NBCCEDP Program Manual: NBCCEDP Policies and Procedures Chapter

I. INTRODUCTION TO THE CHAPTER

The NBCCEDP is grounded in Public Law, regulated by the Federal Government, and administered by the Centers for Disease Control and Prevention (CDC). Therefore, it has several layers of regulations with which grantees must comply. This chapter distinguishes

- requirements based in law,
- requirements based on regulations of the Federal Government, and
- those policies established by the Division of Cancer Prevention and Control (DCPC) at CDC.

There are two significant amendments to Public Law 101-354:

- Public Law 103-183 –the Preventive Health Amendments of 1993-was enacted December 14, 1993. It specifically allowed NBCCEDP funds to be awarded to tribes and tribal organizations.

- Public Law 105-340 -the Women's Health Research and Prevention Amendments of 1998 was enacted on October 31, 1998. It specified that appropriate follow-up services included support services such as case management.

This law, and its amendments, specifies the necessary activities of any NBCCEDP grantee. These activities include

- Screening women for breast and cervical cancer, with priority to low-income women;
- Providing appropriate follow-up services, support services such as case management, and referrals for medical treatment;
- Developing and disseminating public information and education programs;
- Improving the education, training, and skills of health professionals;
- Monitoring the quality and interpretation of screening procedures; and
- Evaluating the above activities.

Public Law 101-354 specifies clinical breast exams (CBE), pelvic exams, Pap tests, and mammograms as approved screening tests, and requires that if a superior procedure becomes available and is recommended for use, the program will provide reimbursement for this procedure.

Public Law 101-354 and its amendments outline several unique requirements for the NBCCEDP with which programs must comply. Regulations described in this chapter that are derived from law are labeled with "L" prefixes. Those that come from Federal regulations bear an "F" prefix. Policies developed by CDC are labeled with "P" prefixes. These distinctions clarify the basis of various regulations and policies for users of this manual. The full text of Public Law 101-354 (and its amendments), the Breast and Cervical Cancer Mortality Prevention Act of 1990, which established the NBCCEDP can be found in Attachment A.

II. POLICIES BASED ON LAW

The most frequently referenced requirements are described below and are identified by the prefix "L," to highlight their basis in law rather than CDC policy.

L.1: CONTRACTS AND CONSULTANTS

Programs are allowed to contract with non-profit and for-profit entities. If a non-profit entity and a for-profit entity compete for a contract and they are determined to be equally qualified, the program may give priority to the non-profit entity.

L.2: MATCHING FUNDS

Programs are required to match $1 of nonfederal resources for each $3 of Federal funds that they receive. Programs must identify, secure, ensure, and budget the resources and allowances of non-Federal contributions for the program. Official notification of the required amount of matching funds is provided to programs in the Notice of Grant Award (NGA) issued by the Procurement and Grants Office (PGO). The basis for determining this match is the total amount of Federal monies (financial assistance) awarded to the program. For further guidance regarding match, please refer to Attachment B.

L.3: MAINTENANCE OF EFFORT

Matching funds must be in excess of the amount that the program was contributing prior to its initial award of Federal funds. In determining the amount of non-Federal contributions to credit toward the matching funds requirement, the program can only use funds over and above the average annual amount the program had contributed toward breast and cervical cancer programs and activities in the 2 years before the first fiscal year of Federal funding for this program.

L.4: MEDICAID AS IT RELATES TO MAINTENANCE OF EFFORT OR MATCH

Non-Federal Medicaid amounts are allowable as sources of match. However, the State Medicaid contribution is subject to the maintenance-of-effort requirement, must be program related, and cannot be used for any other program.

L.5: MEDICARE REIMBURSEMENTS FOR SCREENING AND DIAGNOSTIC SERVICES

The amount paid by a program to an entity for screening and follow-up services may not exceed the amount that would be paid under part B of Title XVIII of the Social Security Act (maximum Medicare rates in the State).

For each of the screening and diagnostic services paid for by NBCCEDP, the program may choose to reimburse providers at either a single rate [based upon the Medicare rates approved by the Centers for Medicare and Medicaid Services (CMS) for that state], or using multiple rates, such as a single urban and a single rural rate or the various regional Medicare rates approved by CMS.

L.6: PAYOR OF LAST RESORT

NBCCEDP funds cannot be used to pay for any service for which payment has been made or can be made by a State compensation program, under an insurance policy, under a Federal or State health benefits program, or by an entity that provides health services on a prepaid basis. This use of NBCCEDP funds only after all other sources have been exhausted means that the NBCCEDP is the "payor of last resort."

The exception to this rule is clinics or offices which are administered by the Indian Health Service (IHS) or individual American Indian tribes. IHS is the payor of last resort for persons who have an alternate resource (42 CFR 136.61[2002]); the NBCCEDP has historically been considered such an alternative resource. Attachment C provides greater detail about the payor of last resort as applied to IHS and tribally operated clinics.

L.7: 60 /40 PERCENT DISTRIBUTION REQUIREMENT

Sixty-Percent Distribution: At least 60% of program funds must be used for direct clinical services. Costs allowable in the 60% category are allocated for: screening, diagnostic workup, referral for treatment, and essential support services (e.g., case management).

Forty-Percent Distribution: No more than 40% of program funds may be allocated to other required program functions, such as

- Management activities;
- Development and dissemination of public information and education (recruitment and outreach);
- Improvement of the education, training, and skills of health professionals (professional development)
- Establishment of mechanisms through which programs can monitor the quality of screening procedures and their interpretation (data management, quality assurance, and quality improvement);
- Development and maintenance of partnerships; and
- Surveillance and evaluation activities

The basis for calculating the 60/40 distribution is the total amount of Federal monies awarded to the program. It does not apply to the non-Federal matching funds. Further guidance regarding 60/40 distribution decisions can be found in Attachment D.

L.8: TEN-PERCENT ADMINISTRATIVE COSTS

No more than 10% of the Federal monies may be used for administrative expenses. The total dollar amount of Federal monies awarded to the program is the figure that should be used as the basis for determining the 10% administrative costs. The 10% administrative costs will be considered part of the 40% budget distribution to support infrastructure activities. The 10% limitation on administrative costs is *in lieu of indirect costs*. Each program may define the basis for its administrative costs. However, administrative expenses (i.e., indirect costs) associated with all contracts are considered part of the limitation placed on overall total administrative costs under the cooperative agreement award.

L.9: RESTRICTIONS ON USE OF GRANT

Other legal requirements of programs include stipulations that

- NBCCEDP funds may not be used to provide inpatient hospital services for any individual.
- Grantees must agree to give priority to low-income women in provision of program services.
- Imposition of fees for services must be limited.
- Program services must be available to women throughout the state, tribe, or territory.
- Program activities must be coordinated with other Federal, State, tribal, and local programs operating in the jurisdiction.
- Grantees must establish fiscal control and fund accounting procedures which are subject to audit.

Further details about these restrictions and requirements are provided in the full text of the law in Attachment A.

III. POLICIES BASED ON FEDERAL REGULATIONS

The following regulations apply to all Federal grants including CDC grants. They are not specific to the NBCCEDP. These regulations are prefaced with the letter "F," to reflect their basis in Federal policy.

F.1: NOTICE OF GRANT AWARD

In addition to the legislative requirements detailed above, grantee activities are governed by the provisions of its NGA. Programs are subject to any terms and conditions noted in the "remarks" section of the NGA, as well as the Public Health Service (PHS) grants policy statements that are in effect as of the beginning of the budget period. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system. A sample NGA with explanatory text is provided in Attachment E. More information on grants is available at http://www.cdc.gov/about/funding.htm .

