Dated: May 21, 2001.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–13465 Filed 5–29–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01038]

Cooperative Agreement for 2001 National Breast and Cervical Cancer Early Detection Program; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 2001 funds to fund a cooperative agreement program for a National Breast and Cervical Cancer Early Detection Program was published in the **Federal Register** on May 17, 2001, [Vol 66, Number 96, Pages 27505–27511]. The notice is amended as follows:

On page 27505, second column, under section B. Eligible Applicants, the first paragraph, second line, insert ''and territories (including the Federated States of Micronesia and the Republic of the Marshall Islands) between the words ''States'' and ''or''.

On page 27505, second column, under section B. Eligible Applicants, the first paragraph, third line, insert ''or instrumentalities'' between the words ''agents,'' and ''including''.

On page 27505, second column, under section B. Eligible Applicants, the first paragraph, line nine, insert ''(including Indian Tribes, Tribal organizations, Alaska Natives and Urban Indian organizations and inter-tribal consortia, hereafter referred to as Tribes). An inter-tribal consortium or American Indian/Alaskan Native (AI/AN) organization is only eligible for funding if its primary purpose for incorporation is to improve AI/AN health, and it is representative of the Tribes, Alaska Native villages, or Urban Indian communities in which it is located. Tribes are encouraged to collaborate with other Tribes to expand the potential screening population.'' after the words ''Tribal government''

On page 27507, third column, under section F. Program Requirements, Recipient Activities, delete item 1.c.

Dated: May 22, 2001.

Henry S. Cassell III,

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

[FR Doc. 01–13497 Filed 5–29–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01038]

Cooperative Agreement for 2001 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) 2001 funds for a cooperative agreement program for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). This program addresses the ''Healthy People 2010'' priority area related to cancer.

The purpose of the NBCCEDP is to apply a State, territorial, or tribal public health approach to increase access to and use of screening services. The NBCCEDP was established through the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101–354) and provides screening services for low income women. Funded programs will establish a comprehensive breast and cervical cancer early detection screening program that includes the following program components: Breast and cervical cancer screening, tracking, follow-up and case management; public education and outreach; professional education; quality assurance and improvement; surveillance and evaluation; coalitions and partnerships; and management, hereafter referred to as the NBCCEDP program components.

The President has committed the nation to an ambitious goal: By the year 2010, to eliminate the disparities in health status experienced by racial and ethnic minority populations. The NBCCEDP has been established to move closer to this goal by addressing the deficits in breast and cervical cancer screening and management among these women.

B. Eligible Applicants

Assistance will be provided only to the official health departments of States and territories (including the Federated States of Micronesia and the Republic of the Marshall Islands) or their bona fide agents or instrumentalities, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, and federally recognized Indian Tribal governments (including Indian Tribes, Tribal organizations, Alaska Natives and Urban Indian organizations and inter-tribal consortia, hereafter referred to as Tribes).

An inter-tribal consortium or American Indian/Alaskan Native (AI/AN) organization is only eligible for funding if its primary purpose for incorporation is to improve AI/AN health, and it is representative of the Tribes, Alaska Native villages, or Urban Indian communities in which it is located. Tribes are encouraged to collaborate with other Tribes to expand the potential screening population.

States and Tribes currently receiving CDC funds under Program Announcement 96023, entitled 1996 National Breast and Cervical Cancer Early Detection Program, are eligible to apply for funding under this announcement.

1. The following States and Territories are not eligible to apply:

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

b. Alaska, Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Iowa, Kansas, Louisiana, Maine, Massachusetts, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhodes Island, Utah, Vermont, Washington, Wisconsin, Puerto Rico, and Guam, which are funded under Program Announcement 99052 entitled National Breast and Cervical Cancer Early Detection Program.

2. The following Tribes are not eligible to apply:

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

b. Arctic Slope Native Association (AK), Cherokee Nation (OK), Cheyenne River Sioux Tribe (OK), Poarch Band of Creek Indians (AL), South Central Foundation (AK), and South Puget Intertribal Planning Agency (WA), which are funded under Program announcement 99052 entitled National

Breast & Cervical Cancer Early Detection Program.

