women to be screened and rescreened annually by age, racial and ethnic groups, and areas or locality in the State/territory/tribe. (Section 1505(2) of the PHS Act, as amended.) Estimate the number of abnormal screening exams expected annually. Applicants are encouraged to include a completed Screening and Diagnostic Worksheet (sample included in the NBCCEDP PPM) in their application.

b. Describe the State/territory/tribe's: (1) Health care delivery system; (2) proposed Statewide/territorial/tribal screening system; (3) proposed proactive tracking and follow-up system for women requiring diagnostic procedures and medical treatment not provided by the program; and (4) proposed tracking and follow-up system for women screened and rescreened by the program; and (5) proposed support services such as case management (Section 1501 (a)(1) and (2) of the PHS Act, as amended.)

c. For those applicants previously receiving National Breast and Cervical Cancer Early Detection Program Cooperative Agreement funding, describe, in detail, the operational plan related to rescreening efforts (including staff responsible for oversight, the process to monitor rescreening rates and

the system to assess the strategies used) and rescreening protocol (including a systematic and comprehensive reminder system). Include the calculation of mammography and cervical cancer rescreening rates for clinical services previously provided to eligible enrolled NBCCEDP women.

d. Document available resources in the State/territory/tribe for the payment or reimbursement of breast and cervical cancer screening, including the Medicaid Program. (Section 1504(d) of the PHS Act, as amended.)

e. Describe the ability to establish a screening program that meets FDA regulations for mammography screening; uses the American College of Radiology Breast Imaging Reporting and Data System (BI–RADS); meets the standards and regulations of the Clinical Laboratory Improvement Act (CLIA) for cervical cancer screening; and, uses the Bethesda System.

f. Provide a projected timetable for program implementation that displays dates for the accomplishment of specific proposed activities.

g. Describe the current or proposed plan for evaluating (1) the program's progress in meeting specific objectives outlined in the implementation plan by program component area, and (2) overall success based on performance indicators established by the applicant. Describe the types of indicators to be used to assess outcomes that will occur as a result of this funding. Baseline measures should be identified and assessed to allow for comparisons after implementation has begun. Specify the kind of data/performance indicator that will be used, how the data will be obtained, how information will be used to improve the overall efficiency and effectiveness of the program, as well as individual program components, who is responsible for each evaluation task, and a timeline for accomplishing each evaluation task.

h. Describe how the State/territory/tribe will assure that funds will be used in a cost-effective manner. (Section 1505 (4) of the PHS Act, as amended.)

4. Partnership Development and Community Involvement

The applicant should describe:

a. How the program will develop linkages and coordinate with other Federal, State and local programs, voluntary and professional organizations, private physicians, and mammography facilities and other groups, agencies, and businesses in the community that provide health care and related support services to women. (Section 1504(e) of the PHS Act, as amended.)

b. The current or proposed broad-based coalitions that will advise and support the breast and cervical cancer early detection program, including the identification of current members or proposed representatives, their charge, and their proposed roles and responsibilities. Specific subcommittees of the coalition should be described (e.g., Medical Advisory, public information education and outreach, and professional education).

c. Letters of support (dated within the last three months) from key partners, participants, and community leaders should be included in the application.

5. Management and Organizational Structure

The applicant should submit a Management plan. This plan should include a description of the structure to ensure the implementation of a comprehensive breast and cervical cancer program that includes 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. The information should also include the following:

a. A copy of the organizational chart indicating the placement of the proposed program in the department/organization.

b. Documentation of available resources in the State/territory/tribe for the payment or reimbursement of breast and cervical cancer screening, including the Medicaid and Medicare Programs. (Section 1504 (d) of the PHS Act, as amended.)

c. The proposed schedule of fees and charges for breast and cervical cancer screening and diagnostic services, consistent with maximum Medicare reimbursement rates, and include a description of its use in the program. In States/territories/tribes where there are multiple Medicare rates and a single reimbursement rate is being proposed, the applicant must provide justification for approval. (Section 1504 (b) of the PHS Act, as amended.)

6. Capability for Program Implementation

The applicant should describe proposed activities as measured by:

a. Accomplishments of an existing breast and cervical cancer early detection program funded by CDC or relevant past experiences funded by other sources:

(1) States Currently Receiving CDC Comprehensive Funds:

Accomplishments in establishing a comprehensive breast and cervical cancer early detection program, including the total number, age and racial/ethnic distribution of women screened; percent of abnormal findings by age and race/ethnicity; rate of cancer age adjusted or age-group specific; follow-up time between screening and diagnosis and between diagnosis and treatment initiation; and, percent of women who are routinely rescreened by the program.

Accomplishments in establishing an infrastructure to support a breast and cervical cancer screening program and in resolving program challenges, such as mammography screening for Medicare Part B unenrolled women 50 years and older, the timely follow-up of women with abnormal screening and diagnostic results, or the use of the American College of Radiology BI-RADS by radiologists to report mammogram results.

(2) Territory currently receiving CDC Capacity Building Funds: Accomplishments in establishing a comprehensive infrastructure to support a breast and cervical cancer screening program including screening, tracking, follow-up and case management information, public education and outreach, professional education, quality assurance and improvement, surveillance, and partnership development and community involvement.

(3) Territories/Tribes not currently Receiving CDC Breast and Cervical Cancer Funds: Relevant past experiences of the applicant in conducting screening, tracking, follow-up, case management; public information, education and outreach; professional education; quality assurance and improvement; surveillance; and, partnership development and community involvement for cancer control, chronic disease control or other relevant areas.