F.2: COMPETITIVE APPLICATION OR INTERIM PROGRESS REPORT (IPR)

All programs must submit an annual request for funding for CDC review and approval. If it is a competitive year (the first year of a new program announcement) a competitive application must be submitted. If it is a non-competitive, continuation year, an IPR must be submitted. Both types of applications should include all information and data specified in the program announcement and its amendments. The competitive application or IPR for the NBCCEDP also must outline proposed reimbursement rates.

If applicable, the application should also include the information requested on the "Clinical Cost Worksheet," (Attachment F) which is used by the grantee to estimate the number of women to be served and the screening and diagnostic services to be provided during that budget period.

The date for the receipt of these applications will be established by the CDC's PGO.

F.3: FINANCIAL STATUS REPORT (FSR)

An FSR is due to the CDC's PGO ninety days after the end of each budget period. However, adjustments may be made up to 15 months after the end of the budget period. An FSR is the mechanism by which unobligated financial assistance funds are officially reported to CDC. Programs should also submit documentation of their current year's "estimated" unobligated dollars on their 424-A or via letter prior to the end of the project or approved no-cost or cost extension period. Further information is available at the PGO Web site (http://www.cdc.gov/about/funding.htm).

F.4: PRIOR APPROVAL

Recipients are allowed a certain degree of latitude in making postaward programmatic changes and budget revisions. The grantee is permitted to rebudget within and between budget categories in the approved direct cost budget of the project to meet unanticipated requirements or to accomplish certain programmatic changes. Nevertheless, Federal grants require that certain program changes receive prior approval from PGO. Failure to obtain prior approval, when required, may result in disallowance of costs. Examples of these prior approval items include

- a change in principal investigator or key personnel;
- spending funds that have been restricted;
- subcontracting a substantial amount of work;
- spending unobligated funds;
- continuing operations through cost or no-cost extensions;
- establishing or changing contracts or consulting agreements; or
- making significant budget changes (i.e., those of $250,000 or more or exceeding 25% of the award, whichever is less).

Attachment E contains a sample NGA with explanatory notes.

F.5: CONTRACTOR AND CONSULTANT APPROVAL PROCESS

To obtain approval of a contractor or consultant, a program is required to submit the elements below to PGO.

Required Elements: Contractor

- Name of Contractor- This element identifies the name of the proposed contractor.
- Method of Selection- This element indicates whether the contract is sole source or competitive bid. The program should describe the qualifications of the contractor and identify whether the contractor is a private, for-profit organization.
- Period of Performance- This element specifies the beginning and ending dates of the contract. It also indicates whether this is a new or continuation contract.
- Scope of Work- This element is used by the program to describe, in outcome terms, the specific services/tasks to be performed by the contractor as related to the accomplishment of program objectives (e.g., screen 250 program-eligible women for breast and cervical cancer). Deliverables (e.g., development of a curriculum, design of a survey questionnaire)

should be clearly defined. For screening services where multiple providers have the same contract, only a single description of the required information is needed. The program does not need to send a copy of the actual or individual contracts to CDC.

- Method of Accountability- This element is used to describe how the progress and performance of the contractor will be monitored during and at the close of the contract period. The program should identify who will be responsible for supervising the contract. If a contractor has been used previously, the program should describe the contractor's previous performance
- Itemized Budget and Justification- This element is used by the program to provide an itemized budget with appropriate justification. Indirect costs paid under the contract must be itemized and included when the program calculates its overall administrative costs. These costs must not exceed 10% of the total award.

If the above information is unknown for any contractor at the time the application is submitted, funds may be restricted until the required information is submitted. The information may be submitted at a later date as a revision to the budget. The body of the budget request should include a summary of the proposed contractors and amounts for each.

Required Elements: Consultants

- Name of consultant- This element identifies the name of the consultant and describes his or her qualifications.
- Organizational affiliation- This element identifies the organizational affiliation of the consultant, if applicable.
- Nature of services to be rendered- The program uses this element to describe, in outcome terms, the consultation to be provided, including the specific tasks to be completed and specific deliverables. The program does not need to send a copy of the actual consultant agreement to CDC.
- Relevance of service to the project- This element is used to describe how the consultant services relate to the accomplishment of specific program objectives.
- Number of days of consultation- This element specifies the total number of days of consultation.
- Expected rate of compensation- This element specifies the rate of compensation for the consultant (e.g., rate per hour, rate per day). The program should include a budget showing other costs, such as travel, per diem, and supplies.
- Method of accountability- This element is used to describe how the progress and performance of the consultant will be monitored. The grantee should identify who is responsible for supervising the consultant agreement. In addition, for continuation consultants, the program should describe their previous performance.

If the above information is unknown for any consultant at the time the application is submitted, the information may be submitted at a later date as a revision to the budget. The body of the budget request should include a summary of the proposed consultants and amounts for each.

IV. CDC-BASED PROGRAM POLICIES

The following policies were developed by CDC's DCPC specifically for the NBCCEDP. They include the letters "PD" for program data management policies.

DATA MANAGEMENT POLICIES

PD.1: INCLUSION OF DATA IN THE MDES

Minimum Data Elements (MDEs) are a set of standardized data elements used to collect demographic and clinical information on women screened with NBCCEDP funds. The MDEs should include screening and/or diagnostic data for eligible women in the following scenarios

- Services solely paid for by NBCCEDP funds
- Services paid for in part by NBCCEDP funds and any other funding source (e.g., State, private or other Federal funds) with the ability to distinguish the funds contributed by the NBCCEDP

Screening and diagnostic data collected on women reported in the MDEs must meet all data quality standards set by the CDC. Programs should not submit data on women for whom clinical services are covered solely by State, private or other Federal funds; this includes women for whom clinical services are used as a source of matching funds. Programs can refer to Attachments E and G, (Data Management Orientation Web Conference), as well as the Data Management chapter of this manual, to determine what data to report in the MDEs.

PD.2: DATA SHARING

As part of the Institutional Review Board (IRB) agreement for collection and analysis of data elements from the NBCCEDP, CDC maintains a data sharing policy regarding requests for MDE data for research use by CDC or external investigators. Data requests must include a research proposal which is subject to requirements of confidentiality, human subjects protection, and clearance procedures. Proposals are reviewed and approved through the MDE Committee, a multidisciplinary workgroup of CDC's DCPC. The policy calls for removal of personal identifiers and geographic indicators to provide 'national level' data. Other than program-specific data presented on CDC's public Web site, which is provided so residents can view statistics for their state, CDC does not release program-specific data for use outside of CDC without notifying the program. This policy does not apply to data inquiries from the Office of Management and Budget (OMB), Congress or similar entities, or to aggregate data shared with the general public to describe results of the program. CDC's legal counsel determined that MDE data are subject to the Freedom of Information Act.

CLINICAL MANAGEMENT AND REIMBURSEMENT POLICIES FOR BREAST CANCER SCREENING

The following policies were developed by CDC's DCPC specifically for the NBCCEDP. They include the prefix "PC" for program clinical policies.

The broader eligible population for breast and cervical cancer screening in the NBCCEDP includes low-income (up to 250% of the Federal poverty level), uninsured, and underinsured women (whose health insurance does not fully cover screening services). Once a woman is enrolled in the NBCCEDP, the grantee is responsible for the provision of rescreening mammograms and cervical cancer screening at appropriate, recommended screening intervals.

The NBCCEDP provides mammograms to program-eligible women as recommended by the United States Preventive Services Task Force (USPSTF) (http://www.ahcpr.gov/clinic/3rduspstf/breastcancer/), that is, mammography is provided to women 40 and older every 1-2 years. The *priority* population for NBCCEDP mammography services is women between the ages of 50 and 64 who are low-income (up to 250% of federal poverty level), who have not been screened in the past year, and who have no other source of health-care reimbursement, such as insurance. Recruitment efforts should be concentrated on this population.