C. Availability of Funds

1. Funds Available for States

Approximately $22,421,667 is available in FY 2001 to fund approximately 15 States and the District of Columbia. It is expected that awards will range from $600,000 to $4,000,000.

2. Funds Available for Territories and Tribes

Approximately $5,400,000 is available in FY 2001 to fund approximately nine Territories or Tribes. It is expected that awards will range from $200,000 to $1,000,000.

It is expected that awards will begin on September 30, 2001, 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 for funded projects within an approved project period will be made on the basis of disease burden, performance, and the availability of funds.

3. Direct Assistance

Applicants may request Federal personnel as direct assistance, in lieu of a portion of financial assistance.

4. Requirements Related To Use of Funds

a. *60/40 Requirement:* Not less than 60 percent of cooperative agreement funds must be expended for screening, tracking, follow-up and the provision of appropriate support services such as case management. Cooperative agreement funds supporting public education and outreach, professional education, quality assurance and improvement, surveillance and program evaluation, coalitions and partnerships, and management may not exceed 40 percent of the approved budget. [Section 1503(a)(1) and (4) of the PHS Act, as amended] Further information about the 60/40 distribution is provided in the NBCCEDP Policies and Procedure Manual, Section II, beginning on page 10. The NBCCEDP Policies and Procedures Manual can be accessed through the Internet at http://www.cdc.gov/cancer/nbccedp or the program technical assistant contact listed in Section M, ''Where to Obtain Additional Information.''

b. *Inpatient Hospital Services:* Cooperative agreement funds must not be expended to provide inpatient hospital or treatment [1] services [Section 1504(g) of the PHS Act, as amended]. Refer to the NBCCEDP Policies and Procedures Manual, Section IV, ''Reimbursement Policies for Screening and Diagnostic Services,'' beginning on page 1, for additional information about allowable screening and diagnostic services.

c. *Administrative Expenses:* Not more than 10 percent of the total funds awarded may 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.] Administrative expenses are considered a portion of the 40 percent component of the budget.

D. Recipient Financial Participation Requirement

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, Title 48 of the U.S. Code 1469a(d) requires DHHS to waive matching fund requirements for Guam, U.S. Virgin Islands, American Samoa and the Commonwealth of the Northern Mariana Islands up to $200,000.

Matching funds may be cash or equivalent in-kind or donated services, including equipment, fairly evaluated. Contributions may be made directly or through donations from public or private entities. Public Law 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.

Applicants may also designate as State, Territory, or 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 cancers.

Matching funds may not include: (1) 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.

In determining the matching fund contribution, applicants should calculate the average amount of non-Federal contributions toward breast and cervical cancer programs and activities for the two year period preceding the first Federal fiscal year of funding for NBCCEDP. This amount is referred to as Maintenance of Effort (MOE). Only those non-Federal contributions in excess of the MOE amount may be considered as matching funds. Supplanting existing program efforts with Federal or non-Federal sources is not allowable.

Costs used to satisfy the matching requirements are subject to the same prior approval requirements and rules of allowability as those which govern project costs supported by Federal funds. All costs used to satisfy the matching requirements must be documented by the applicant and will be subject to audit. Specific rules and regulations governing the matching fund requirement are included in the OMB Circular A–87 ''Cost Principles for State, Local and Indian Tribal Governments'' and PHS Grants Policy Statement, Section 6.

For further information about the matching fund requirement, see the NBCCEDP Policies and Procedures Manual, Section II, pages 19–21 and page 35.

E. Requirements of the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101–354) and Related Amendments

1. Required Screening Services

Programs must ensure that screening and rescreening procedures are available for both breast and cervical cancers and include a clinical breast exam, mammography, pelvic exam and Pap test. [Section 1503(a)(2)(A) and (B).]

