FISCAL YEAR 2007

POLICIES
and
PROCEDURES
MANUAL

for

Breast and Cervical Cancer Control

Department of State Health Services
Division for Family and Community Health Services

Table of Contents

Table of Contents

Introduction

General Information

PROGRAM AUTHORIZATION AND SERVICES

The Breast and Cervical Cancer Control (BCCC) is authorized by the Public Health Service Act (PHS Act), Title XV, [42 U.S.C. 300k et. seq.] and established by Public Law 101-354, "Breast and Cervical Cancer Mortality Prevention Act of 1990," and amended by 105-340, the Women's Health Research and Prevention Amendments of 1998.

The Texas Department of State Health Services received funding for the period of June 30, 2006 - June 29, 2007, through a cooperative agreement with the Centers for Disease Control and Prevention. The purpose of the cooperative agreement is to administer breast and cervical cancer early detection and screening services to low income women in Texas. The state program will be referred to in this manual as Breast and Cervical Cancer Control (BCCC).

The BCCC enables women with low incomes to have access to high quality screening and diagnostic services for breast and cervical cancer. This is accomplished through an extensive network of contractors and, private and public stakeholders.

RESPONSIBILITIES – State Office

In partnership with its contractors, the BCCC is responsible for attaining the goals and objectives of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The BCCC achieves program goals and objectives through implementation and monitoring of the following program components: management, screening, tracking and follow-up, case management, quality assurance, professional education, public information/outreach, coalition/partnerships, surveillance, and evaluation.

Management – The purpose of management is to maximize available resources to implement all BCCC components in accordance with established policies and procedures. The major management activities include:

- Establishing annual work plans and developing guidelines and protocols for each BCCC component;
- Working with the BCCC Clinical Workgroup on clinical protocols, outreach and gaps in service to priority populations, quality assurance issues, and strategies and resources to achieve BCCC goals and objectives;
- Developing a BCCC budget including tracking and monitoring of contractor expenditures;
- Providing technical assistance to contractors;
- Updating and disseminating a BCCC Policy Manual; and
- Maintaining communications with CDC.

Screening – The purpose of screening is to reduce mortality from breast and cervical cancers by detecting pre-cancerous or cancerous lesions at their earliest stages. BCCC has established requirements for eligibility to ensure eligible women receive BCCC-funded services. Additionally, BCCC staff provides training and technical assistance to contractors to meet CDC guidelines.

Tracking and Follow-up – The purpose of tracking and follow-up is to ensure contractor's compliance with the recommended diagnostic and initiation of treatment requirement. BCCC must maintain accurate data to track each client's receipt of BCCC services.

Case Management – The purpose of case management is to ensure that clients enrolled in the BCCC receive timely and appropriate diagnosis and initiation of treatment.

Quality Assurance – The purpose of quality assurance is to ensure the services delivered through the BCCC are in compliance with the State and NBCCEDP requirements. BCCC coordinates with the DSHS Performance Management Unit to ensure timely quality assurance visits, appropriate review of findings, and implementation of plans to correct findings. Performance Management Unit policies and procedures can be found at: http://www.dshs.state.tx.us/qmb/

Professional Education – The purpose of professional education is to assure that contractor staff provides clinical and other BCCC services in compliance with BCCC standards and requirements.

Public Information/Outreach – The purpose of public information and outreach is to increase awareness among the priority population of the need for and availability of breast and cervical cancer screening services, address barriers to services, and motivate women to seek these services.

Coalition and Partnership Building – The purpose of coalition and partnership building is to expand and maximize resources, coordinate BCCC activities, overcome obstacles to the recruitment of priority populations, and promote the delivery of comprehensive breast and cervical cancer screening services.

Surveillance – The purpose of surveillance is to plan and monitor BCCC activities using cancer data from the BCCC and other sources.

Evaluation – The purpose of evaluation is to assess the quality, effectiveness and efficiency of the BCCC and to gather useful information to aid in planning and decision-making.

PURPOSE OF MANUAL

The Department of State Health Services (DSHS) Policy and Procedure Manual for Breast and Cervical Cancer Control is a guide for contractors who deliver BCCC services using CDC funds in Texas. The policy manual has been structured to provide contractor staff with information needed to comply with BCCC Administrative, Client Services and Community Activities, and Reimbursement, Data Collection and Reporting policies.

To provide BCCC services, contractors are required to be in compliance with specific federal and state laws outlined in the manual. The state rules that apply most specifically to BCCC services in Texas are found in the Texas Administrative Code (TAC), Title 25 Part 1, Chapter 61.

DEFINITIONS

The following words and terms, when used in this manual, have the following meanings.

Centers for Disease Control and Prevention (CDC) – The federal agency responsible for protecting the health and safety of all Americans and for providing essential human services, especially for those people who are least able to help themselves; CDC issues funds and develops policy for the National Breast and Cervical Cancer Early Detection Program

Client – An individual who has been screened, determined to be eligible for services and has successfully completed the eligibility process

Contractor – The entity the Department of State Health Services has contracted with to provide services. The contractor is the responsible entity even if there is a subcontractor involved who actually provides the services

Department of State Health Services (DSHS) - The agency responsible for administering physical and mental health-related prevention, treatment, and regulatory programs for the State of Texas

Diagnosis – The recognition of disease status determined by evaluating the history of the client and the disease process, and the signs and symptoms present. Determining the diagnosis may require microscopic (i.e. culture), chemical (i.e. blood tests), and/or radiological examinations (x-rays)

Federal Poverty Level (FPL) - Determined by the U.S. Department of Health and Human Services, the minimum amount of income that a family needs for food, clothing, transportation, shelter and other necessities adjusted according to family size. The number is also adjusted for inflation and is reported annually in the form of the Federal Poverty Guidelines. Public assistance programs often define eligibility income limits as a percentage of FPL

Health and Human Services Commission (HHSC) – State agency that has oversight responsibilities for designated Health and Human Services agencies, including DSHS, and administers certain health and human services programs including the Texas Medicaid Program, Children's Health Insurance Program (CHIP), and Medicaid waste, fraud, and abuse investigations

Health Service Region (HSR) - For administrative purposes, DSHS has grouped counties within a specified geographic area into 11 Health Service Regions

Medicaid – Title XIX of the Social Security Act; reimburses for health care services delivered to low-income clients who meet eligibility guidelines

Minimum Data Elements – A set of standardized data elements developed by CDC to monitor clinical services provided to BCCC-enrolled women

Monthly Packet – A group of reports sent monthly to BCCC contractors, which may include data forms with errors, abnormal cases pending diagnosis/treatment and summary of clients to be rescreened

National Breast and Cervical Cancer Early Detection Program – A federal program, administered by the CDC that helps women who are low-income, uninsured and underserved to gain access to screening programs for early detection of breast and cervical cancer

Outreach – Activities that are conducted with the purpose of informing and educating the community about services and increasing the number of participants

Provider – An individual clinician or group of clinicians who provide services

Treatment Act – Federal and state legislation that gives Texas the authority to provide Medicaid eligibility to BCCC-enrolled women

Treatment Act/Medicaid – Medical assistance for eligible BCCC enrolled women who are in need of treatment for certain breast or cervical cancer

ACRONYMS

Acronym	Term
BCCC	Breast and Cervical Cancer Control
CLIA	Clinical Laboratory Improvement Amendments
CMB	DSHS Contract Management Branch
CDSB	DSHS Contract Development and Support Branch
CDC	Centers for Disease Control and Prevention
DHHS	U.S. Department of Health and Human Services
DSHS	Texas Department of State Health Services
FPL	Federal Poverty Level
HIPAA	Health Insurance and Portability Accountability Act
HHSC	Texas Health and Human Services Commission
HSR	DSHS Health Service Region
LEP	Limited English Proficiency
MDE	Minimum Data Element
QMB	DSHS Quality Management Branch
RFP	Request for Proposal
SUM	BCCC Summary Billing Form
TAC	Texas Administrative Code

Section I
Administrative Policies

Purpose: Section I assists the contractor in conducting administrative activities such as assuring client access to services and managing client records.

CLIENT ACCESS

The contractor must ensure that clients are provided services in a timely and nondiscriminatory manner. The contractor must:

- Have a policy in place that delineates the timely provision of services
- Comply with all applicable civil rights laws and regulations including Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973, and ensure services are accessible to persons with limited English proficiency and speech or sensory problems
- Have a system to prioritize clients' needs
- Have a triage system that utilizes qualified staff
- Continue to provide services to established clients once funds have been expended
- Screen clients in a way that is respectful and convenient
- Provide referral resources for individuals that cannot be served or cannot receive a specific services

Continuity of Care – Clients receiving screening, rescreening, and case management services through the BCCC must receive continuity of care. If an agency discontinues BCCC services due to termination of its contractual agreement with DSHS, clients with abnormal screening or diagnostic results must receive continued follow-up and case management services.

(See also Section 1, Chapter 3)

CHILD ABUSE REPORTING

While the majority of BCCC clients are adults, it is mandatory to be familiar with and comply with Child Abuse Reporting in Texas.

DSHS RIDER 33 COMPLIANCE AND MONITORING

Chapter 261 of the Texas Family Code requires child abuse reporting. Contractors/providers are required to develop policies and procedures that comply with the child abuse reporting guidelines and requirements set forth in Chapter 261 and the DSHS Child Abuse, Screening, Documenting and Reporting Policy for Contractors/Providers. Contractors/Providers shall develop a policy specific to how these reporting requirements will be implemented through out their agency, how staff will be trained and how internal monitoring will be done to ensure timely reporting.

The following outlines how the Quality Management Branch (QMB) staff will review for contractor/provider compliance with these requirements.

Policy – Contractors/providers will be monitored to ensure compliance with screening for child abuse and reporting according to Chapter 261 of the Texas Family Code and the DSHS Child Abuse Screening, Documenting, and Reporting Policy for Contractors/Providers.

Procedures – During site monitoring of contractors/providers by QMB the following procedures will be utilized to evaluate compliance:

1) The contractor's/provider's process used to ensure that staff are reporting according to Chapter 261 and the DSHS Child Abuse Screening, Documenting and Reporting Policy for Contractors/Providers will be reviewed as part of the Core Tool. To verify compliance with this item, monitors must review: a) that the contractor/provider adopted the DSHS Policy; b) the contractor's/provider's internal policy which details how the contractor/provider will determine, document and report instances of abuse, sexual or non-sexual for all clients who have never been married and are under the age of 17 in compliance with the Texas Family Code, Chapter 261 and the DSHS Policy; c) the contractor/provider followed their internal policy and the DSHS Policy; and d) the contractor/provider's documentation of staff training on child abuse reporting requirements and procedures.

2) All clinical/case management records of clients under 14 years of age who are pregnant or have a confirmed diagnosis of an STD acquired in a manner other than through perinatal transmission or transfusion will be reviewed for appropriate screening and reporting documentation as required in the clinic or site being visited during a site monitoring visit. The review of the records will involve reviewing that the Checklist for DSHS Monitoring was utilized; a report was made; and the report was made in the proper timeframes required by law.