PC.1: MAMMOGRAPHY FOR WOMEN 50 YEARS OF AGE OR OLDER

A minimum of ***75%*** percent of all NBCCEDP reimbursed mammograms should be provided to program-eligible women who are 50 years of age and older and not enrolled in Medicare Part B**.**

- If a woman is eligible to receive Medicare benefits, but is not enrolled, she should be encouraged to enroll. Women enrolled in Medicare Part B are not eligible for the NBCCEDP clinical services.

- Women aged 50 years or older who are not eligible to receive Medicare Part A and B are eligible to receive mammograms through the NBCCEDP. Mammograms provided to these women will be counted in the 75%.

- Medicare-eligible women with low incomes (250% poverty or less) who cannot pay the premium to enroll in Medicare-Part B are eligible to receive mammograms through the NBCCEDP. Mammograms provided to these women will be counted in the 75%.

PC.2: MAMMOGRAPHY FOR WOMEN UNDER 50 YEARS OF AGE

Mammograms provided to program-eligible women less than 50 years of age should not exceed ***25%*** of all mammograms provided by the NBCCEDP.

- *Asymptomatic women ages 40-49* – This population may be screened in the program, subject to the restriction noted above.
- *Symptomatic women under the age of 40* — NBCCEDP funds can be used to reimburse CBEs for women under the age of 40. If the findings of the CBE are considered to be abnormal, including a discrete mass, nipple discharge, and skin or nipple changes, a woman can be provided a diagnostic mammogram by the program and/or referred for a surgical consultation. *Asymptomatic women under the age of 40 at increased risk for breast cancer* —NBCCEDP funds cannot be used to screen asymptomatic women under the age of 40, even if they are considered to be at high risk (e.g., women who have a personal history of breast cancer or first degree relative with pre-menopausal breast cancer) for breast cancer.

PC.3: SCREENING MALES

Men are not eligible to receive NBCCEDP screening and/or diagnostic services.

PC.4: DIGITAL MAMMOGRAPHY

Reimbursement for digital mammography is capped at the conventional film mammography reimbursement rate.

PC.5: COMPUTER-AIDED DETECTION (CAD)

Reimbursement of CAD is not permitted.

PC.6: MANAGING WOMEN WITH ABNORMAL BREAST CANCER SCREENING RESULTS

The management of women whose mammogram and/or CBE yielded abnormal results relies on a body of scientific literature which is constantly growing and changing. Clinical management strategies also may vary by geographic region and by provider. Grantees are urged to develop their clinical policies in close consultation with their medical advisory board or consultants, and in consideration of standards established by organizations such as the National Comprehensive Cancer Network (http://www.nccn.org/) and the American College of Radiology (http://www.acr.org/).

CLINICAL MANAGEMENT AND REIMBURSEMENT POLICIES FOR CERVICAL CANCER SCREENING

The *priority* population for NBCCEDP cervical cancer screening services is women between the ages of 40 and 64 who have low-incomes (up to 250% of federal poverty level), who have never been screened or not been screened in the past five years, and who have no other source of health care reimbursement, such as insurance. Recruitment efforts should be concentrated on this population. The broader *eligible* population, which includes low-income (up to 250% of the Federal poverty level), uninsured, and underinsured women (whose health insurance does not fully cover screening services)., and women younger than 40 years of age, is described below.

PC.7: INCREASING SCREENING FOR NBCCEDP ELIGIBLE WOMEN NEVER OR RARELY SCREENED

Twenty-percent of all clients *newly* enrolled for cervical cancer screening should be women who have never been screened for cervical cancer or who have not had a Pap test in the past 5 years.

PC.8: CERVICAL CANCER SCREENING FOR WOMEN 18 - 64 YEARS OF AGE

NBCCEDP funds may be used to reimburse for Pap tests at appropriate, recommended intervals for women 18 to 64 years of age, have an intact cervix and are not enrolled in Medicare Part B. When a woman has had three consecutive, normal Pap tests documented within a 60-month period, the screening interval shall increase to once every three years. (In calculations of time period for the three normal screening tests using conventional technologies, the first test date should be considered month

0, the second test would occur around month 12, and the third around month 24. If a woman receives an abnormal screening test result, policies for follow-up of abnormal cervical cancer screening tests and reimbursement of diagnostic procedures should be followed.

PC.9: CERVICAL CANCER SCREENING FOR WOMEN OVER 64 YEARS OF AGE

If a woman is eligible to receive Medicare benefits, but is not enrolled, she should be encouraged to enroll. Women enrolled in Medicare Part B are not eligible for the NBCCEDP clinical services.

Women who are eligible for Medicare Part B but have low incomes (up to 250% Federal poverty level) and cannot pay the premium to enroll in Medicare Part B are eligible to receive services through the NBCCEDP.

PC.10: CERVICAL CANCER SCREENING FOLLOWING HYSTERECTOMY

NBCCEDP-funds CANNOT be used to pay for cervical cancer screening in women with total hysterectomies (i.e., those without a cervix), unless the hysterectomy was performed due to cervical neoplasia (precursors to cervical cancer) or invasive cervical cancer.

The presence of a cervix can be determined on physical examination. NBCCEDP-funds CAN be used to pay for an initial examination (i.e., pelvic examination) to determine if a woman has a cervix.

POLICY PC.11: POLICY ON LIQUID-BASED CYTOLOGY (LBC) TECHNOLOGIES FOR PRIMARY CERVICAL CANCER SCREENING

Programs may reimburse for liquid-based cervical cytology (such as ThinPrep® or SurePath®) for primary cervical cancer screening, up to the allowable Medicare rate. The screening interval when using liquid-based tests is once every 2 years if the result is normal. Programs must develop a means of ensuring that reimbursement for the liquid-based test is not provided more frequently than once every 2 years.

As with conventional Pap tests, when a woman has had three consecutive, normal cervical cancer screening tests documented within a 60-month period, the screening interval with LBC will increase to once every 3 years (In calculations of the time period for the three normal screening tests, the first test date should be considered month 0, the second test would occur around month 24, and the third around month 48). If a woman receives an abnormal screening test result, policies for follow-up of abnormal cervical cancer screening tests and reimbursement of diagnostic procedures should be followed.

The specific cervical cancer screening method must be indicated in the MDEs, so that the number of liquid-based tests can be distinguished from the number of conventional Pap tests performed. This will provide a means by which the test-specific diagnostic outcomes can be compared.

PC.12: USE OF AUTOMATED SCREENING TECHNOLOGIES FOR QUALITY ASSURANCE

NBCCEDP funds may not be used to reimburse automated technologies when they are used as a secondary assessment of Pap testing for quality assurance purposes. These quality assurance costs are built in to the pricing of tests and are paid by the cytopathology laboratories.

PC.13: MANAGING WOMEN WITH ABNORMAL CERVICAL CANCER SCREENING RESULTS

The management of women whose cervical cancer screening tests yield abnormal results relies on a body of scientific literature which is constantly growing and changing. Clinical management strategies may also vary by geographic region and by provider. Grantees are urged to develop their clinical policies in close consultation with their medical advisory board or consultants, and in consideration of standards established by organizations such as the American Society of Colposcopy and Cervical Pathology (http://www.asccp.org) and the American College of Obstetrics and Gynecology (http://www.acog.org/).

To arrive at a definitive diagnosis for a woman with an abnormal cervical cancer screening test, programs may use NBCCEDP funds may be used to reimburse for colposcopy, colposcopy-directed biopsy, endocervical curettage, and, in unusual cases, diagnostic excisional procedures (such as the loop electrode excision procedures and cold-knife excisions), as well as associated pathology. Grantees are asked to formulate methods by which the use of these procedures may be closely monitored so that they are used appropriately.