2. Screening Procedures

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. Priority for Low-income Women

Eligibility for screening services under the NBCCEDP is limited to uninsured or under insured [2] women at

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

[2] CDC, through its delegation from the Secretary, is tasked with implementing its programs. Therefore, when questions regarding the programs and the statutes behind them arise, CDC may provide definitions or explanations of what the statute as a whole, or terms contained therein, mean, in order to ensure proper implementation of its programs. CDC is entitled to deference in its interpretation of such statutes. CDC interprets ''low income women'' to include those that are ''uninsured'' and ''underinsured.'' For the NBCCEDP, CDC defines an uninsured woman as one who has no health insurance and an underinsured women as one who meets at least one of the following criteria: (1) a woman who has health insurance but whose coverage does not, to any extent, reimburse for the allowable screening or diagnostic procedure; (2) a woman who cannot

Continued

or below 250 percent of the Federal poverty line. The official poverty line is 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(a) of the PHS Act, as amended]. Policies related to eligibility for screening are detailed in the NBCCEDP Policies and Procedures Manual, Section IV.

4. Medical Referrals

Programs are required to provide appropriate referrals for medical treatment of women screened in the Program and to ensure, to the extent practicable, the provision of appropriate, affordable[3] and timely diagnostic and treatment services [Section 1501(a)(2) of the PHS Act, as amended.] The Breast and Cervical Cancer Treatment and Prevention Act (BCCTPA) of 2000 (Public Law 106–354) amends Title XIX of the Social Security Act to give States the option to provide Medicaid coverage to women who have been screened under the NBCCEDP and found to have breast or cervical pre-cancerous conditions or cancer. Additional information about this law can be obtained from the following web site: http://www.cdc.gov/cancer/nbccedp.

5. Service Delivery Area

Programs are required to establish breast and cervical cancer screening services throughout the State, Territory, or Tribe. [Section 1504(c)(1) of the PHS Act, as amended.] Funds may not be awarded under this announcement unless the State, Territory, or 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). CDC may waive [Section 1504 (c)(2) of the PHS Act, as amended] this requirement if it is determined that compliance by the State, Territory, or 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.

6. Payer of Last Resort

Funds may not be awarded under this announcement unless the State, Territory, or 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, or Tribe compensation program, insurance policy, or Federal or State, Territory, or Tribe health benefits program.

b. An entity that provides health services on a prepaid basis. [Section 1504(d)(1) and (2) of the PHS Act, as amended.]

7. Medicare Limit for Reimbursement of Services

The amount paid by a State, Territory, or 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].

8. Limitation on Imposition of Fees for Services

Funds may not be awarded under this announcement unless the State, Territory, or Tribe involved agrees that if charges are to be imposed on clients for the provision of services or program activities, such fees/charges for allowable screening and diagnostic evaluation will be:

a. Assessed according to a schedule of fees 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.]; and

c. Totally waived for any woman with an income of less than 100 percent of the Federal poverty line [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 (Public Law 101–508) which provides limited coverage for screening mammography services.

9. Quality Assurance Requirements

Cooperative agreement funds may not be awarded [under Section 1501(a)(5) of the PHS Act, as amended] unless the State, Territory, or Tribe involved agrees to assure, in accordance with the applicable law, the quality of screening procedures provided.

a. All facilities conducting mammography screening procedures funded by the Program must be MQSA certified (Mammography Quality Standards Act of 1992). [Section 1503 (c) of the PHS Act, as amended]. Additional information about quality assurance is included in the NBCCEDP Policies and Procedures Manual, Section II, page 14.

b. All facilities conducting cervical screening procedures funded by the Program must be CLIA certified (Clinical Laboratory Improvement Amendments of 1988). Pathologists participating in the Program must record their findings using the Bethesda System. [Section 1503(d) of the PHS Act, as amended] Additional information about quality assurance is included in the NBCCEDP Policies and Procedures Manual, Section II, page 14.

10. Grantee Contracting

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].

F. Program Requirements

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

1. Recipient Activities

a. Implement a comprehensive breast and cervical cancer early detection screening program that includes the NBCCEDP program components delineated in the Purpose, Section A [Section 1501(a)(1–6)]. Descriptions of

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afford her insurance provider's deductible or required co-payment for the allowable screening or diagnostic procedure; (3) a woman whose insurance supports the allowable screening and diagnostic procedure but at intervals greater than those recommended by the NBCCEDP; and (4) a woman who does not have reasonable access to a provider included under her insurance coverage.