3) If during the record review process, noncompliance is identified, the staff person responsible will be notified and asked to make a report as required by law. The contractor/provider. Director will be notified of the problem (or WIC Director for contractors that are WIC only contractors). Noncompliance will again be identified during the Exit Conference with the contractor/provider. During Quality Management (QM) site monitoring reviews since May 15, 2003, the first violation constitutes noncompliance. However, with a second or subsequent incidence of noncompliance, there is a potential for financial sanctioning.

4) If it is found during routine record review of other records for services that a report should have been made as evidenced by the age of the client and evidence of sexual activity, the failure to appropriately screen and report will be identified as lack of compliance with the DSHS Policy; and the QMB will identify the need for the contractor/provider to train staff. Failure to report will be brought to the attention of the staff person who should have made the report or the appropriate supervisor with a request to immediately report. This failure to report will also be discussed with the contractor/provider Director (or if a WIC only contractor, the WIC Director). During QM site monitoring reviews since May 15, 2003, the first violation constitutes noncompliance. However, with a second or subsequent incidence of noncompliance, there is a potential for financial sanctioning.

5) The report sent to the contractor/provider will also indicate the number of records reviewed in each clinic that were found to be out of compliance. This report will be sent to the contractor/provider 4 to 6 weeks from the date of the review, which is the usual process for Site Monitoring Reports.

6) The contractor/provider will then be given 6 weeks to respond with written corrective actions to all findings. If the contractor/provider has other findings that warrant technical assistance or accelerated monitoring review, either regional or central office staff will make the necessary contacts. Records and/or policies will again be reviewed to ensure compliance with Chapter 261 and the DSHS Policy requirements. Only records created or amended since the last visit will be reviewed during subsequent monitoring. If any subsequent finding of noncompliance is identified during a subsequent monitoring or technical assistance visit, the contractor/provider will be referred for financial sanctioning.

7) If the contractor/provider does not provide corrective actions during the required time period, the contractor/provider will be sent a past due letter with a time period of 10 days to submit the corrective actions. If the corrective actions are not submitted during the time period given, failure to submit the corrective action is considered a subsequent finding of noncompliance and the contractor/provider will be referred for financial sanctioning due to noncompliance with Chapter 261 and the DSHS Policy.

8) If a contractor/provider is found to have minimal findings overall but did have findings of noncompliance with Chapter 261 and the DSHS Policy, an additional sanction accelerated monitoring visit solely to review child abuse reporting will not be conducted. For agencies that receive technical assistance visits as a result of a quality assurance review, the agency will again be reviewed for compliance with child abuse reporting for the requirements with which the agency did not comply. In all cases, the corrective actions submitted by the contractor/provider will be reviewed to ensure that the issues have been addressed. Agencies who do not receive a sanction or technical assistance visit will be required to complete the DSHS Progress Report, Compliance with Child Abuse Reporting within 3 months after the corrective actions are begun (no later than 6 months from the initial visit). Failure to submit a Progress Report within the required time period or submission of a report that is not adequate, constitutes a subsequent finding of noncompliance with the DSHS Child Abuse Screening, Documenting, and Reporting Policy for Contractors/Providers and the contractor/provider will be referred for financial sanctions.

Information about this topic is available under the Quality Management Section of the manual and on the Internet at:
http://www.dshs.state.tx.us/childabusereporting/default.shtm

NON-DISCRIMINATION

DSHS contractors are required to follow Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, and other applicable civil rights laws and regulations*.

Collectively these laws and regulations require that DSHS contractors do not exclude, deny benefits to, or otherwise discriminate against any person on the basis of race, color, national origin (including individuals with limited English proficiency (LEP)), religion, sex, age, or disability in admission to, participation in, or receipt of the services and benefits of any of its programs and activities. In addition, no applicant or client who has opposed an unlawful practice, filed a complaint, testified, assisted, or participated in any manner in the investigation of a complaint, shall be intimidated, threatened, coerced, or discriminated against in retaliation for such participation.

To ensure compliance with DSHS non-discrimination policies DSHS contractors must:

- have a written policy that states the contractor does not discriminate on the basis of race, color, national origin including LEP, religion, disability, age, or sex;
- sign a written assurance as to compliance with applicable federal and state civil rights laws and regulations;
- have procedures for notifying the HHSC Civil Rights Office of any program or
- service-related discrimination allegation or complaint within ten (10) calendar days of the allegation or complaint;
- notify all clients and applicants of the contractor's nondiscrimination policies and complaint procedures;
- ensure that all contractor staff is trained in the agency's nondiscrimination policies and complaint procedures;
- take reasonable steps to ensure that LEP persons have meaningful access to its programs and services, and not require a client with LEP to use friends or family members as interpreters. However, a family member or friend may serve as an interpreter if requested, and the family member or friend does not compromise the effectiveness of the service or violate client confidentiality;
- post the following sign in a location visible to all employees, applicants, and clients: "Your Rights Clients and Applicants" poster (Spanish/English) that informs clients of the following: "Discrimination is Against the Law." The Texas Health and Human Services Agencies (HHS) are committed to protecting your civil rights as defined by law and recognized in HHS policy and procedures. Texas HHS and its contractors and licensees will not discriminate against you, directly or through contractual or other arrangements. If you believe that you have been discriminated against in any agency activity, service, or program, immediately contact the Civil Rights Office listed below: Assistant Director - Civil Rights Office, Texas Health and Human Services Commission, 701 West 51st Street, Suite 104, MC W-206, Austin, Texas 78751, Phone: (888) 388-6332, TDD (512) 438-2960, Fax: (512) 438-5885";
- and, have available completed and signed copies of the Non-Discrimination Policies and Procedures Survey, ADA/Section 504 Policies and Procedures Survey, and

Limited English Proficiency (LEP) Policies and Procedures Survey prior to any scheduled on-site review by the Quality Management Branch (QMB) review team.***

* More Information about applicable laws and regulations can be found on the HHSC Civil Rights Office Website at:
http://www.hhs.state.tx.us/aboutHHS/CivilRights.shtml

****** Copies of the "Your Rights Clients and Applicants" poster will be available in the fall of the calendar year 2006. This free poster will be available for downloading and printing from the HHSC Civil Rights Office website at:
http://www.hhs.state.tx.us/aboutHHS/CivilRights.shtml

*** The Non-Discrimination Policies and Procedures Survey, ADA/Section 504 Policies and Procedures Survey, and Limited English Proficiency (LEP) Policies and Procedures Survey and their instructions can be downloaded at the QMB Website at:
http://www.dshs.state.tx.us/qmb/contact.shtm

CONFIDENTIALITY

DSHS and contractors must ensure the safeguarding of client information:

- The confidentiality of a client must be maintained at all times. Each contractor must keep files and medical records in a secure location and assure that information gathered verbally or in writing remains confidential.
- All personnel (both paid and volunteer) must be informed during orientation of the importance of keeping information about a client confidential and that a breach of confidentiality may result in civil damages and criminal penalties.
- The client's preferred method of follow-up (cell phone, work phone, email) must be documented in the client's record.
- Each client must receive verbal assurance of confidentiality and an explanation of what confidentiality means (kept private and not shared without the client's permission) and any applicable exceptions such as abuse reporting (See Section I Chapter 2).

The U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) established standards for protection of client privacy. Information about HIPAA can be found at the following web site: **http://www.hhs.gov/ocr/hipaa/**

TERMINATION OF SERVICES

Contractors have the right to terminate services to a client if the client is disruptive, threatening or uncooperative to the extent that the client impairs the contractor's ability to provide services or if the client's behavior jeopardizes the safety of him/herself, clinic staff, or other clients.

Policy related to termination of services must be included in the contractor's policy and procedures manual.

RESOLUTION OF GRIEVANCES

Contractors must ensure that clients have the opportunity to express concerns about care received and to further ensure that those complaints are handled in a consistent manner. Contractor's policy and procedures manuals must explain the process clients will follow if they are not satisfied with the care received or feel that they have been discriminated against or treated inappropriately. The policy must include contact information for the DSHS Regional Coordinator if the client believes that the issue has not been resolved at the level of the contractor.

Notice of the grievance process must be visibly posted or provided in writing at the time of initial enrollment.

Any client grievance must be documented in the client's record.

DSHS contractors must have an organized and secure client record system. The contractor must ensure that the record is organized and readily accessible, available to the client upon request with a signed release of information, and confidential and secure, as follows:

- Safeguarded against loss or use by unauthorized persons
- Secured by lock when not in use or inaccessible to unauthorized persons
- Maintained in a secure environment in the facility as well as during transfer between clinics and in between home and office visits

In addition, a confidentiality assurance statement must appear in the client's record. The written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality. HIV information should be handled according to law.

When information is requested, contractors should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form that does not identify particular individuals. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care. Electronic records are acceptable as medical records.

Contractors, providers, subrecipients and subcontractors must maintain for the time period specified by DSHS all records pertaining to client services, contracts, and payments. Record retention requirements are found in 15 TAC §354.1003 (relating to Time Limits for Submitted Medicaid Claims) and 22 TAC 165 (relating to Medical Records). Contractors must follow contract provisions and the DSHS Retention Schedule for Medical Records. All records relating to services must be accessible for examination at any reasonable time to representatives of DSHS and as required by law. DSHS guidelines for medical record retention are available at: http://www.dshs.state.tx.us/records/medicalrec.shtm.

PERSONNEL POLICY AND PROCEDURES

Contractors must develop and maintain personnel policies and procedures to ensure that clinical staff are hired, trained, and evaluated appropriate to their job position. Personnel policies and procedures should address job descriptions, including contracted positions that contain required qualifications and licensure, a written orientation plan for new staff and annual job evaluations. All staff must be appropriately identified with a name badge.

Contractors must show evidence that employees meet all required qualifications of written job descriptions and licensure, annual orientation of all staff was provided and job evaluations included observation of staff/client interactions during clinical, counseling and educational services.

Contractors shall establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest or personal gain. (See General Provisions – fee-for-service, Article 7).

Contractors must have a documented plan of organized staff development based on an assessment of training needs, quality assurance indicators, and changing regulations/requirements, and must include orientation and in-service training for all personnel, including volunteers. There must be documentation of initial employee orientation and continuing education.

New contractor/provider staff must be oriented to BCCC policies, standards, requirements, and recommendations to conduct breast and cervical cancer screening activities.

Contractors must assure that:

- breast and pelvic examinations and Pap tests are performed by physicians, physician's assistants, nurse practitioners, certified nurse midwives, or qualified registered nurses who have had specialized training;
- clinical personnel follow procedures according to current medically acceptable methods for breast and pelvic examinations and specimen collection;
- clinical breast examinations, clinical pelvic examinations and Pap tests are performed in accordance with clinical guidelines in Section II, Chapter 3 of this manual.