PC.14: REIMBURSEMENT OF HPV DNA TESTING

HPV DNA testing is a reimbursable procedure if it is used in follow-up of an ASC-US result from the screening examination, or for surveillance at 1 year following an LSIL Pap test without evidence of CIN on colposcopy-directed biopsy. It is not reimbursable as a screening test. Providers should specify the high-risk HPV DNA panel; reimbursement of screening for low-risk genotypes of HPV is not permitted.

POLICIES FOR ADEQUACY AND TIMELINESS OF FOLLOW-UP FOR WOMEN WITH ABNORMAL SCREENING RESULTS

Public Law 101-354 requires programs to take all appropriate measures to ensure the provision of necessary follow-up services required by women with abnormal screening results whose clinical services are paid for in whole or in part by NBCCEDP funds.

PC15: ADEQUACY OF FOLLOW-UP FOR WOMEN WITH ABNORMAL SCREENING RESULTS

A woman whose breast or cervical cancer screening was abnormal or suspicious must receive appropriate diagnostic procedures (as defined by the program's medical advisory board or consultants) to arrive at a final diagnosis.

Women with a diagnosis of breast or cervical cancer must be referred for appropriate treatment.

PC.16: TIMELINESS OF FOLLOW-UP FOR WOMEN WITH ABNORMAL SCREENING RESULTS

The interval between initial screening and diagnosis of abnormal breast and cervical cancer screenings should be 60 days or less.

The interval between diagnosis and initiation of treatment for breast cancer and invasive cervical cancer should be 60 days or less.

The interval between diagnosis and initiation of treatment for cervical intraepithelial neoplasia should be 90 days or less.

PC.17: CASE MANAGEMENT

All NBCCEDP-enrolled women with an abnormal screening result must be assessed for their need of case management services and provided with such services accordingly. Examples of screening results requiring a case management assessment are BIRADS 3, 4, 5 for mammograms; and LSIL and high-grade lesions or greater for Pap tests. If resources are limited, LSIL screening results may only warrant a brief case management needs assessment. Case management services conclude when a client initiates treatment, refuses treatment, or is no longer eligible for the NBCCEDP. When a woman concludes her cancer treatment, has been released by her treating physician to return to a schedule of routine screening, and continues to meet NBCCEDP eligibility requirements, she may return to the program and receive all its services.

Attachments

Attachment A: Public Law 101-354 and its Amendments

Attachment B: Matching Funds

Attachment C: Payor of Last Resort as Applied to IHS and Tribally Operated Clinics

Attachment D: Framework for Determining 60 / 40 Percent Distribution

Attachment E: Sample Notice of Grant Award

Attachment F: Sample Clinical Costs Worksheet

Attachment G: Data Management Orientation Web Conferences

Attachment A: Public Law 101-354 and its Amendments (P.L 103-183 and 105-340)

Title 42. The Public Health and Welfare
Chapter 6a. The Public Health Service
Preventive Health Measures with Respect to Breast and Cervical Cancers
42 U.S.C. § 300k

Note: Amendments to 42 USC § 300k are indicated in bold and italics, followed by a reference to the amending law in parentheses.

§ 300k. Establishment of program of grants to States

(a) In general. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs—

(1) to screen women for breast and cervical cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services ***and support services such as case management (Women's Health Research and Prevention Amendments of 1998, Public Law 105- 340);***

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;

(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.

(b) Grant and contract authority of States.

(1) In general. A state receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such subsection ***through grants to public and non profit private entities and through contracts with public and private entities (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).***

(2) CERTAIN APPLICATIONS- If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a State to receive an award of a grant or contract pursuant to paragraph (1), the State may give priority to the application submitted by the

nonprofit private entity in any case in which the State determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).

(3) Payments for screenings. The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of Title XVIII of the Social Security Act [42 U.S.C. §§ 1395j et seq.] if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

(c) Special consideration for certain States. In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—

(1) has been approved through a process of peer review; and

(2) is made with respect to geographic areas in which there is—

(A) a substantial rate of mortality from breast or cervical cancer; or

(B) a substantial incidence of either of such cancers.

[(d)](c) Coordinating committee regarding year 2000 health objectives. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2000. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

§ 300l. Requirement of matching funds

(a) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) Determination of amount of non-Federal contribution.

(1) In general. Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) Maintenance of effort. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 [42 U.S.C. § 300k] for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

(3) Inclusion of relevant non-Federal contributions for Medicaid. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to Title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

§ 300l-1. Requirement regarding Medicaid

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] for a program in a State unless the State plan under title XIX of the Social Security Act [42 U.S.C. §§ 1396 et seq.] for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 1503(a)(2) [42 U.S.C. § 300m(a)(2)(A), (B)] as medical assistance provided under the plan.

§ 300m. Requirements with respect to type and quality of services

(a) Requirement of provision of all services by date certain. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)], including making available screening procedures for both breast and cervical cancers;

(2) subject to subsection (b), to ensure that—

(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a Pap test are conducted;

(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)] is provided; and

(4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.

(b) Use of improved screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use,

any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c) Quality assurance regarding screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section ***(''Breast and Cervical Cancer Amendments of 1993'', Public Law 103-183)***.

§ 300n. Additional required agreements

(a) Priority for low-income women. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

(b) Limitation on imposition of fees for services. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981 [42 U.S.C. § 9902(2)].

(c) Statewide provision of services.

(1) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that services and activities under the grant will be made available throughout the State, 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 [25 U.S.C. § 450b]).

(2) Waiver. The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a) [42 U.S.C. § 300k(a)].

(3) Grants to tribes and tribal organizations.

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 1501(a) [42 U.S.C. § 300k(a)]. This title applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such title applies

to a grant to a State under section 1501 [42 U.S.C. § 300k] (in relation to the jurisdiction of the State).

(B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under section 1501 [42 U.S.C. § 300k], the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2) ***(''Breast and Cervical Cancer Amendments of 1993'', Public Law 103- 183).***

(d) Relationship to items and services under other programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

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

(e) Coordination with other breast and cervical cancer programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.

(f) Limitation on administrative expenses. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(g) Restrictions on use of grant. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(h) Records and audits. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(I) Reports to Secretary. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

§ 300n-1. Description of intended uses of grant

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)];

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public and nonprofit private entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

§ 300n-2. Requirement of submission of application

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505 [42 U.S.C. § 300n-1], and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title [42 U.S.C. §§ 300k et seq.].

§ 300n-3. Technical assistance and provision of supplies and services in lieu of grant funds

(a) Technical assistance. The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501 [42 U.S.C. § 300k]. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) Provision of supplies and services in lieu of grant funds.

(1) In general. Upon the request of a State receiving a grant under section 1501 [42 U.S.C. § 300k], the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments. With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 [42 U.S.C. § 300k] to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

§ 300n-4. Evaluations and reports

(a) Evaluations. The Secretary shall, directly or through contracts with public private entities, provide for annual evaluations of programs carried out pursuant to section 1501 [42 U.S.C. § 300k]. Such evaluations shall include evaluations of the extent to which States carrying out such programs are in compliance with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504© [42 U.S.C. § 300n(c)].

(b) Report to Congress. The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a) [42 U.S.C. § 300n-5(a)], and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title [42 U.S.C. §§ 300k et seq.] as the Secretary determines to be appropriate, including recommendations regarding compliance by the States with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504© [42 U.S.C. § 300n(c)].