[3] CDC, through its delegation from the Secretary, is tasked with implementing its programs. Therefore, when questions regarding the programs and the statutes behind them arise, CDC may provide definitions or explanations of what the statute as a whole, or terms contained therein, mean, in order to ensure proper implementation of its programs. CDC is entitled to deference in its interpretation of such statutes. Because the NBCCEDP gives priority to serving low-income women, CDC interprets ''appropriate referrals'' to also mean ''affordable referrals.''

the NBCCEDP program components, including each component's minimum core expectations, are provided in Attachment 1.

b. Attend and participate in sponsored events: Attendance at sponsored training, meetings, site visits, reverse site visits, and conferences is required. Funds may be included in the budget request for this purpose.

2. CDC Activities

Provide technical assistance to Grantees to support their planning, implementation and evaluation of each NBCCEDP program component. Technical assistance from CDC may address:

a. Practical application of Public Law 101–354, including amendments to the law;

b. Design and implementation of program components;

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

d. Interpretation of program outcome, screening and surveillance data;

e. Overall operational planning and program management.

3. Assist With Training on Selected Topics.

4. Conduct Site Visits

Program Consultants may conduct site visits or coordinate reverse site visits to assess program progress and/or mutually resolve problems.

G. Application Content

Use the information in the Requirements (Section E), Recipient Activities (Section F and related attachments), and Evaluation Criteria (Section G) sections to develop the application content. Applications will be evaluated on the criteria listed in Section G. Because this is a competitive program announcement, CDC requires Applicants to submit certain data and performance indicators in order that it be considered in making funding decisions. The application, including budget, justification and appendices, should be no more than 125 double-spaced unbound pages, printed on one side of 8½ × 11'' paper, suitable for photocopying, with one inch margins and 12 point font. Applicants should number each page and include a header with the Applicant's program name. Please interpret the maximum page limits as a ceiling, rather than a goal.

1. Executive Summary (Maximum 4 Pages)

The applicant should provide a clear, concise summary to include the: (1) need for the program; (2) number and characteristics of women to be screened; (3) requested amount of Federal funding; and (4) past performance indicating the applicant's capability to implement the program.

2. Background and Need (Maximum 6 Pages, Including Matrix)

The applicant should describe:

a. The State, Territory, or Tribal breast and cervical cancer age-adjusted mortality rates averaged over five years and ranked nationally (States should use SEER or State Cancer Registry data for the period 1993–1997);

b. The State, Territory, or tribal incidence rates for breast and cervical cancer by age, race, and ethnicity (where available) (States should use data from their Cancer Registries for 1998 or the most recent year available);

c. The number of women who are at or below 250 percent of the Federal poverty level and uninsured, by age (18–39; 40–49; 50–64; 65+) and racial/ethnic distribution (if possible, use 1990 Census data, unless 2000 Census data is available); and

d. The unmet screening and rescreening needs of uninsured and under-insured women (where available).

Applicants are encouraged to present these data (a–d above) using the Background and Need matrix, Attachment 2.

e. The priority populations for screening, including supporting data and/or justification for their selection. Broadly, priority populations can be described as women who are racial, ethnic and/or cultural [4] minorities, such as American Indians, Alaska Natives, African-Americans, Hispanics, Asian and Pacific Islanders, lesbians, women with disabilities, and women who live in geographically or culturally isolated communities in urban and rural areas. The term priority populations, as defined above, will be used throughout this document.

Breast and cervical cancer death rates vary by race and ethnicity; therefore, applicants must review related state and local morbidity and mortality rates to identify specific priority populations in need of breast and cervical cancer screening in their geographic area. Programs should aim to eliminate racial health disparities by prioritizing populations that are under screened and/or disproportionately affected by breast and/or cervical cancer for recruitment and enrollment.

Regardless of the geographic area, priority for breast cancer screening should be given to women age 50 to 64 years of age. Priority for cervical cancer screening should be given to rarely [5] or never screened women.

f. The specific barriers to screening services that impede women in the priority populations from participating in breast and cervical cancer screening and diagnostic services.

3. Capability for Program Implementation (Maximum 10 Pages, Not Including Letters of Commitment)

a. Applicants should address their capability to implement the proposed activities as measured by their accomplishments as part of an existing or past NBCCEDP program or relevant past experiences funded by other sources.