FACILITIES AND EQUIPMENT

DSHS contractors are required to maintain a safe environment at all times. Contractors must have written policies and procedures that address:

Hazardous Materials:

- the handling storage and disposing of hazardous materials and waste according to applicable laws and regulations;
- the handling, storage and disposing of chemical and infectious waste including sharps;
- and, an orientation and education program for personnel who manage or have contact with hazardous materials and waste.

Fire Safety – Contractors must have a written fire safety policy that includes a schedule for testing and maintenance of fire safety equipment. Evacuation plans for the premises must be clearly posted and visible to all staff and clients.

Medical Equipment – Contractors must have a written policy and maintain documentation of the maintenance, testing, and inspection of medical equipment. Documentation must include:

- assessments of the clinical and physical risks of equipment through inspection, testing and maintenance;
- reports of any equipment management problems, failures and use errors; and
- an orientation and education program for personnel who use medical equipment.

Smoking Ban – Contractors must have written policies that prohibit smoking in any part of their indoor facilities. If a contractor subcontracts with another entity for the provision of health services, the subcontractor must also comply with this policy.

QUALITY MANAGEMENT

Organizations that embrace Quality Management (QM) concepts and methodologies and integrate them into the structure of the organization and day-to-day operations discover a very powerful management tool. Quality Management programs can vary in structure and organization and will be most effective if they are individualized to meet the needs of a specific agency, services and the populations served.

Contractors are expected to develop quality processes based on the four core Quality Management principles of focusing on: the client, systems and processes, measurement and teamwork. Contractors must have a Quality Management program individualized to their organizational structure and based on the services provided. The goals of the quality program should ensure availability and accessibility of services, and quality and continuity of care.

A Quality Management program must be developed and implemented that provides for ongoing evaluation of services. Contractors should have a comprehensive plan for the internal review, measurement and evaluation of services, the analysis of monitoring data, and the development of strategies for improvement and sustainability. Contractors who subcontract for the provision of services must also address how quality will be evaluated and how compliance with policies and basic standards will be assessed with the subcontracting entities.

The Quality Management Committee, whose membership consists of key leadership of the organization, including the Executive Director/CEO and the Medical Director, where applicable, annually reviews and approves the quality work plan for the organization.

The Quality Management Committee must meet at least quarterly to:
- receive reports of monitoring activities
- make decisions based on the analysis of data collected
- determine quality improvement actions to be implemented
- reassess outcomes and goal achievement

Minutes of the discussion and actions taken by the committee must be maintained.

The quality work plan at a minimum must:
- include clinical and administrative standards by which services will be monitored
- include process for credentialing and peer review of clinicians
- identify individuals responsible for implementing monitoring, evaluating and reporting
- establish timelines for quality monitoring activities
- identify tools/forms to be utilized
- outline reporting to the Quality Management Committee

Although each organization's quality program is unique, the following activities must be undertaken by all agencies providing client services:

- on-going eligibility, billing, and clinical record reviews to assure compliance with program requirements and clinical standards of care
- tracking and reporting of adverse outcomes
- client satisfaction surveys
- annual review of facilities to maintain a safe environment, including an emergency safety plan
- annual review of policies, clinical protocols and standing delegation orders (SDOs) to ensure they are current

Data from these activities must be presented to the Quality Management Committee. Plans to improve quality should result from the data analysis and reports considered by the committee and should be documented.

Information on the operating process of DSHS's Quality Management Branch as well as policies and review tools can be located at http://www.dshs.state.tx.us/qmb/default.shtm

REVISIONS TO CONTRACT PROVISIONS

There are three (3) types of modifications that can be made to a contract. Each category of change will have its own modification process in order for the requested changes to be incorporated into the contract. The three (3) types of contract modifications are:

1. Administrative Contract Revisions: The following changes may be made to the contract without the Department's prior approval (only notification to DSHS is required) and will be administratively incorporated into the contract upon receipt of notification:

- Contractor's contact person and contact information.
- Contact information for key personnel, as stated in the application.
- A cost reimbursement contract for less than $100,000 and the cumulative transfer of funds among direct cost categories (except equipment) exceeds 10% of the total budget. The total budget amount is unchanged. Note: Cumulative transfers of funds among direct cost categories that are 10% or less do not require notification to DSHS.
- Minor corrections or clarifications to the contract language that in no way alters the contract scope of work, objectives or performance measures.
- A change in the contractor's share of the budget via program income or match, regardless of the amount of the change.

NOTE: Contractor must notify the Contract Development and Support Branch (CDSB) in writing no later than ten calendar days after initiating an administrative contract revision specified above. The notification may be by letter, fax or email.

Department of State Health Services
Contract Development and Support Branch (CDSB)
1100 W. 49th Street, Mail Code 1914
Austin, Texas 78756
Fax (512) 458-7235
mailto:michael.montgomery@dshs.state.tx.us

2. Formal Contract Revision: Contractor must request a formal contract revision [using the Contract Revision Request (CRR) form referenced below] when one or more of the following conditions exist:

- A cost reimbursement contract for $100,000 or more and the cumulative transfer of funds among direct cost categories (except equipment) exceeds 10% of the total budget. The total budget amount is unchanged. Note: Cumulative transfers of funds among direct cost categories that are 10% or less do not require notification to DSHS.
- Line-item budget transfer of funds for direct payment of training allowances for any cost reimbursement contract.
- Change in clinic hours or clinic location.
- Change in equipment list substituting an item of equipment equivalent to an item of equipment on the approved budget (Cost-reimbursement contracts only).

- Changes in the equipment line-item category of a previously approved equipment budget (other than acquisition of additional equipment, which requires an amendment to the contract).
- Changes specified in applicable cost principles as requiring prior approval, regardless of dollar threshold.

In order to request a contract revision, the contractor must complete and submit the CRR (Form #EF29-12414) which is available from the DSHS website at (**<http://www.dshs.state.tx.us/grants/forms.shtm>**). For this type of revision, two copies of the completed CRR must be signed by a representative who is authorized to sign contracts on behalf of the contractor and submitted to:

Department of State Health Services
Contract Development and Support Branch (CDSB)
1100 W. 49th Street, Mail Code 1914
Austin, Texas 78756

Note: Contracts will not be formally revised or amended within the last 90 days of the contract period except under justifiable situations that will be examined on a case-by-case basis. The contractor may still make administrative contract revisions during this period with written notification to DSHS.

3. Formal Contract Amendment: Unless otherwise specified in the General Provisions of the contract, all other modifications to the contract must be in writing and agreed to by both parties and will constitute a formal amendment to the contract.

Contractor's request for a formal contract amendment must be submitted in writing using the Contract Revision Request (CRR) (Form #EF29-12414) which is available from the DSHS website at (**<http://www.dshs.state.tx.us/grants/forms.shtm>**). The CRR requires a justification for the request. If a formal contract amendment is requested during the last quarter of the contract term, contractor's written justification must include a reason for the delay in making the request. Revision or amendment requests may be granted at the discretion of DSHS. Signatures are not required on the CRR for a formal contract amendment because DSHS will develop an amendment document requiring original signatures from both parties before the amendment is fully executed. Once the amendment is signed by both parties and fully executed, the contractor will receive one of the two signed original contract amendment documents.

CONTRACTS WITH SUBRECIPIENT SUBCONTRACTS

Contractors may enter into contracts with subrecipient subcontractors unless restricted or otherwise prohibited in a specific Program Attachment(s). Prior to entering into an agreement equaling $25,000 or twenty-five percent (25%) of a Program Attachment amount, whichever is greater, Contractors shall obtain written approval from DSHS. Contracts with subcontractors shall be in writing and include the following:

- Name and address of all parties;
- A detailed description of the services to be provided;
- Measurable method and rate of payment and total amount of contract;
- Clearly defined and executable termination clause;
- Beginning and ending dates that coincide with the dates of the applicable Program Attachment(s) or cover a term within the beginning and ending dates of the applicable Program Attachment(s);
- Access to inspect the work and the premises on which any work is performed, in accordance with the Access and Inspection Article in this Contract; and
- A copy of these General Provisions and a copy of the Statement of Work and any Special Provisions in the Program Attachment(s) applicable to the subcontract.

Contractor is responsible to DSHS for the performance of any subcontractor. Contractor shall monitor both financial and programmatic performance and maintain pertinent records that shall be available for inspection by DSHS. Contractor shall ensure that subcontractors are fully aware of the requirements placed upon them by state/federal statutes and regulations and under this Contract. Contractor shall not contract with a subcontractor, at any tier, that is debarred or suspended or excluded from or ineligible for participation in federal assistance programs**.**

Status of Subcontractors – Contractor shall require that all subcontractors certify that they are in good standing with all state and federal funding and regulatory agencies; are not currently debarred, suspended, revoked, or otherwise excluded from participation in federal grant programs; are not delinquent on any repayment agreements; and have not had a contract terminated by DSHS. Contractors shall further require that subcontractors certify that they have not voluntarily surrendered within the past three (3) years any license issued by DSHS.

Mammography Quality Assurance – All mammography facilities, including subcontracted facilities, providing services to the BCCC must:

- possess a current and unrevoked Certificate of Mammography Systems from DSHS Regulatory Licensing Unit, Mammography Program (each mammography unit must be fully accredited or undergoing accreditation); and
- possess a current, unrevoked, and unsuspended mammography facility certificate from the appropriate agency certifying compliance with the U.S. Food and Drug Administration Mammography Quality Standards, Final Rules, 21 CFR Part 900.

The DSHS Regulatory Licensing Unit, Mammography Program can be contacted at 512.834.6688 to obtain results of inspections of mammography facilities participating in

the BCCC. The Regulatory Licensing Unit, Mammography Program generally will notify the BCCC if a mammography facility is in "escalated enforcement" or "cease and desist" status. **The BCCC will not reimburse for services provided by a mammography provider with "escalated enforcement" status or "cease and desist" status.**

Cytology Quality Assurance – Contractors subcontracting for screening and diagnostic cytology services must have current documentation that the subcontractor for cytology meets all quality assurance standards required by the BCCC as established under state and federal laws.

All cytology laboratories providing services to BCCC contractors/subcontractors must:

- Possess a current, unrevoked and unsuspended registration certificate issued by the U.S. Department of Health and Human Services (DHHS) under the terms of the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88);
- Use the 2001 Bethesda System for Reporting Cervical/Vaginal Cytological Diagnoses;
- Be accredited by a Centers for Medicare and Medicaid services-approved accrediting organization, or be certified by DSHS as in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 USC §263a; and
- Report CIN III or greater Pap test results within 24 hours.

Section II
Client Services and Community Activities

Purpose: Section II provides policy requirements for providing client services and community activities.

GENERAL ELIGIBILITY

Financial Eligibility – BCCC contractors are required to determine BCCC eligibility prior to enrolling women in the BCCC.