§ 300n-4a. Supplemental grants for additional preventive health services

(a) Demonstration projects. In the case of States receiving grants under section 1501 [42 U.S.C. § 300k], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

> (1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;
>
> (2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and
>
> (3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) Status as participant in program regarding breast and cervical cancer. The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501 [42 U.S.C. § 300k].

(c) Applicability of provisions of general program. This title [42 U.S.C. §§ 300k et seq.] applies to a grant under subsection (a) to the same extent and in the same manner as such title applies to a grant under section 1501[42 U.S.C. § 300k].

(d) Funding.

> (1) In general. Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated $ 3,000,000 for fiscal year 1994, and such sums as may be

necessary for each of the fiscal years 1995 ***through 2003 (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).***

(2) Limitation regarding funding with respect to breast and cervical cancer. The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 1510(a) [42 U.S.C. § 300n-5(a)] for the fiscal year is equal to or greater than $ 100,000,000.

§ 300n-5. Funding for general program

(a) Authorization of appropriations. For the purpose of carrying out this title [42 U.S.C. §§ 300k et seq.], there are authorized to be appropriated $ 50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $ 150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 ***through 2003 (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).***

(b) Set-aside for technical assistance and provision of supplies and services. Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507 [42 U.S.C. § 300n-3].

Attachment B: Matching Funds

Generally, if Federal monies are allowed for a service or activity, then non-Federal contributions for the same service or activity may be allowed as a source of matching funds. Non-Federal contributions may be made directly or through donations from public or private entities. Contributions from private for-profit entities are allowable sources of matching funds. The types of contributions may be cash or in-kind, including equipment, services, or clinical services. Treatment, indirect, or overhead costs are disallowed as a source of matching funds. In addition, programs are restricted by maintenance of effort and Medicaid provisions in the law for determining the amount of their non-Federal contributions. Tribal organizations contracting under the authority of Title I and compacting under the authority of Title III are permitted to use funds received under the Indian Self-Determination Act as matching funds.

Examples of Non-Federal Cash Resources and Amounts (details must be provided on each source):

- State, tribal, territorial, and local program appropriations for screening, tracking, and follow-up;
- State Medicaid payments for breast and cervical cancer screening (above maintenance of effort);
- State tobacco tax revenue used to support program activities;
- Cash donations (please list each contributor and the dollar amount); and
- Community fund-raising (please list each event and the amount raised).

Examples of Non-Federal Non-Cash Resources and Amounts (an itemized breakdown must be provided for each source, describing the method used to determine its value):

- Donated vehicles and equipment (e.g., vans for transportation, laboratory equipment, computers);
- Donated services (e.g., screening tests, diagnostic tests, transportation, volunteer time, ACS, YWCA. If using the difference between the Medicare rate and the usual and customary provider charge, document how the usual and customary charge was determined. See Attachment 2 for additional guidance.) ;
- Donated supplies (e.g., education materials, promotional materials);
- Donated media time (e.g., television, radio, print); and
- Donated professional time (e.g., service on coalitions, advisory committees, and advertising/marketing consultation).

ATTACHMENT C: PAYOR OF LAST RESORT AS IT APPLIES TO IHS CLINICS AND TRIBALLY OPERATED CLINICS

This interpretation of the Code of Federal Regulations, Title 42, Section 136.61 (2002) was provided by Clayton F. Old Elk of the Indian Health Service (email communication, September 9, 2005):

The IHS provides health services to more than 1.8 million AI/AN through 155 IHS and tribally operated Service Units composed of over 600 direct health care delivery facilities, 49 hospitals, 231 health centers, 5 school health centers, and 309 health stations. Within this system Indian tribes deliver IHS funded services to their own communities with approximately 50 percent of the IHS budget in 13 hospitals, 172 health centers, 3 school health centers, and 260 health stations. The range of services includes traditional inpatient and ambulatory care. Because IHS programs are not fully funded, the contract health services (CHS) program relies on specific regulations relating to eligibility, notification, residency, and the IHS medical priority system. This system renders the CHS programs to authorize care at restricted levels and results in a rationed health care system that provides services based on the most relative medical need.

The IHS is designated as the payor of last resort meaning that all other available alternate resources including IHS facilities must first be used before payment is expected. The Code of Federal Regulations, Title 42, Section 136.61 (2002), states that the IHS is the payor of last resort for persons who have an alternate resource, notwithstanding any State or local law or regulation to the contrary. Accordingly, the IHS will not be responsible for or authorize payment for medical services to the extent that an alternate resource is available. Alternate resources are defined as health care resources other than those of the IHS, including but not limited to programs under Title XVIII and Title XIX of the Social Security Act (Medicare and Medicaid), State or local health care programs, and private insurance. The IHS will not pay for medical bills when any of the following situations exist: (1) the patient was eligible for alternate resources when the medical services were provided; (2) the patient would have been eligible for alternate resources if the person had applied for them; or (3) the patient would have been eligible for alternate resources under State or local law or regulation but for his eligibility for CHS or other health services from the IHS or an IHS-funded program. These mechanisms enhance the IHS to stretch the limited CHS dollars and help extend services throughout the year as well as operate within budget.

Attachment D

Framework for Determining 60% / 40% Distribution

Law (60%)	CDC Interpretations (60%)	CDC Interpretations (40%)	Law (40%)
Screening tests: Clinical Breast Exam Mammogram Pelvic Exam Pap Test **Follow-up and support services:** Client Case Management	Office visits Laboratory fees **Diagnostic services:** Diagnostic mammogram Fine-needle aspiration Ultrasound Cyst aspiration Breast biopsy Endocervical curettage Colposcopy Colposcopy with biopsy Surgical consultation Others as determined by medical advisory board or consultants Client Interpretation Services Client Transportation Client intake Client counseling One-to-One recruitment **By Exception Only* (requires program consultant's approval):** Clinical supplies and equipment Incentives	Management and planning Partnership development Data management /entry/analysis Promotional materials Administrative costs Billing*	Public education Professional development Quality assurance Evaluation Surveillance

*Items marked with * have an effective date of July 1, 2007.

POINTS TO CONSIDER IN DETERMINING THE CLASSIFICATION OF A PROGRAM COST AS PART OF THE 60-PERCENT DISTRIBUTION CATEGORY

As specified by law, 60% of program funds are to be devoted to providing direct clinical services, particularly screening, for eligible women. The law specifies that funds are not to be used to pay for treatment, but is silent on the topic of diagnostic procedures. CDC's DCPC has determined that diagnostic services are integral to the NBCCEDP, and fees for these services should be considered part of the 60% category.

Other program components, such as management and planning, public education, professional development, quality assurance, evaluation, surveillance and administrative costs, while necessary to the functioning of an individual program, must not exceed 40% of the overall program budget. Regardless of the inherent value of any support services, grantees must ensure their program – and therefore, their budgets – remain focused on screening.

Effective with the start of the next program grant cycle (June 30, 2007), costs associated with tracking and data entry will no longer be considered allowable as 60% activities. Incentives will also, in general, no longer be considered allowable 60% costs. Programs can request that client incentives be considered as 60% when the incentives are clearly part of the screening (and not marketing or outreach) process. The CDC program consultant must approve the inclusion of these incentives in the 60% category.

The following questions may help grantees clarify whether a particular expense falls into the 60% or 40% category.

What is the intent of this activity?

Example: Are you contacting an individual woman to address barriers to screening and follow-up (60%), or to resolve billing issues (40%)?

Example: Are you using a translator to help women communicate with their health provider at a screening site (60%), or are you using a translator to develop a new brochure (40%)? The costs to develop and duplicate an educational brochure even if used for one-to-one recruitment, are not considered in your 60% budget category.

What documentation is available to support the purpose of this activity?