(1) States, Territories, or Tribes currently receiving NBCCEDP funds should detail their accomplishments in operating a comprehensive breast and cervical cancer early detection program. Applicants should address accomplishments in program and fiscal management, infrastructure development, and service delivery by summarizing progress in meeting NBCCEDP fiscal year 2001 Program Progress Indicators.[6] These program progress indicators are listed in the NBCCEDP Policies and Procedures Manual, Section III, beginning on page 3. Applicants should use the most recent data available to summarize these indicators.

(2) Territories and Tribes not currently receiving CDC NBCCEDP funds should address relevant past experiences in conducting any of the NBCCEDP program components for cancer control, chronic disease control or other relevant areas.

b. *Letters of Commitment:* Applicants should include letters of commitment (dated within the last three months) from key partners, participants, and community leaders that detail their commitment to and participation in the proposed program. If the applicant is a Tribe, also include either of the following documentation, as appropriate: (1) A signed and dated tribal resolution supporting the application from the Indian Tribe served by the project. If the applicant includes more than one Indian Tribe, resolutions from all Tribes to be served must be

[4] Cultural minorities are defined as communities which, in order to preserve or protect cultural or religious beliefs or practices, limit contact with other people or the larger community.

[5] Rarely screened is defined by the NBCCEDP as a woman who has not received a Pap test during the past five years.

[6] Program Progress Indicators have been developed to provide a systematic approach for rapid assessment of program progress. Program progress indicators are defined as performance measures used to track critical processes over time to signify progress toward a particular goal or outcome of the program.

included; or (2) A letter of support for the application from the Board of Directors of an Urban Indian organization(s) or Indian Health organization(s), signed by the Board Chairman.

c. *Other Accomplishments:* Applicants should include information about any other accomplishments that reflect capability and capacity for implementing a breast and cervical cancer early detection program.

4. Work Plan (Maximum 30 Pages)

The applicant should develop a detailed work plan that, for each NBCCEDP program component, describes: proposed goals; measures of success related to goals; specific, measurable, attainable, realistic and time-phased objectives; and activities to attain the objectives. The minimum core expectations for each program component should be addressed in the work plan. Be reminded that descriptions of the NBCCEDP program components are included as Attachment 1.

The work plan should include a time table for program implementation that specifies dates for the accomplishment of all proposed activities. Applicants are encouraged to use the NBCCEDP work plan template available through the Internet at http://www.cdc.gov/cancer/nbccedp/training/index.htm. This template is included in the 30-page limit but may be single spaced.

Applicants should include an attachment to the work plan with realistic screening projections for fiscal year 2001–2002 that are based on past screening performance. Screening projections should be provided with the following detail: the number of women to be screened by the program by age, race, ethnicity and other identified priority populations (applicant's cultural minorities identified in the Background and Need section as priority populations). In addition, the applicant should include a projection of the number of rarely and never screened women to receive a Pap test. Projected screening levels for racial and ethnic populations should be based on population estimates of the number of women in the Program area who meet NBCCEDP age and income eligibility guidelines, as well as past screening performance. Applicants are encouraged to present the screening projections using the Screening Projections matrix, Attachment 3. Applicants with current NBCCEDP funding from CDC should provide a brief narrative justification that includes recent screening data supporting the projections.

If the applicant has submitted a request to the HCFA and received approval to provide Medicaid coverage for treatment to women screened under the NBCCEDP with breast or cervical cancer, or pre-cancerous conditions of the breast or cervix, complete Attachment 4, the Breast and Cervical Cancer Prevention and Treatment Act Form.