Contractors must:

- determine if the woman meets the BCCC minimum financial eligibility requirements, which include:
  - income at or below 200% of the federal poverty level;
  - no insurance, OR unable to pay her insurance deductible or co-payment; and
  - not eligible for Medicare Part B or unable to pay premium for Medicare Part B.
- document financial eligibility for the BCCC in the client's record;
- determine if the woman has ever received services funded by the BCCC;
- apply for all other available sources of third party funding before submitting reimbursement claims to the BCCC for services rendered;
- document special eligibility circumstances for women 65 and older who are not eligible for Medicare Part B in the client's record; and
- offer breast and cervical cancer screening free-of-charge to eligible women.

Breast Cancer Screening Services Eligibility – Screening refers to procedures, such as clinical breast examination (CBE) and mammogram, for women who present without symptoms that are suspicious for breast cancer. A screening mammogram must be provided within 60 days following the CBE. The BCCC follows National Cancer Institute recommendations for mammography screening:

- Ages 50 and older: Women should be screened every year.
- Ages 40-49: Asymptomatic women ages 40-49 may be screened subject to the restriction of not exceeding 25% of BCCC funded mammograms to women under the age of 50.
- Women under age 40 can receive a CBE only if they are symptomatic. If CBE is abnormal, refer for diagnostic assessment.

Breast Cancer Diagnostic Services Eligibility – Women of any age can be enrolled in the BCCC for diagnostic assessment if they are:

- symptomatic; AND
- have an abnormal clinical breast examination; AND/OR
- have an abnormal mammogram.

Cervical Cancer Screening Services Eligibility – To be eligible for cervical cancer screening services, a woman must meet financial eligibility and be age 18 or older.

A woman who meets the financial and age criteria and has had a hysterectomy is eligible for cervical cancer screening services only if the hysterectomy was due to cervical cancer or neoplasia, or if the cervix remains. The presence of a cervix can be determined on physical examination. BCCC funds can be used to pay for an initial examination, i.e., pelvic examination to determine if a woman has a cervix.

Cervical Cancer Diagnostic Services Eligibility – Woman age 18 and older may be enrolled in the BCCC for diagnostic assessment provided there is:

- documentation of two abnormal Pap results of ASC-US which are 6 months apart or one abnormal Pap result of ASC-US HPV positive for high risk types; OR
- one abnormal Pap result of ASC-H; LSIL; HSIL or AGC.

(See Algorithm #1A for diagnostic procedures.)

LEGEND:
ASC-US = Atypical Squamous Cells of Undetermined Significance
ASC-H = Atypical Squamous Cells: Cannot exclude High-grade Squamous Intraepithelial Lesion
LSIL = Low-grade Squamous Intraepithelial Lesion
HSIL = High-grade Squamous Intraepithelial Lesion
AGC = Atypical Glandular Cells
HPV = Human Papillomavirus

Rescreening Eligibility – Rescreening is the process of returning for a breast cancer screening test at a predetermined interval, usually one year, when no symptoms are present. Contractors must verify each previously enrolled woman's eligibility for BCCC services. A woman is eligible for rescreening if she:

- received a BCCC-funded breast cancer screening (clinical breast examination and mammogram) during the previous 12-month budget period (the baseline year); **and**
- still meets the BCCC eligibility requirements.

Note: A woman may not be clinically eligible for rescreening during a particular rescreening interval if she is receiving treatment or follow-up for a previous abnormality. Her next screening date should be determined by the clinician.

Exceptions – Contractors **are not required to rescreen a woman** if the contractor has documented that she:

- cannot be located or has moved from the contractor's service area;
- no longer meets the BCCC income eligibility standard;
- has Medicare Part B or other health insurance which provides coverage for breast cancer screening;
- refuses (in writing or verbally) to return for BCCC services;
- received a BCCC-funded breast cancer screening within the previous 11 months;
- is age 40-49 and received a BCCC-funded breast cancer screening within the last 24 months; or
- is clinically ineligible (i.e., her screening cycle has changed due to an abnormal result, treatment for breast cancer or any other medical condition for which the clinician recommends delaying rescreening).

CONSENT FOR SERVICES

Consent information must be effectively communicated to every client, including those who have language barriers (in compliance with Limited English Proficiency regulations) or who have disabilities that impair communication. If the client does not understand the language of the consent form, the form must be interpreted.

Contractors must obtain the client's written, informed, voluntary general consent to receive services prior to the client receiving any services. If there is a period of time of two years or more during which a client does not receive services, the general consent must be signed again prior to delivery of services.

CLIENT HEALTH RECORD (MEDICAL RECORD)

Contractors must ensure that a client health record (medical record) is established for every client who obtains clinical services. These records must be maintained according to accepted medical standards and State laws, including those governing record retention.

All client records must be:

- Complete, legible, and accurate, documenting all clinical encounters, including those by telephone, in ink without erasures or deletions
- Signed by the provider making the entry, including name of provider, provider title and date for each entry
- Readily accessible to assure continuity of care and availability to client
- Systematically organized to allow easy documentation and prompt retrieval of information

The client's record must include:

- Client identification and personal data
- Preferred language/method of communication
- Where and how to contact the client (to facilitate continuity of care and assure confidentiality, adhering to HIPAA* regulations)
- Medical history
- Physical examination
- Laboratory and other diagnostic tests orders, results and follow-up
- Assessment or clinical impression
- Plan of care, including education/counseling, treatment, special instructions and referrals
- Scheduled revisits
- Informed consent documentation
- Refusal of services documentation
- Allergies and untoward reactions to drugs recorded prominently in specific location
- Problem list to provide a consistent mechanism to document and track health and social problems/issues and to promote continuity of care

**Health Insurance Portability and Accountability Act of 1996*

BREAST CANCER SCREENING SERVICES

Breast cancer is the most common cancer among women in Texas. The American Cancer Society estimates that approximately 11,200 new cases of breast cancer are diagnosed annually among women in Texas and each year 2,444 women will die of breast cancer in Texas.

Goals of Breast Cancer Screening – The goal of breast cancer screening is to reduce premature mortality from breast cancer and to improve survival of breast cancer by ensuring quality breast cancer screening and diagnostic services for women.

Definition of Screening – Screening is a process to detect unsuspected disease in asymptomatic women. The methods used for early detection and screening of breast cancer are clinical breast examination (CBE) and mammography.

Components of Breast Cancer Screening

Client Education – The contractor must provide and document breast cancer information to every woman who receives breast cancer screening and/or diagnostic services through BCCC. The following information must be explained verbally to each woman in her primary language and may be supplemented with printed or audio-visual materials in the woman's primary language:

- description of cancer;
- risk factors for breast and cervical cancer;
- signs and symptoms of breast and cervical cancer;
- importance of screening at regular intervals;
- medical procedures as part of her current check-up;
- steps a woman must take to complete her current check-up;
- description of possible results of the medical procedures;
- date of next appointment and a telephone number to call with questions and/or to make her next appointments;
- eligibility to receive BCCC services can change from year to year; and
- information on the limitations of breast cancer screening e.g., a normal screening result does not necessarily indicate the absence of disease; normal results never rule out the later development of disease, which is why ongoing regular screening is recommended; and that an abnormal finding does not necessarily mean that the finding is cancerous.

Clinical Breast Examination (CBE) – CBEs must be performed by a qualified clinician, such as a Registered Nurse, Advanced Nurse Practitioner, a Certified Nurse Midwife, a Physician's Assistant, or a Physician. Complete documentation of the CBE must be included in the client record. The BCCC follows the National Cancer Institute's recommendations for CBE. The CBE should include the following components:

- **With the woman sitting:** Inspection for asymmetry, abnormal superficial vascular patterns, nipple retraction, and peau d' orange.

  Palpation of axillary and supraclavicular/infraclavicular nodes. Note size, location, mobility, and consistency of nodes palpated.

- **With the woman supine:** Palpation of the breast to include palpation of the axillary tail; areola and nipples.

A breast health history must be included as part of the CBE. The health history includes:

- date and time intervals of previous mammograms;
- date and results of the last CBE;
- date and results of any previous breast surgery;
- date of last menstrual period;
- history of medications (hormonal replacement therapy, oral contraceptives);
- risk factors for breast cancer (advancing age, personal history of breast cancer or breast biopsy results with moderate, severe, or atypical epithelial hyperplasia; or family history of first degree relatives with breast cancer); and
- Description of breast symptoms.

Screening Test – The contractor must provide a complete breast cancer screening which includes both a CBE and mammogram, for women who present without symptoms that are suspicious for breast cancer. A screening mammogram must be provided within 60 days following the CBE. Contractor must document CBE and mammogram results in the clients record. The BCCC follows National Cancer Institute recommendations for mammography screening:

- Ages 50 and older: Women should be screened every year.
- Ages 40 to 49: Women are encouraged to discuss, with a health care professional, the advisability of breast cancer screening with mammography.

Mammography Reports – Facilities must prepare a written report of the results of each mammography examination. This report must include the following:

- the name of the client and an additional client identifier;
- the name of the physician who interpreted the mammogram;
- an overall final assessment of findings, classified in one of the following categories:
  - *Negative*
  - *Benign*
  - *Probably benign* (Finding has a high probability of being benign.)
  - *Suspicious* (Finding lacks all the characteristic morphology of breast cancer, but indicates a definite probability of being malignant.)
  - *Highly suggestive of malignancy*

- *Assessment is incomplete: need additional imaging evaluation* (Finding for which additional imaging evaluation is needed. This is almost always used in a screening situation and should rarely be used after a full imaging work up. A recommendation for additional imaging evaluation includes the use of spot compression, magnification, special mammographic views, ultrasound, etc.)

When both CBE and screening mammogram results are normal, routine follow-up is recommended.

Follow-Up For Abnormal Screening Results

Follow-up of CBE results – Abnormal CBEs always require further diagnostic evaluation.

- Normal/benign CBE results require diagnostic referral only if mammogram results are abnormal.
- Abnormal (suspicious for cancer)CBE results require referral for a diagnostic mammogram, ultrasound, and/or consultation with a surgeon or breast specialist (any two).

Follow-up of screening mammography results – Abnormal mammograms always require further diagnostic evaluation.

- Negative screening mammography results require diagnostic referral only if CBE results are abnormal.
- Benign screening mammography results require diagnostic referral only if CBE results are abnormal.
- Probably Benign screening mammography results (with normal/benign CBE results) require radiologist recommendation for the next screening or diagnostic examination; **AND,** diagnostic referral if CBE results are abnormal.
- Suspicious screening mammography results require a consultation with surgeon or breast specialist with tissue sampling (biopsy).
- Highly Suggestive of Malignancy screening mammography results require referral for consultation with surgeon or breast specialist with tissue sampling (biopsy).
- Incomplete - Additional Imaging Evaluation Needed screening mammography results require additional imaging (mammography and/or ultrasound).