Example: Do you have staff timekeeping records or activity reports that can verify the amount of time a staff member spent calling an individual woman for scheduling a follow-up appointment (60%) rather than to gather data / information missing from her enrollment form (40%)?

What are program funds actually paying for?

Example: A program is designed to train community volunteers to recruit individual women for screening. The final outcome is one-to-one recruitment, but the program funds are actually paying to train volunteers (40%), not to conduct one-to-one recruitment (60%).

Exceptions: Clinical supplies and equipment

Clinical supplies and equipment, in general, are considered to be built into the reimbursement structure in a fee-for-service reimbursement system; they should not be reimbursed separately. Clinical supplies CAN be justified in situations where the grantee provides the direct clinical services and pays for the professional fees in an hourly fashion. Clinical supplies can also be requested as a one-time expense with appropriate justification for the need.

Equipment can be justified in rare instances where it is clear that such purchases are absolutely necessary in order for screening services to be available for program eligible women. In such cases, allowances for discounting future fee-for-service charges should be made.

Exceptions: Incentives

Generally, "giveaway items" are not allowable in the 60% category, because they are used for marketing purposes. Promotional materials (e.g, tote bags, nail files) are intended to attract *potential clients.* They are marketing tools used to interest women in enrolling in the program. As such, these expenditures fall in the 40% category. Occasionally rewards/gifts (such as $15 gift cards) are given to *program clients* upon completion of a screening exam, particularly in cultural settings in which gifting is expected. These incentives would be considered tools for screening; the program consultant could approve their inclusion in the 60% category.

ATTACHMENT E: SAMPLE NOTICE OF GRANT AWARD

2 05/13/2004 | 93.938

SUPERSEDES AWARD NOTICE DATED
EXCEPT THAT ANY ADDITIONS OR RESTRICTIONS
PREVIOUSLY IMPOSED REMAIN IN EFFECT UNLESS SPECIFICALLY RESCINDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION

NOTICE OF COOPERATIVE AGREEMENT

AUTHORIZATION (LEGISLATION/REGULATION)
301A311BANDC317K242U.S.C.241A,243B/C247

3. GRANT NO.	5. ADMINISTRATIVE CODES
U87/CCU323766-01	CCU87
4. PROJECT PERIOD FROM 05/15/2004	THROUGH 05/14/2006
5. BUDGET PERIOD FROM 05/15/2004	THROUGH 05/14/2005

1. TITLE OF PROJECT (OR PROGRAM)
PROGRAMS TO IMPROVE THE HEALTH, EDUCATION,AND WELL-BEING OF YOUNG PEOPLE. 6

9. GRANTEE NAME AND ADDRESS
NEA HEALTH INFORMATION NETWORK
NEA HEALTH INFORMATION NETWORK
1201 16TH STREET N.W.
WASHINGTON, DC 20036

10. DIRECTOR OF PROJECT (PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR)
JERALD NEWBERRY, EXECUTIVE DIRECTOR
NEA HEALTH INFORMATION NETWORK
1201 16TH STREET N.W.
WASHINGTON, DC 20036 7

11. APPROVED BUDGET (EXCLUDES PHS DIRECT ASSISTANCE) 8

PHS GRANT FUNDS ONLY
I TOTAL PROJECT COSTS INCLUDING GRANT FUNDS AND ALL OTHER FINANCIAL PARTICIPATION
(PLACE NUMERAL ON LINE) I

a. SALARIES AND WAGES	108,818
b. FRINGE BENEFITS	34,822
TOTAL PERSONNEL COSTS	143,640
c. CONSULTANT COSTS	37,560
d. EQUIPMENT	0
e. SUPPLIES	600
f. TRAVEL	19,080
g. PATIENT CARE-INPATIENT	0
h. PATIENT CARE-OUTPATIENT	0
i. ALTERATIONS AND RENOVATIONS	0
j. OTHER	13,896
k. CONSORTIUM/CONTRACTUAL COSTS	15,120
l. TRAINEE RELATED EXPENSES	0
m. TRAINEE STIPENDS	0
n. TRAINEE TUITION AND FEES	0
o. TRAINEE TRAVEL	0
p. TOTAL DIRECT COSTS	229,896
q. INDIRECT COSTS (21.00 % OF S&W/TADC)	45,103
r. TOTAL APPROVED BUDGET	274,999
s. SBIR FEE	0
t. FEDERAL SHARE	274,999
u. NON-FEDERAL SHARE	0

12. AWARD COMPUTATION FOR FINANCIAL ASSISTANCE

a. AMOUNT OF PHS FINANCIAL ASSISTANCE (FROM 11.U)	274,999
b. LESS UNOBLIGATED BALANCE FROM PRIOR BUDGET PERIODS	0
c. LESS CUMULATIVE PRIOR AWARD(S) THIS BUDGET PERIOD	0
d. AMOUNT OF FINANCIAL ASSIST. THIS ACTION	274,999

9

13. RECOMMENDED FUTURE SUPPORT (SUBJECT TO THE AVAILABILITY OF FUNDS AND SATISFACTORY PROGRESS OF THE PROJECT)

BUDGET YEAR	TOTAL DIRECT COSTS	BUDGET YEAR	TOTAL DIRECT COSTS
a. 2	274,999	d. 0	0
b. 0	0	e. 0	0
c. 0	0	f. 0	0

14. APPROVED DIRECT ASSISTANCE BUDGET (IN LIEU OF CASH)

a. AMOUNT OF PHS DIRECT ASSISTANCE	0
b. LESS UNOBLIGATED BALANCE FROM PRIOR BUDGET PERIODS	0
c. LESS CUMULATIVE PRIOR AWARDS FROM THIS BUDGET PERIOD	0
d. AMOUNT OF DIRECT ASSISTANCE THIS ACTION	0

15. PROGRAM INCOME SUBJECT TO 45 CFR PART 74,SUBPART F,OR 45 CFR 92.25, SHALL BE USED IN ACCORDANCE WITH ONE OF THE FOLLOWING ALTERNATIVES: (SELECT ONE AND PUT LETTER IN BOX.)

A. DEDUCTION
B. ADDITIONAL COSTS
C. MATCHING — B 10
D. OTHER RESEARCH(ADD/DEDUCT OPTION)
E. OTHER (SEE REMARKS)

THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY, THE PHS ON THE ABOVE TITLED PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING: A.THE GRANT PROGRAM LEGISLATION CITED ABOVE. B.THE GRANT PROGRAM REGULATION CITED ABOVE. C.THIS AWARD NOTICE INCLUDING TERMS AND CONDITIONS,IF ANY,NOTED BELOW UNDER REMARKS. D.PHS GRANTS POLICY STATEMENT INCLUDING ADDENDA IN EFFECT AS OF THE BEGINNING DATE OF THE BUDGET PERIOD. E.45 CFR PART 74 OR 45 CFR PART 92 AS APPLICABLE. IN THE EVENT THERE ARE CONFLICTING OR OTHERWISE INCONSISTENT POLICIES APPLICABLE TO THE GRANT, THE ABOVE ORDER OF PRECEDENCE SHALL PREVAIL. ACCEPTANCE OF THE GRANT TERMS AND CONDITIONS IS ACKNOWLEDGED BY THE GRANTEE WHEN FUNDS ARE DRAWN OR OTHERWISE OBTAINED FROM THE GRANT PAYMENT SYSTEM. 11

REMARKS (OTHER TERMS AND CONDITIONS ATTACHED - ___ YES X NO)

SPONSOR: NATL. CTR. FOR CHRONIC DISEASE PREV. & HEALTH PROMOTION
*IDC RATE BASE: SEE ATTACHED

1 PHS GRANTS MANAGEMENT OFFICER: (SIGNATURE) Carlos Smiley (NAME-TYPED/PRINT) CARLOS SMILEY (TITLE) GRANTS MANAGEMENT OFFICER

17. OBJ. CLASS. 41.51 | 18. CRS.EIN: 1-581898631-A1 | 19. LIST NO.: CO-120-L04

FY-CAN	DOCUMENT NO.	ADMINISTRATIVE CODE	AMT.ACTION FIN.ASST	AMT.ACTION DIR.ASST
a. 04-11282 04-9213202	b. CCU323766	c. CCU87	d. 274,999	e. 0
1.A	b.	c.	d.	e.
2.A	b.	c.	d.	e.