5. Organizational Structure (Maximum 15 Pages)

The applicant should provide the following supporting documents related to organizational structure:

a. An organizational chart (can be single spaced) indicating the placement of the proposed Program in the department or organization and the structure of the proposed breast and cervical cancer early detection program management and staffing;

b. Documentation of available resources in the State, Territory, or Tribe for the payment or reimbursement of breast and cervical cancer screening, including the Medicaid program;

c. The proposed schedule of fees and charges for breast and cervical cancer screening and diagnostic services, consistent with maximum Medicare reimbursement rates, if fees will be imposed (single line spacing is acceptable). Include a description of the use of the proposed schedule of fees and charges in the Program. In States, Territories, or Tribes where there are multiple Medicare rates and a single reimbursement rate is being proposed, the applicant must provide justification for approval.

d. Documentation of how the State, Territory, or Tribe will assure that funds will be used in a cost-effective manner.

e. A description of how the State, Territory, or Tribe will establish or enhance linkages with their State Cancer Registry program if the Applicant has a State Registry with the North American Association of Central Cancer Registries (NAACCR) certification. For more information about Cancer Registries see http://www.cdc.gov/cancer/npcr, http://www-seer.ims.nci.nih.gov, and for NAACCR certification see http://www.NAACCR.org.

6. Source Data for Matching Requirement (Maximum 5 Pages)

a. *Maintenance of Effort:* The applicant should detail the average amount of non-Federal dollars expended for breast and cervical cancer programs and activities made by a State, Territory, or Tribe for the two year period preceding the first Federal fiscal year of NBCCEDP funding. This amount will be used to establish the maintenance of effort baseline for current and future match requirements.

b. *Sources of Match:* The applicant should detail the State, Territory, or tribal allowable sources of matching funds for the Program and the estimated amounts from each. The applicant should document the procedures for determining the value of non-cash matching funds. Further information about the Matching Funds Requirement can be found in the NBCCEDP Policies and Procedures Manual, section II, pages 19–21 and page 35.

c. *Documentation of Match Received:* The applicant should describe procedures for documenting the actual amount of match received.

7. Budget With Justification (Maximum 7 Pages)

a. Provide a detailed line item-budget (can be single spaced) with a separate narrative justification (for both Federal and non-Federal funds) of all proposed operating expenses consistent with the program activities described in this announcement. The budget may include line items for personnel, fringe benefits, travel, contractors, consultants, equipment, administrative, and other expenses. 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. The following information is required for all contracts: (1) name of contractor; (2) method of selection; (3) period of performance; (4) scope of work; (5) method of accountability; and (6) itemized budget with justification for each contract.

b. A detailed line-item breakdown of the 60/40 distribution should be provided. A sample 60/40 budget breakdown is included in the NBCCEDP Policies and Procedures Manual, section II, page 38. For further information about the 60/40 requirement, please refer to the NBCCEDP Policies and Procedures Manual, section II, page 10.

c. The applicant should submit a completed Screening and Diagnostic Worksheet which is used to estimate the amount of funding needed to reimburse providers for allowable clinical services provided to eligible women served in your program. Further information about the Screening and Diagnostic Worksheet is provided in the NBCCEDP Policies and Procedures Manual, Section IV, pages 21–25. An electronic version of the Screening and Diagnostic Worksheet, an EXCEL spreadsheet, may be obtained through the program technical assistance contact listed in

Section L, Where To Obtain Additional Information.

d. To request Federal, 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).

H. Submission and Deadline

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm

On or before June 27, 2001 submit the application to the Grants Management Specialist identified in the ''Where To Obtain Additional Information'' section of this announcement.

I. Evaluation Criteria (100 Points)

Applications will be evaluated individually against the criteria below which reflect an emphasis on disease burden and program quality. Funding for Tribes and Territories will be competitive based on review by a panel of independent reviewers. All applicants representing States will be funded. State applications will undergo technical acceptability reviews by independent reviewers.

1. Background and Need (20 Points)

The extent and clarity with which the applicant describes the disease burden, size of potentially eligible population, unmet screening needs, size, selection and characteristics of the priority populations and extent to which the applicant has identified barriers to care that can be addressed through program activities.

2. 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. Prior performance reflected by the NBCCEDP program progress indicators or, for applicants not currently receiving NBCCEDP funds, their success as measured by relevant past experiences in conducting a similar program(s).

b. Letters of commitment from key partners, participants, and community leaders that detail their commitment to and participation in the proposed program. If the applicant is a Tribe, the inclusion of a tribal resolution(s) or letter of support from the Board of Directors is required.

c. Other accomplishments that reflect the capability of the applicant to implement a breast and cervical cancer screening program.