Note: This is the expected minimum follow-up. More procedures or examinations may be necessary to clarify screening examination results and to obtain a final diagnosis. A normal mammogram does not rule out cancer.

Professional Consultations for Screening Follow-up – Referrals for follow-up of screening results must be made to physicians with expertise in managing breast problems. Radiologists, obstetricians, and gynecologists may be considered breast specialists depending on the focus of their practice. A consultation can only be performed by a physician who did not perform the original screening examination.

Consultations must involve direct examination. (Note: Interpretation of other images and imaging reports by a radiologist as a second opinion without direct examination of the client cannot be reported as a professional consultation.) Nurses, midwives, nurse practitioners, physician assistants, and primary care physicians do NOT qualify as breast specialists.

CERVICAL CANCER SCREENING SERVICES

Approximately 1,100 women in Texas are diagnosed with cervical cancer each year. Another 300 die from the disease each year. Of all cancers, cervical cancer is among the most amenable to prevention and early detection through screening. Most cervical cancers can be prevented in two ways. The first way is to prevent pre-cancers. The second way to prevent cervical cancer is to have regular Pap tests, which can detect pre-cancers and human papilloma virus (HPV) infection. Treating these problems can stop cervical cancer before it fully develops.

Goals of Cervical Cancer Screening – The goal of cervical cancer screening for the BCCC is to reduce premature mortality from cervical cancer and to improve survival of cervical cancer by ensuring quality cervical cancer screening and diagnostic services for women in Texas.

Definition of Screening – Screening is a process to detect unsuspected disease in asymptomatic women. The methods used for early detection and screening of cervical cancer are pelvic examination and Pap test.

Components of Cervical Cancer Screening

Client Education – The contractor must provide and document cervical cancer information to every woman who receives cervical cancer screening and/or diagnostic services through. The following information must be explained verbally to each woman in her primary language and may be supplemented with printed or audio-visual materials in the woman's primary language:

- description of cervical cancer;
- risk factors for cervical cancer;
- signs and symptoms of cervical cancer;
- information on HPV and safer sex practices;
- clinical procedures (pelvic exam and Pap test);
- importance of screening at regular intervals;
- steps a woman must take to complete her current check-up;
- description of possible results of the medical procedures;
- date of next appointment and a telephone number to call with questions and/or to make her next appointments; and
- eligibility to receive BCCC services can change from year to year.

Clinical Examination – A comprehensive assessment should include Clinical Breast Examination (CBE), pelvic examination and a Pap test.

- CBE (Refer to follow-up recommendations if an abnormality is detected.);
- assessment of the abdomen;
- assessment of the external genitalia;
- visual assessment of the cervix and collection of cervical cells for cytological analysis (Pap test);
- visual inspection of the vaginal vault during withdrawal of the speculum and the bimanual examination; and
- recto/vaginal examination.

A complete cervical health history must be included as part of the examination. The health history includes:

- date and results of the last pelvic examination and Pap test;
- date and results of any previous pelvic surgery, chemotherapy, and/or radiation therapy;
- date of last menstrual period and history of pregnancies;
- history of medications including oral contraceptives and hormonal replacement therapy;
- risk factors for cervical cancer; and description of present pelvic symptoms.

Cytology Reports – The 2001 Bethesda System for Reporting Cervical/Vaginal Diagnoses must be used for reporting cytology results. The three components of a cytology report using the Bethesda system are:

- statement of adequacy of the specimen;
- general categorization of the diagnosis:
  - Negative for Intraepithelial Lesion or Malignancy
  - Epithelial Cell Abnormality
  - Other: See Interpretation/Result
- Interpretation/Results:
  - Negative for Intraepithelial Lesion or Malignancy
  - Atypical Squamous Cells of Undetermined Significance (ASC-US)
  - Atypical Squamous Cells cannot exclude HSIL (ASC-H)
  - Low Grade SIL (LGSIL)
  - High Grade SIL (HGSIL)
  - Squamous Cell Carcinoma
  - AGUS (Atypical glandular cells of undetermined significance)
  - Other
- Adenocarcinoma

Follow-up of Screening Results

Normal screening examination (pelvic and Pap test) – A negative Pap test needs no further diagnostic workup. The clinician must notify a woman of findings, including the need for continued screening examinations. After a woman has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician.

Management of Abnormal Pelvic Examinations:

- Abnormal pelvic exams and abnormal Pap tests require further diagnostic evaluations. A normal Pap test does not rule out cancer if a woman has a cervical lesion on pelvic examination.
- A colposcopy is allowed with an abnormal pelvic exam if determined by the clinician.

Management of Abnormal Pap Tests:

- **Atypical Squamous Cells of Undetermined Significance (ASC)** – ASC is interpreted as cellular changes that have an atypical appearance. These changes may be due to an inflammatory process, estrogen deficiency (as in a post-menopausal woman), or dysplastic changes. The 2001 Bethesda System subdivides atypical squamous cells of undetermined significance (ASC-US) and atypical squamous cells, cannot exclude HSIL (ASC-H). For ASC-US, the cytology report should contain an opinion from the cytopathologist as to which of the above reasons are responsible for the atypical cellular changes (if possible). The underlying cause (if it can be determined) may be treated, and the Pap test repeated. The woman must be referred for colposcopy in the presence of atypical squamous cells if there is: a repeat Pap test with ASC-US; or one Pap result of ASC-US with high-risk type HPV; or one Pap result of ASC-H. (See Algorithms 2, 3, 4 & 7.)

- **Low Grade Squamous Intraepithelial Lesion (LSIL) –** The woman must be referred for colposcopy. This is mild dysplasia (CIN I) or cellular changes due to the HPV. Mild dysplasia is characterized by definite abnormalities in nuclear development, with retention of an essentially normal cytoplasm. (See Algorithms 2, 5 & 7.)

- **High Grade Squamous Intraepithelial Lesion (HSIL) –** The woman must be referred for colposcopy. With moderate dysplasia, the cell nucleus shows further signs of abnormal development and some abnormalities in the cytoplasm. Severe dysplasia is characterized by severe changes in development of the cell as well as loss of normal structure of the cell's arrangement into tissue. Invasion of the basement membrane can occur at any phase of CIN, but it is more likely to occur at CIN III. A biopsy must be performed to determine if invasion has occurred. When no lesion or only biopsy-confirmed CIN I is identified after satisfactory colposcopy in women with HSIL, a review of the cytology, colposcopy, and histology results must be performed. A second colposcopy may be performed at this time. If a cytological

interpretation of HSIL is upheld or if review is not possible, a diagnostic excisional procedure is preferred in non-pregnant women. (See Algorithm 6A.)

- **Atypical Glandular Cells Of Undetermined Significance (AGC) –** The woman must be referred for colposcopy. The atypical glandular cells category is associated with a substantially greater risk for cervical neoplasia than the ASC or LSIL categories. Colposcopy with endocervical sampling is recommended for women with a Pap result of AGC, with the exception that women with atypical endometrial cells would initially be evaluated with endometrial sampling. Endometrial sampling should be performed in conjunction with colposcopy in women older than 35 years with AGC and in younger women with AGC who have unexplained vaginal bleeding. (See Algorithms 6B.)

- **Squamous Cell Cancer** – Cancerous cells have probably invaded through the basement membrane and into the cervical stroma, where the cells have access to blood and lymph vessels, enabling them to metastasize throughout the body. The woman should be referred for further evaluation to determine the extent of the invasion.

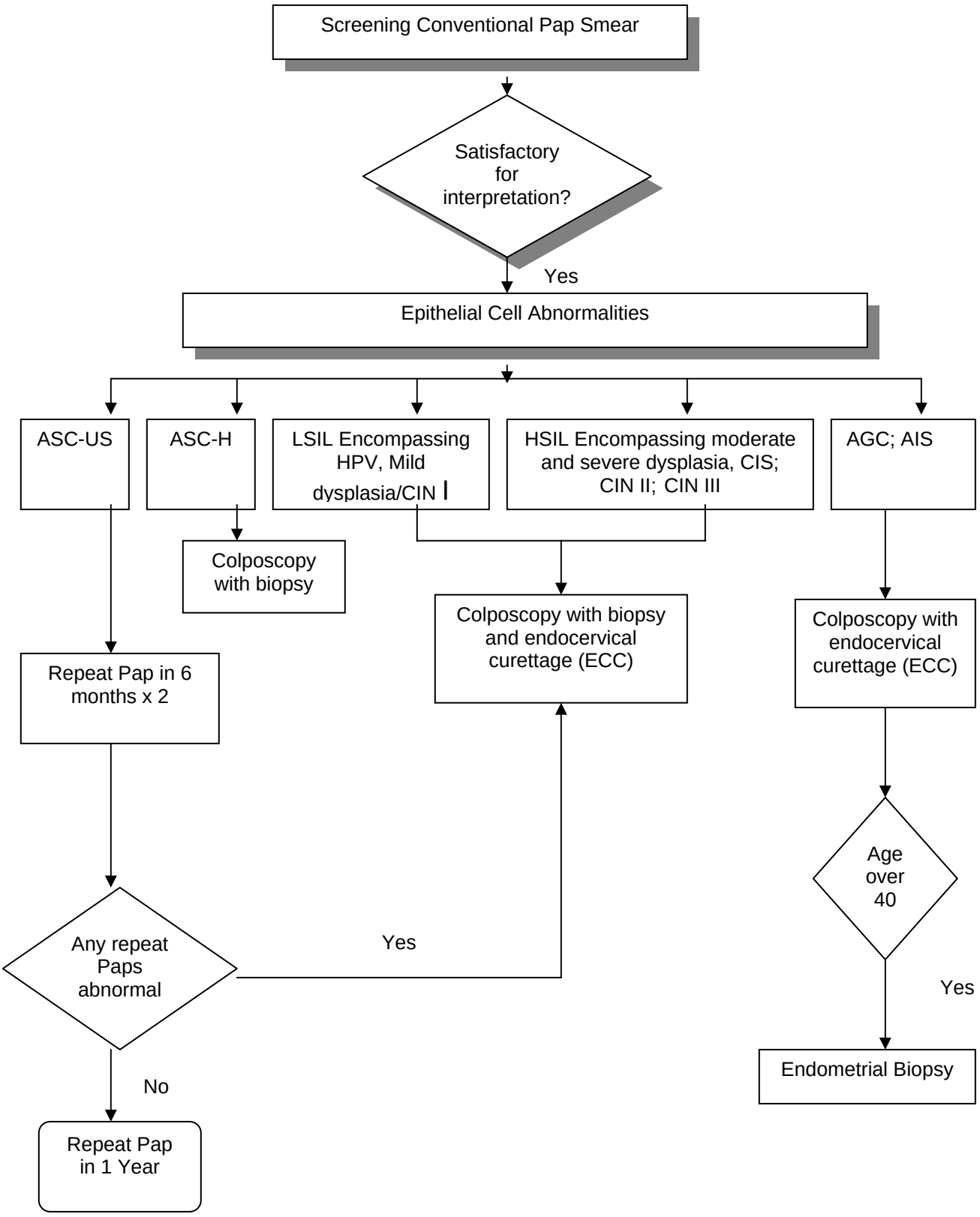
OTHER FINDINGS

Adenocarcinoma – Adenocarcinoma of the uterine cervix is a malignant neoplasm of epithelial cells in a glandular or gland like pattern. The cytology report should include the probable site of origin (endometrial, extra uterine, or endocervical). Most adenocarcinoma occurs within the endocervical canal and carries a poorer prognosis than squamous carcinoma especially if lymph nodes are involved. The woman should be referred immediately.