HHS-5152-1 (REV.7/92) (MODIFIED CDC VERSION 10/92)

GUIDE TO KEY FEATURES OF NGA

1. **Signature**-A signature is required; if the NGA is not signed by a PHS Grants Management Officer, it is not a legal document.

2. **Date on previous award**- This NGA replaces that award.

3. **Grant number**- This number should be referenced in any communication with PGO, and with the submission of all documentation.

4. **Project period-** This number refers to the duration of the overall program (1 to 5 years).

5. **Budget period**- This is only 1 year; specific to current year's budget only.

6. **Title of the project**- This is the title as supplied by the grantee and recorded by PGO.

7. **Name and title of the program director or principal investigator**- CDC approval is required before the program can make changes in either position.

8. **Approved budget-** This section reflects results from budget discussions and negotiations. This amount is monitored to assure that funds are being spent in accordance with the plan.

9. **Award computation for financial assistance**- New money and carry-overs are reflected here.

10. **Program Income**- Deductions, additional costs, and matching funds are reflected here.

11. **The fine print (regulatory guidance)**- Programs should read this section carefully!

ATTACHMENT F: CLINICAL COST WORKSHEET

2006-2007 QUESTIONNAIRE	Andalusia	AA

CLINICAL & CASE MANAGEMENT SERVICES	Your Forecast:
How many new screening mammograms?	2,100
How many re-screening mammograms?	1,400
How many screening CBEs?	6,000
How many Pap tests?	3,500
How many HPV tests?	30
How many anesthesia units/charges?	65
How many facility fees?	0
How many loop electrode excision procedures?	6
How many diagnostic conization procedures?	4
How many endocervical curretage procedures?	2
How many office visits - new patient?	2,000
How many office visits - established patient?	2,400
How many office visits - problem focused?	1,000
How many women referred in for breast diagnostics?	100
How many women referred in for cervical diagnostics?	250

CLINICAL PROCEDURES:	CPT Code(s):	Reimbursement Rate:
Screening Mammogram	76092	$78.75
Pap Test	88164	$14.76
HPV Test	87621	$49.04
Anesthesia	00400	$78.00
Facility Fees	N/A	$0.00
Loop Electrode Excision Procedure (LEEP)	57522	$233.75
Diagnostic Conization	57461	$330.75
Endocervical Curretage	57505	$91.78
Office Visit: New Patient	99202	$61.54
Office Visit: Established Patient	99213	$49.79
Office Visit: Problem Focused	99241	$47.25
Diagnostic Mammogram	76091	$89.86
Ultrasound	76645	$64.39
FNA	10022, 88172, 88173, 76942	$446.57
Non-Excisional Biopsy	19103, 19295, 76098, 76090	$1,065.20
Excisional Biopsy	19125, 19126, 19290, 19291, 76096	$848.97
Surgical consult	99243	$115.48
Breast Pathology	88305	$95.74
Colpo-directed Biopsy	57454	$149.73
Colposcopy alone	57452	$103.99
Cervical Pathology	88305	$95.74

Case Management Cost Unit:	Number of Units:	Reimbursement Rate:
FTE	1	$52,675.00

2006-2007 CLINICAL COSTS WORKSHEET: Andalusia

INPUT FROM QUESTIONNAIRE

SCREENING		CPT CODE	COST PER
Mammograms: New Screenings	2,100	76092	$78.75
Mammograms: Re-Screenings	1,400	76092	$78.75
Screening CBEs	6,000		
Pap Tests	3,500	88164	$14.76
Office Visits: New Patients	2,000	99202	$61.54
Office Visits: Established Patients	2,400	99213	$49.79
Office Visits: Problem Focused	1,000	99241	$47.25
Referred In for Breast Diagnostics	100		
Referred In for Cervical Diagnostics	250		

PROGRAM:
AA

RATES BASED ON PROGRAM-SPECIFIC MDE EXPERIENCE

Rate of abnormal mammograms new screenings	18.5%
Rate of abnormal mammograms rescreenings	9.3%
Rate of abnormal CBEs (with normal mammogram)	14.3%
Rate of ASCUS Paps	5.4%
Rate of LSIL Paps	3.3%
Rate of AGCUS / HGSIL / SqCa Paps	1.5%

MDE Data Extraction Period:	
Screening:	Jul 03 - Dec 03
Diagnostics:	Jul 03 - Jun 04
MDE Submission:	April 2005

RATE OF EACH PROCEDURE FOLLOWING: ABNORMAL MAMMOGRAM		CPT CODE	COST PER
Diagnostic Mam	52.3%	76091	$89.86
Ultrasound	54.0%	76645	$64.39
FNA	4.4%	10022, 88172, 88173, 76942	$446.57
Non-Excisional Biopsy	11.1%	19103, 19295, 76098, 76090	$1,065.20
Excisional Biopsy	22.2%	19125, 19126, 19290, 19291, 76096	$848.97
Surgical consult	21.9%	99243	$115.48
Pathology	37.8%	88305	$95.74

RATE OF EACH PROCEDURE FOLLOWING: ABNORMAL CBE		CPT CODE	COST PER
Diagnostic Mammogram	11.6%	76091	$89.86
Ultrasound	73.3%	76645	$64.39
FNA	3.4%	10022, 88172, 88173, 76942	$446.57
Non-Excisional Biopsy	2.1%	19103, 19295, 76098, 76090	$1,065.20
Excisional biopsy	4.3%	19125, 19126, 19290, 19291, 76096	$848.97
Surgical Consult	49.8%	99243	$115.48
Pathology	9.8%	88305	$95.74

RATE OF EACH PROCEDURE FOLLOWING: ASCUS PAP TEST		CPT CODE	COST PER
Colpo-directed Biopsy	90.0%	57454	$149.73
Colposcopy alone	10.0%	57452	$103.99
Pathology	90.0%	88305	$95.74

RATE OF EACH PROCEDURE FOLLOWING: LSIL PAP TEST		CPT CODE	COST PER
Colpo-directed Biopsy	90.3%	57454	$149.73
Colposcopy alone	9.7%	57452	$103.99
Pathology	90.3%	88305	$95.74

RATE OF EACH PROCEDURE FOLLOWING: AGCUS / HGSIL / SQCA PAP TEST		CPT CODE	COST PER
Colpo-directed Biopsy	74.8%	57454	$149.73
Colposcopy alone	9.9%	57452	$103.99
Pathology	74.8%	88305	$95.74

2006-2007 CLINICAL COSTS WORKSHEET: Andalusia
(Continued)

CALCULATIONS USING ABOVE RATES

PRELIMINARY CALCULATIONS	SCREENING:	REFERRED IN:	TOTAL:
Abnormal Mammograms	520	100	620
Abnormal CBEs (norm mamm)	857		857
ASCUS Paps	191		191
LSIL Paps	116		116
AGCUS/HGSIL/SqCa Paps	53	250	303