3. Work Plan (60 Points)

The degree of comprehensiveness and quality of the work plan represented by the goals, measures of success related to goals, objectives and activities to attain the objectives for each of the NBCCEDP program components and a time table for program implementation. The degree of comprehensiveness in addressing the minimum core expectations for each NBCCEDP program component within the work plan as detailed in the descriptions included as Attachment 1. The extent to which realistic screening projections are provided based on the applicant's past screening history (if applicable) and detailed separately for Pap tests and mammograms by the number of women to be screened for the 2001–2002 program year by age, race, ethnicity, and other priority populations identified by the applicant in the Background and Need section. In addition, the extent to which realistic screening projections are provided for Pap tests among rarely and never screened women.

4. Organizational Structure (10 Points)

The appropriateness of the applicant's organizational structure; documentation of the applicant's available resources for the payment or reimbursement of breast and cervical cancer screening, including the Medicaid program; the proposed schedule of fees consistent with Medicare reimbursement rates, if applicable; the assurance that funds will be used in a cost effective manner; and the description of linkages between the proposed program and the State Cancer Registry, if applicable.

5. Source Data for Matching Requirement (Not Weighted)

The extent to which the applicant provides clear evidence of maintenance of effort, sources of match, and a means to document actual match received.

6. Budget With Justification (Not Weighted)

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

7. Human Subjects (Not Weighted)

The extent to which the application adequately addresses the requirement of 45 CFR Part 46 for the protection of human subjects. An application will be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

J. Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Semiannual progress reports, to be submitted no later than 90 days after each semiannual reporting period. All manuscripts published as a result of the work supported in part or whole by the cooperative agreement must be submitted with the progress reports.

2. Financial status report (FSR), no more than 90 days after the end of each budget period.

3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For descriptions of each, see the Appendix.

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 2010
AR–12 Lobbying Restrictions

K. 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.

L. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Should you have questions after reviewing the contents of all the

documents, business management technical assistance may be obtained from: Glynnis Taylor, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement 01038.

Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: (770) 488–2752, Email address: gld1@cdc.gov.

For program technical assistance, contact: Amy DeGroff, 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 number: (770) 488–4248, Email address: asd1@cdc.gov.

Dated: May 22, 2001.

Henry S. Cassell III,

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

[FR Doc. 01–13498 Filed 5–29–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on June 4, 2001, 10:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD.

Contact: Les Weinstein, Center for Devices and Radiological Health (HFZ–5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–6220, ext. 119, FAX 301–827–2565, lsw@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote regarding a scientific dispute between the agency and Lifecore Biomedical, Inc., related to the approvability of a premarket approval application for Intergel, an adhesion prevention solution. Background information and questions for the committee will be available to the public on June 1, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 31, 2001. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the dispute before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 31, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the June 4, 2001, Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–13639 Filed 5–25–01; 3:08 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Leukemia and Other Hematological Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Leukemia and Other Hematological Diseases Among Cleanup Workers in Ukraine Following the Chornobyl Accident. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* A case-control study will be conducted to investigate the risk of radiation-induced leukemia and other hematological diseases among Chernobyl cleanup workers in Ukraine. Cases and controls (or proxies) will be interviewed to provide details of their work during the Chornobyl clean-up operation. The interview responses combined with environmental measurements will permit individual bone marrow dose estimates to be calculated for each case and control. Dose estimates will be used to calculate the risk of leukemia and other hematological diseases associated with low-dose and low dose-rate radiation exposure. This information, which is essential for radiation protection, is currently not available and standards presently are based on information available only by extrapolation from high-dose, high dose-rate data on A-bomb survivors in Japan. *Frequency of Response:* One time only. *Affected Public:* Ukrainian Chornobyl clean-up workers. *Type of respondents:* Cases, controls, and proxies for deceased subject. *Estimated Number of Respondents:* 700. *Estimated Number of Responses per Respondent:* Variable, about 50. *Average Burden Hours Per Response:* 0.75 hour. *Estimated Total Annual Burden Hours Requested:* 400 hours (interviews to be conducted over 18-month period). There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.