Algorithms

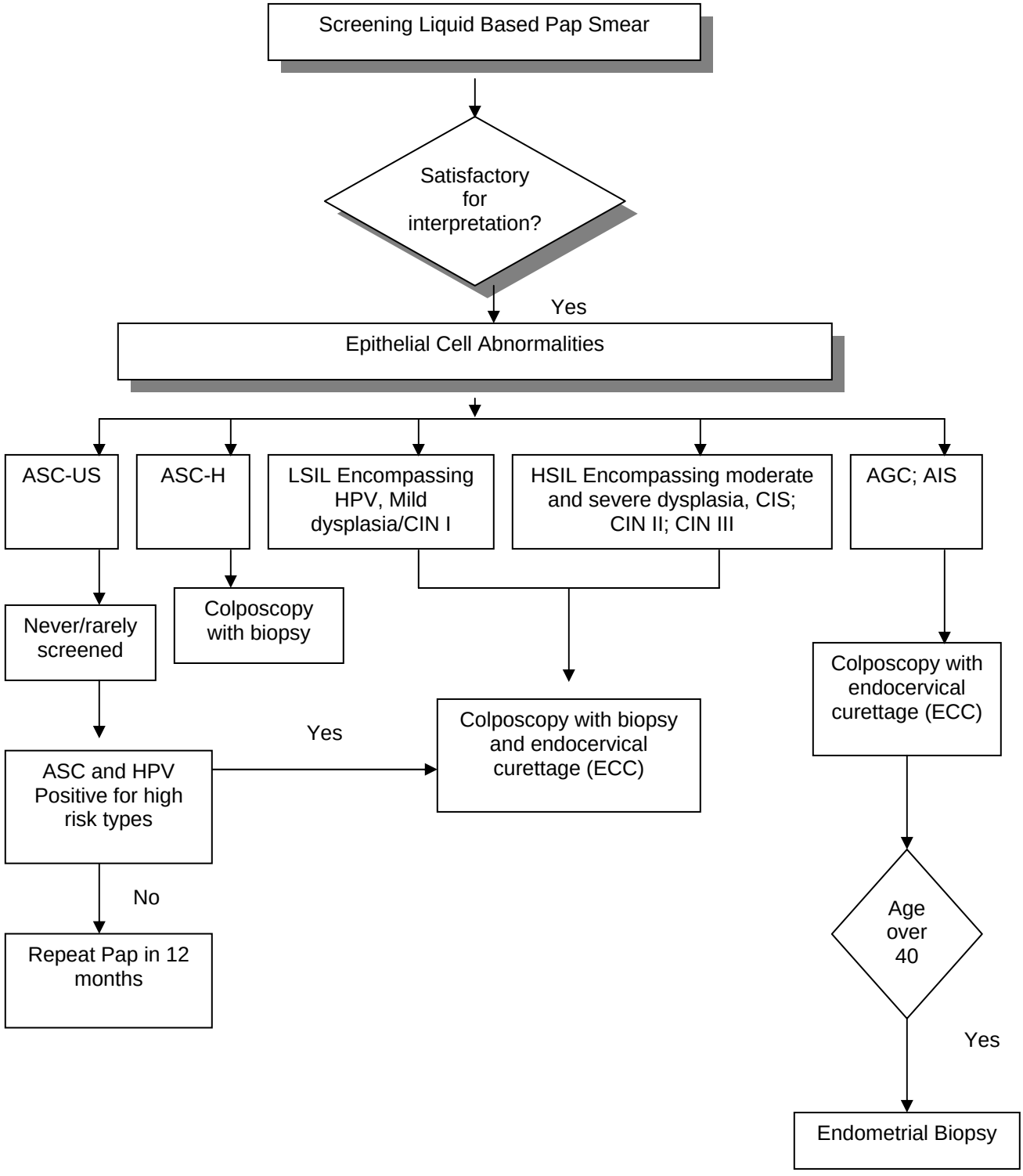
Algorithm #1A

Screening Conventional Pap Smear Abnormalities



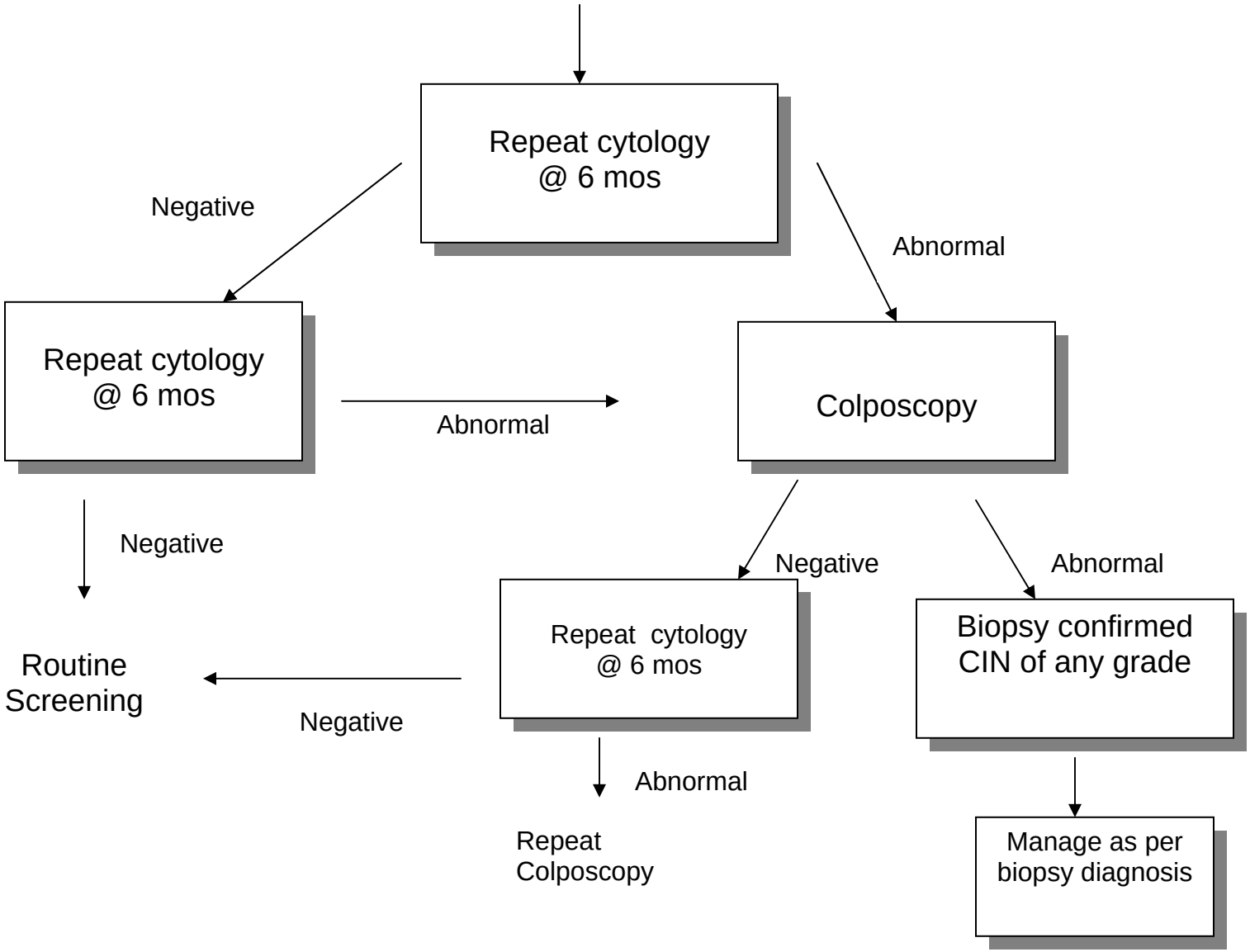
Screening Liquid Based Pap Smears
ASC-US Pap Results

Algorithm #1B



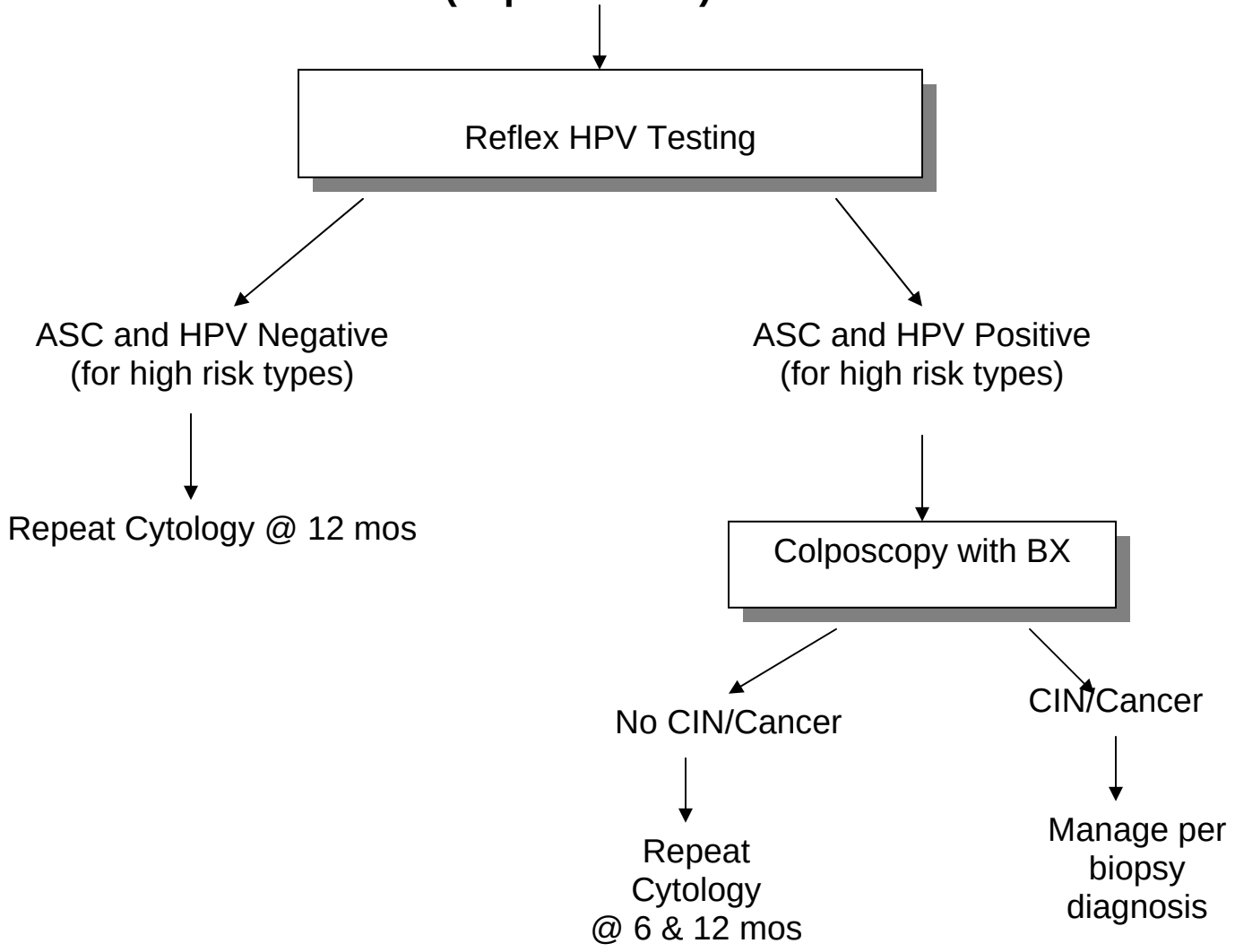
Algorithm #2

Management of ASC-US (Non-menopausal woman)
Management of LSIL (Adolescent)