7. Source Data for Matching Requirement

Identify and describe:

a. Maintenance of Effort (MOE)—The average amount of non-Federal dollars expended for breast and cervical cancer programs and activities made by a State/territory/tribe for the two year period preceding the first Federal fiscal year of the program funding for breast and cervical cancer early detection activities. This amount will be used to establish the maintenance of effort baseline for current and future match requirements;

b. State/territory/tribe allowable sources of matching funds for the

program and the estimated amounts from each;

c. Procedures for documenting the value of non-cash matching funds;

d. Procedures for documenting the actual amount of match received.

8. Budget With Justification

a. Provide a detailed budget request and complete line item justification (for both Federal and non-Federal funds) of all proposed operating expenses consistent with the program activities described in this announcement. Not less than 60 percent of Federal funds will be expended for screening, tracking, follow-up and other support services such as case management. Not more than 10 percent of Federal funds will be expended for administrative expenses. A detailed line-item breakdown of the 60/40 distribution should be incorporated into the budget.

b. The applicant should submit a Screening and Diagnostic Worksheet that details the projected number of women screened, the reimbursement rate provided for each service, and the overall projected clinical costs. A sample Screening and Diagnostic Worksheet is included in the NBCCEDP PPM.

c. To request new direct-assistance assignees, include:

- (1) Number of assignees requested;
- (2) Description of the position and proposed duties;
- (3) Ability or inability to hire locally with financial assistance;
- (4) Justification for request;
- (5) Organizational chart and name of intended supervisor;
- (6) Opportunities for training, education, and work experiences for assignees; and

(7) Description of assignee's access to computer equipment for communication with CDC (e.g., personal computer at home, personal computer at workstation, shared computer at workstation on site, shared computer at a central office).

F. Submission and Deadline

Submit the original and two copies of the completed application Form PHS-5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before May 26, 1999, submit the application to: Mildred S. Garner, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341.

1. Deadline: Applications will 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 orderly processing. (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 acceptable 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, will be returned to the applicant.

G. Evaluation Criteria (100 Points)

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Background and Need (10 points)

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

- a. The State/territorial/tribal breast and cervical cancer age-adjusted mortality rates averaged more than 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 18-39, 40-49, 50-64, 65+ years;
- d. The unmet screening needs of uninsured and under-insured women;
- e. Existing access and barriers to early detection services, (e.g., social, financial, geographic).

2. Implementation Plan (50 points)

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

a. The applicant's proposed work plan that includes overall goals for the program and program components, describes performance indicators related to goals and details measurable, time phased and realistic objectives for each program component. (10 Points)

b. Proposed public education, information, and outreach strategies that are likely to increase the number of low income, uninsured women that are screened and rescreened. (10 points)

c. Proposed professional education strategies that are likely to effect the health care providers knowledge, attitudes, and behaviors in such a way that more women in the target audience are screened and rescreened appropriately. (10 points)

d. Proposed a service delivery program that provides quality screening, rescreening and diagnostic services,

according to established standards, and a proactive tracking, follow-up and case management system. (10 points)

e. Proposed surveillance and evaluation strategies that appear 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. Partnership Development and Community Involvement (10 points)

The feasibility and extent of the applicant's proposal to develop and maintain collaborative partnerships with other Federal, State and local programs, territories, tribes and voluntary, professional, and private-sector agencies. The extent of involvement of a broad-based coalition that advises and supports the program. The extent to which letters of support reflects assistance from key partners, participants, and community leaders.

4. Management and Organizational Structure (15 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 (15 points)

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

a. Accomplishments by comprehensive-funded States and tribes in implementing a breast and cervical cancer early detection program as required through previous funding agreements. These accomplishments should be evaluated in terms of the number of women screened, the number of services provided, and the number of cancers detected.

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

c. 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, does the application adequately address the requirement of 45 CFR part 46 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 risks are inadequate as to make the entire application unacceptable.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semiannual progress reports are required and must be submitted no later than 30 days after each semiannual reporting period. The semiannual progress reports must summarize the following: (1) Major accomplishments including information on women screened; (2) problems encountered in program implementation; and (3) efforts or proposed strategies to resolve problems. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement will be submitted with the progress reports.
2. An annual financial status report (FSR) must be submitted no later than 90 days after the end of each budget period.
3. The final financial status report and progress report is required no later than 90 days after the end of the project period.

Send all reports to: Nealean K. Austin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in application package.

AR-1 Human Subjects Requirement

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2000

AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 1501, 1502, 1507 and 1509 (42 U.S.C. 300k, 42 U.S.C. 300l, and 42 U.S.C. 300n-3) of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.919.

J. Where To Obtain Additional Information

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

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Nealean K. Austin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office Announcement 99052, Centers for Disease Control and Prevention (CDC), Room 3000, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770) 488-2754, E-mail address NEA1@CDC.GOV

For program technical assistance, contact: Amy Harris, Acting Manager, Policy Development and Administrative Coordination, 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 (770) 488-4880, fax (770) 488-4727, or

See also the CDC home page on the Internet: <http://www.cdc.gov> or <http://www.cdc.gov/cancer> for a copy of the PPM.

Dated: March 30, 1999.

John L. Williams,

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

[FR Doc. 99-8207 Filed 4-2-99; 8:45 am]

BILLING CODE 4163-18-P