LINE ITEM COUNTS AND COSTS	Number	Line Item Cost	% of Total	Federal Funds	Other Funds
Screening Mammogram	3,500	$275,625	22.6%	$250,625	$25,000
Pap Tests	3,500	$51,660	4.2%	$41,660	$10,000
Office visits	5,400	$289,826	23.8%	$289,826	
Colpo-directed Biopsy	504	$75,464	6.2%	$75,464	
Colposcopy alone	61	$6,343	0.5%	$6,343	
Diagnostic Mammogram	425	$38,191	3.1%	$38,191	
Ultrasound	963	$62,008	5.1%	$62,008	
FNA	57	$25,454	2.1%	$25,454	
Biopsy(non excisional)	88	$93,738	7.7%	$93,738	
Excisional biopsy	175	$148,570	12.2%	$148,570	
Surgical consult	563	$65,015	5.3%	$65,015	
Pathology; breast	319	$30,541	2.5%	$30,541	
Pathology cervical	504	$48,253	4.0%	$48,253	
HPV Testing	30	$1,471	0.1%	$1,471	
Anesthesia	65	$5,070	0.4%	$5,070	
Facility Fees	0	$0	0.0%	$0	
Loop Electrode Excision Procedure	6	$1,403	0.1%	$1,403	
Diagnostic Conization	4	$1,323	0.1%	$1,323	
Endocervical Curretage	2	$184	0.0%	$184	
CLINICAL SUB-TOTAL:	16,154	$1,217,229	100%	$1,185,138	$35,000

CASE MANAGEMENT COSTS

COST UNIT:	Number	Line Item Cost	Federal Funds	Other Funds
FTE	1	$52,675	$52,675	$0

OTHER CLINICAL OR DIRECT SERVICE COSTS

Procedure/Activity/Ancillary Charge	(Related) CPT:	Number	Unit:	Cost Per Unit:	Total Cost:
Pap Test Requiring Physician Interpretation	88141	60	Test	$21.44	$1,286.40
				OTHER SUB-TOTAL:	$1,286.40

GRAND TOTAL:

$1,239,099

Data Extracted from MDEs (see note below)	Andalusia
Sorted By Program Row:	AA
Abnormal Mammograms (new) Numerator	530
Abnormal Mammograms (new) Denominator	2858
Abnormal Mammograms (new) Rate	0.1854
Abnormal Mammograms (subsequent) Numerator	122
Abnormal Mammograms (subsequent) Denominator	1312
Abnormal Mammograms (subsequent) Rate	0.0930
Abnormal CBEs (with normal mammograms) Numerator	576
Abnormal CBEs (with normal mammograms) Denominator	4037
Abnormal CBEs (with normal mammograms) Rate	0.1427
Number of Mammogram Referrals	182
ASCUS Pap Tests Numerator	530
ASCUS Pap Tests Denominator	9746
ASCUS Pap Tests Rate	0.0544
LSIL Pap Tests Numerator	322
LSIL Pap Tests Denominator	9746
LSIL Pap Tests Rate	0.0330
AGCUS, HSIL and Squamous Cancer Pap Tests Numerator	146
AGCUS, HSIL and Squamous Cancer Pap Tests Denominator	9746
AGCUS, HSIL and Squamous Cancer Pap Tests Rate	0.0150
Number of Pap Test Referrals	155
Dx Mam following an Abnormal Mammogram Numerator	248
Dx Mam following an Abnormal Mammogram Denominator	474
Dx Mam following an Abnormal Mammogram Rate	0.5232
Ultrasound following an Abnormal Mammogram Numerator	256
Ultrasound following an Abnormal Mammogram Denominator	474
Ultrasound following an Abnormal Mammogram Rate	0.5401
FNA following an Abnormal Mammogram Numerator	21
FNA following an Abnormal Mammogram Denominator	474
FNA following an Abnormal Mammogram Rate	0.0443
Biopsy following an Abnormal Mammogram Numerator	158
Biopsy following an Abnormal Mammogram Denominator	474
Biopsy following an Abnormal Mammogram Rate	0.3333
Surgical Consult following an Abnormal Mammogram Numerator	104
Surgical Consult following an Abnormal Mammogram Denominator	474
Surgical Consult following an Abnormal Mammogram Rate	0.2194
Dx Mam following an Abnormal CBE Numerator	51
Dx Mam following an Abnormal CBE Denominator	438
Dx Mam following an Abnormal CBE Rate	0.1164
Ultrasound following an Abnormal CBE Numerator	321
Ultrasound following an Abnormal CBE Denominator	438
Ultrasound following an Abnormal CBE Rate	0.7329
FNA following an Abnormal CBE Numerator	15
FNA following an Abnormal CBE Denominator	438
FNA following an Abnormal CBE Rate	0.0342
Biopsy following an Abnormal CBE Numerator	28
Biopsy following an Abnormal CBE Denominator	438
Biopsy following an Abnormal CBE Rate	0.0639
Surgical Consult following an Abnormal CBE Numerator	218
Surgical Consult following an Abnormal CBE Denominator	438
Surgical Consult following an Abnormal CBE Rate	0.4977
Colpo-directed Biopsy following ASCUS Pap Test Numerator	18
Colpo-directed Biopsy following ASCUS Pap Test Denominator	20
Colpo-directed Biopsy following ASCUS Pap Test Rate	0.9000
Colposcopy Alone following ASCUS Pap Test Numerator	2
Colposcopy Alone following ASCUS Pap Test Denominator	20
Colposcopy Alone following ASCUS Pap Test Rate	0.1000
Colpo-directed Biopsy following LSIL Pap Test Numerator	121
Colpo-directed Biopsy following LSIL Pap Test Denominator	134
Colpo-directed Biopsy following LSIL Pap Test Rate	0.9030
Colposcopy Alone following LSIL Pap Test Numerator	13
Colposcopy Alone following LSIL Pap Test Denominator	134
Colposcopy Alone following LSIL Pap Test Rate	0.0970
Colpo-directed Biopsy following HSIL/SqCa Pap Tests Numerator	98
Colpo-directed Biopsy following HSIL/SqCa Pap Tests Denominator	131
Colpo-directed Biopsy following HSIL/SqCa Pap Tests Rate	0.7481
Colposcopy Alone following HSIL/SqCa Pap Tests Numerator	13
Colposcopy Alone following HSIL/SqCa Pap Tests Denominator	131
Colposcopy Alone following HSIL/SqCa Pap Tests Rate	0.0992

Screening Data Time Period:	Jul 03 - Dec 03
Diagnostic Data Time Period:	Jul 03 - Jun 04
MDE Submission:	April 2005

ATTACHMENT G: DATA MANAGEMENT ORIENTATION WEB CONFERENCES

The following sessions related to data management are available through Web conference replay files, accessible at the NBCCEDP Resources Web site (http://www.nbccedp.org). New sessions will be added as they become available

MDE ORIENTATION

Three sessions present a comprehensive orientation to MDE data collection and reporting

- MDE Orientation Session1, Overview of the Web Conference Series, MDEs, and Screening Cycles
- MDE Orientation Session2, Submission Requirements and Feedback Reports
- MDE Orientation Session3, Maintaining a Screening, Tracking, and Follow-up Program

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MDE ALGORITHMS

Technical presentations describe the algorithms commonly used in MDE feedback and reporting

- Standard terminology and algorithms used by CDC/Information Management Services (IMS) to quantify services funded through the program (e.g., women screened, women served, screening tests provided.
- Algorithms used to compute Data Quality Indicator Guide (DQIG) core indicator percentages.
- Hypothesis test used in determining if the CDC performance standard was met on DQIG core indicators.
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ORIENTATION TO NBCCEDP WEB RESOURCES

Overviews are available at the following two Web sites

- NBCCEDP Program and Partners Forum (http://forumx.cdc.gov)
- NBCCEDP Resources Web site (http:// www.nbccedp.org)