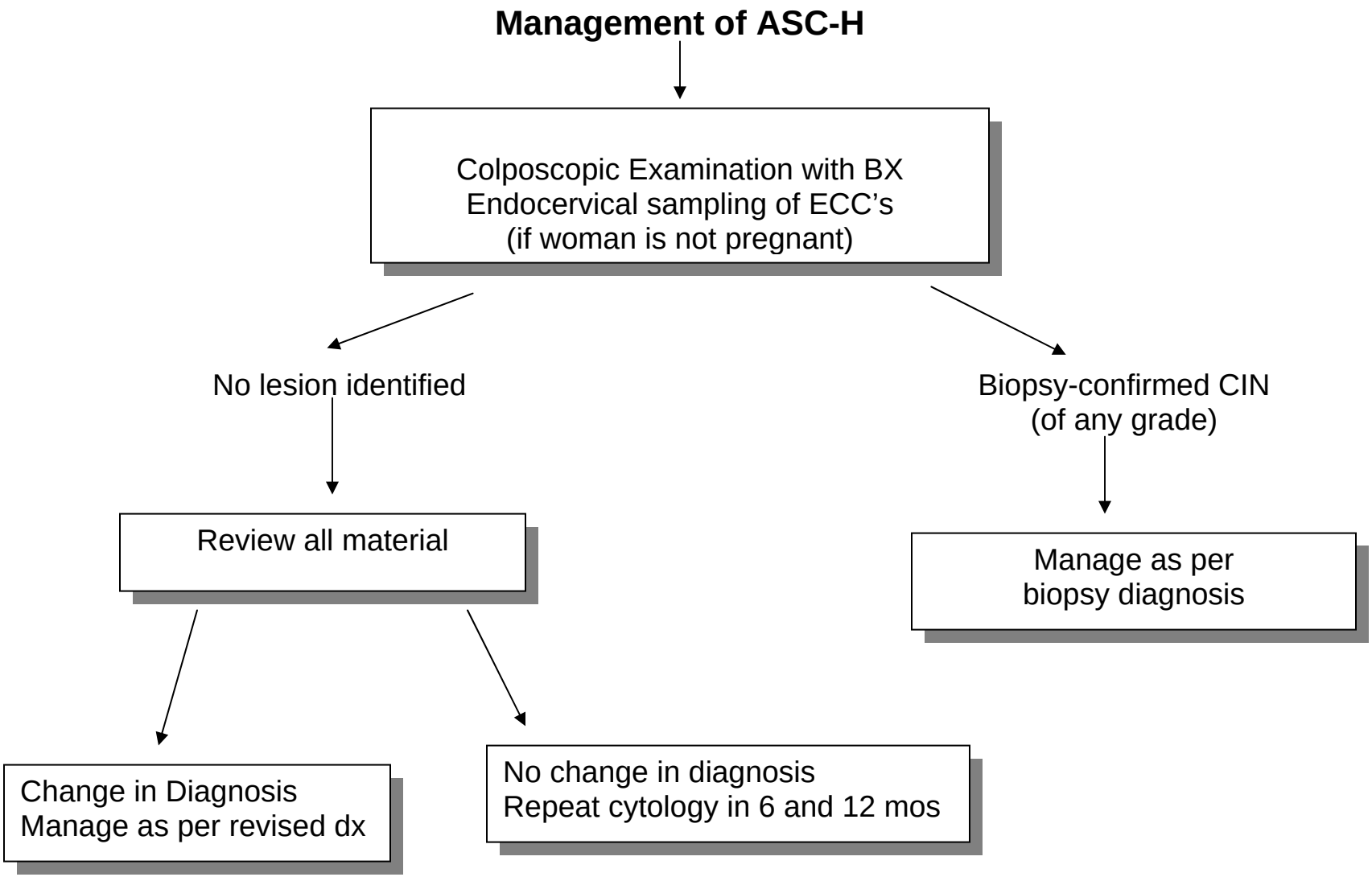
Algorithm #3

Management of ASC-US (Liquid-Based)

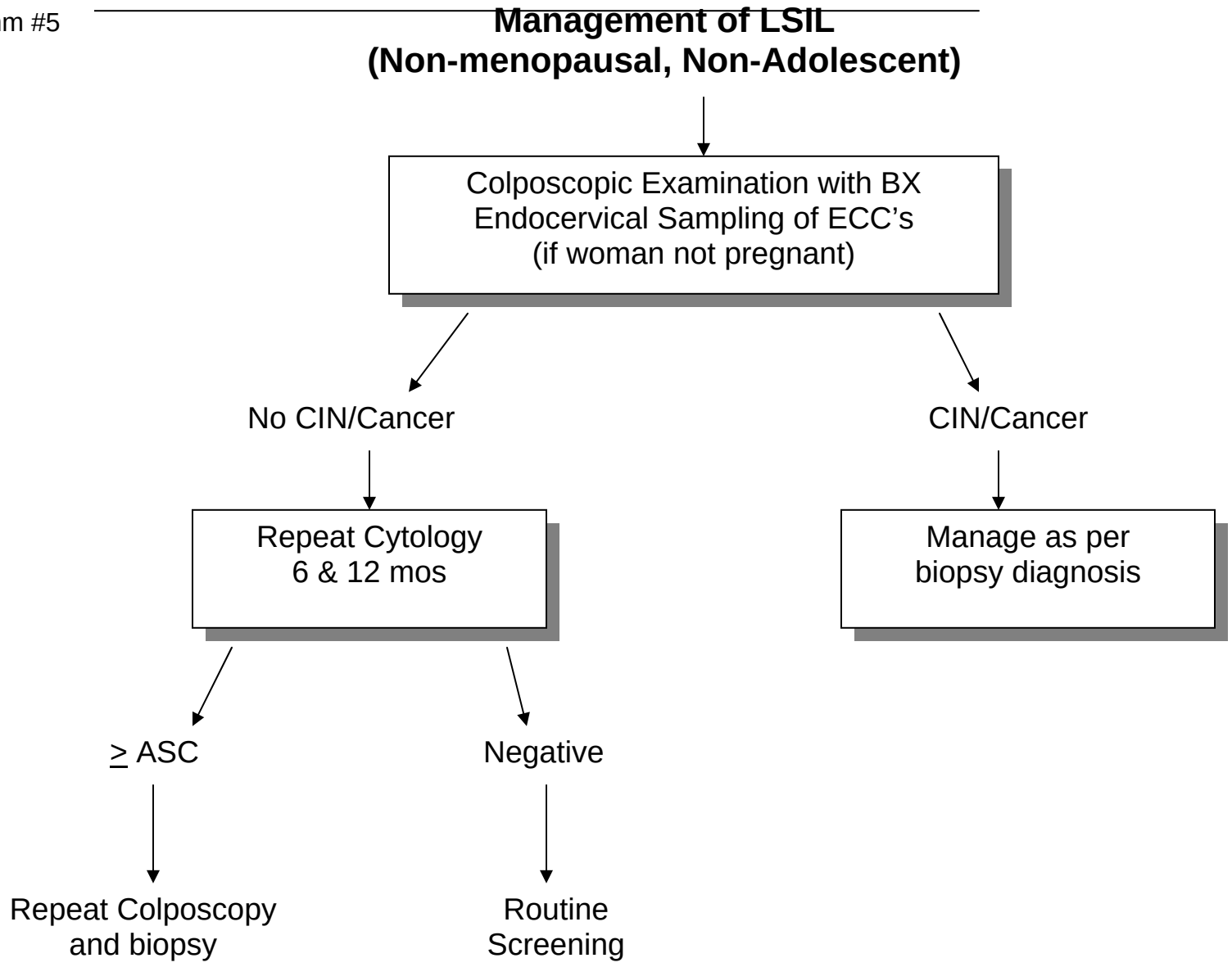


Note: HPV Testing not currently reimbursed.

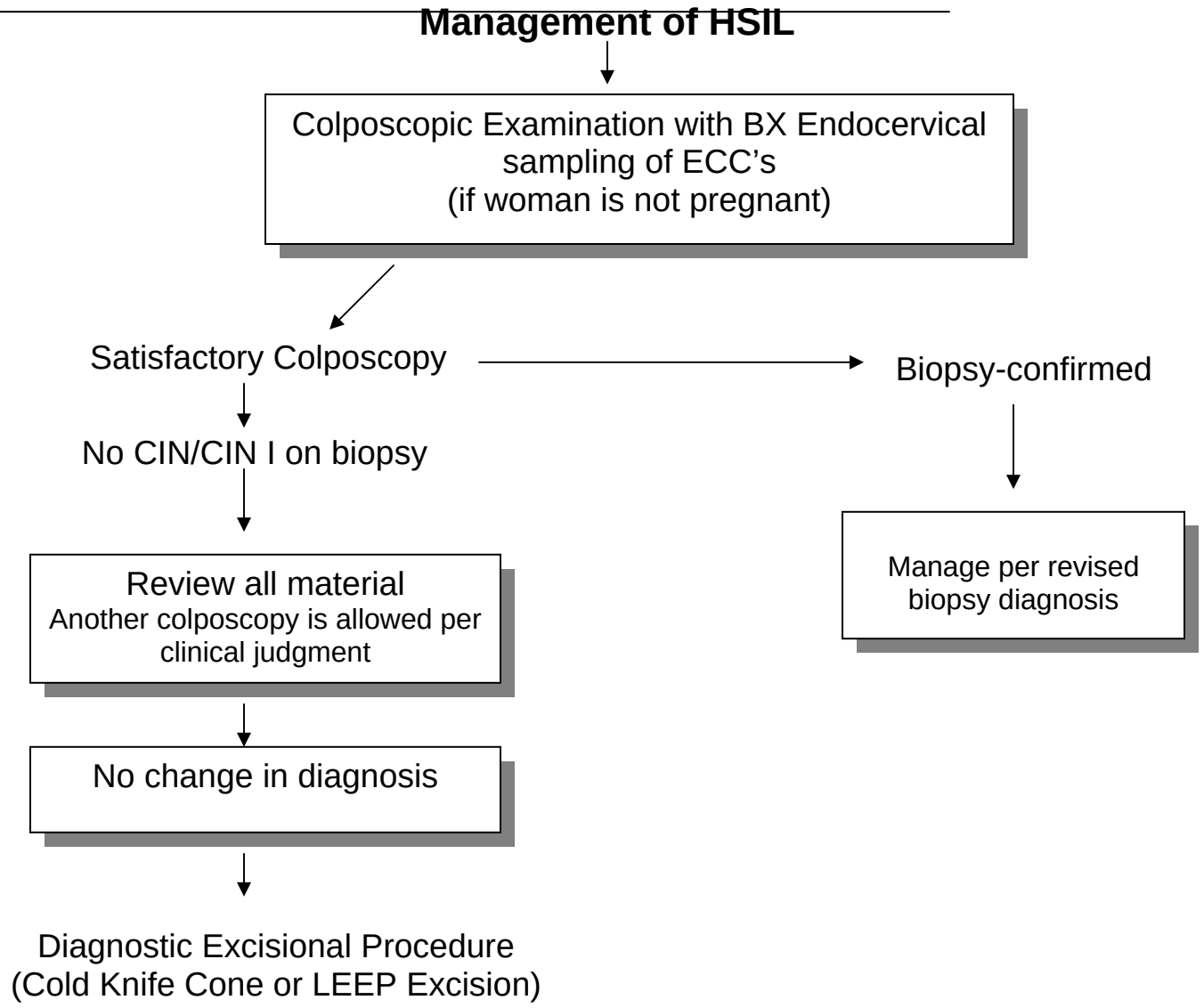
Algorithm #4


Management of ASC-H
Colposcopic Examination with BX
Endocervical sampling of ECC's
(if woman is not pregnant)
No lesion identified
Biopsy-confirmed CIN
(of any grade)
Review all material
Manage as per
biopsy diagnosis
Change in Diagnosis
Manage as per revised dx
No change in diagnosis
Repeat cytology in 6 and 12 mos

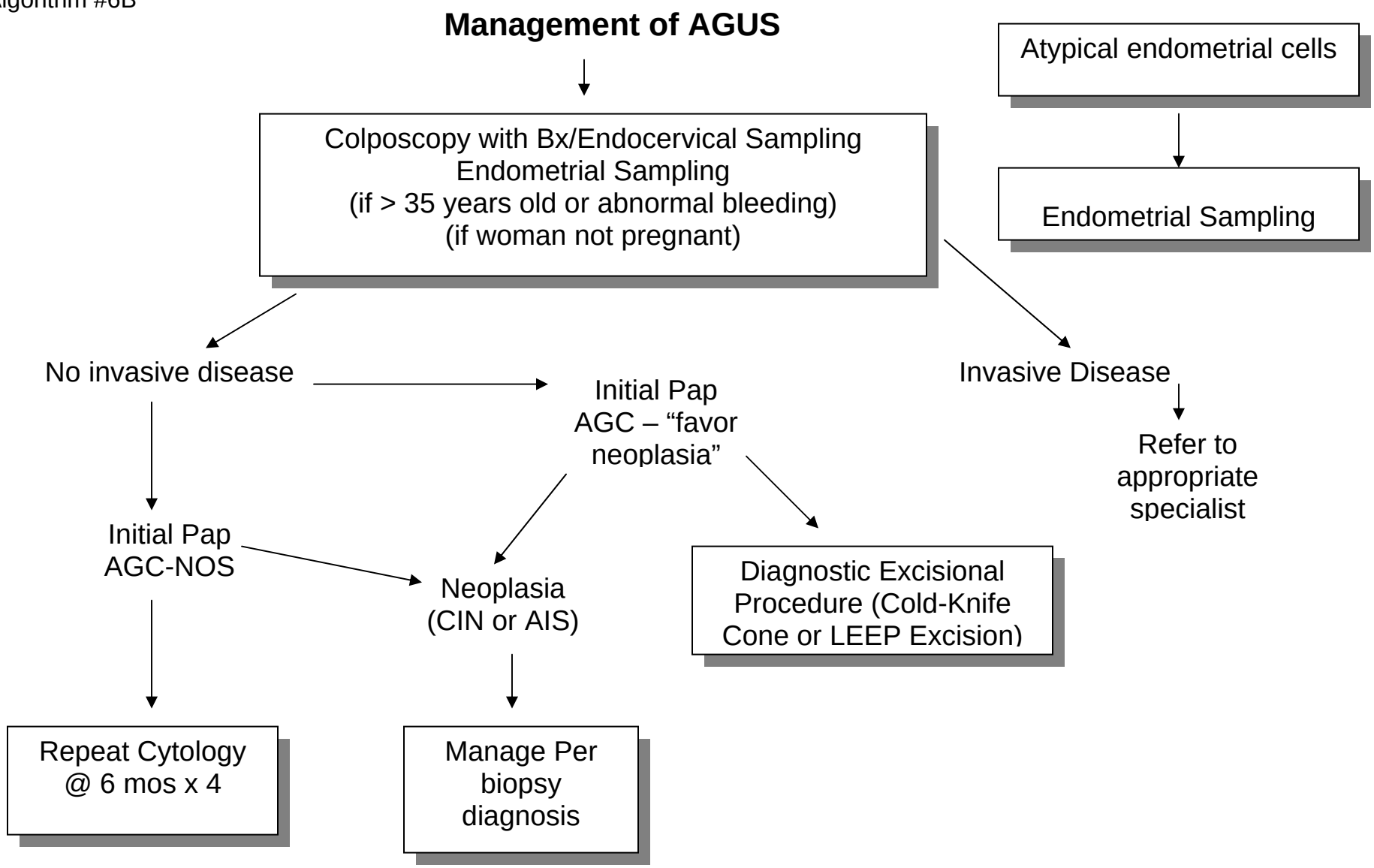
Algorithm #5


Management of LSIL
(Non-menopausal, Non-Adolescent)
Colposcopic Examination with BX
Endocervical Sampling of ECC's
(if woman not pregnant)
No CIN/Cancer
CIN/Cancer
Repeat Cytology
6 & 12 mos
Manage as per
biopsy diagnosis
≥ ASC
Negative
Repeat Colposcopy
and biopsy
Routine
Screening

Algorithm #6A

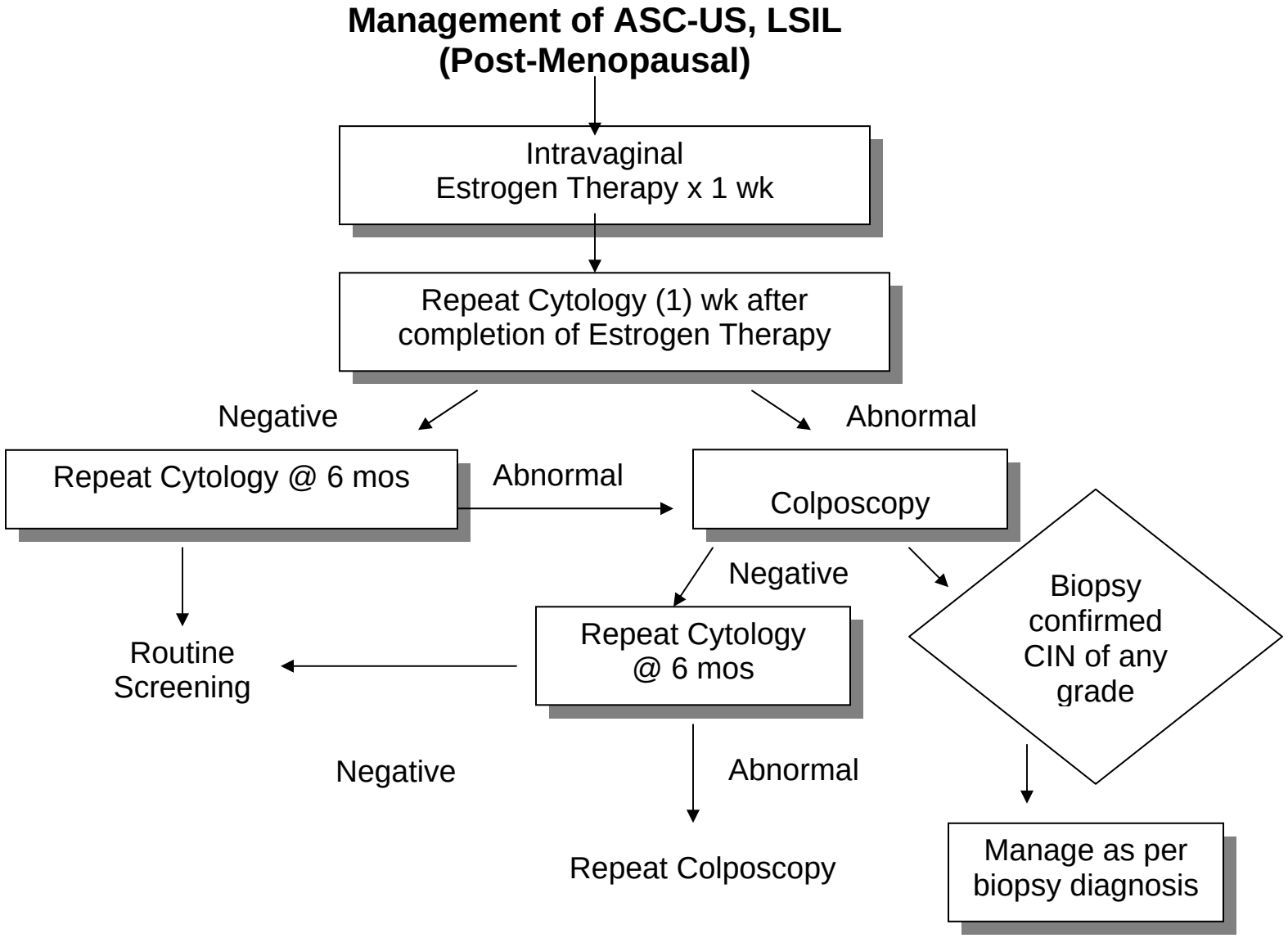


Algorithm #6B



*If woman is pregnant refer to Medical Director

Algorithm #7


Management of ASC-US, LSIL
(Post-Menopausal)
Intravaginal
Estrogen Therapy x 1 wk
Repeat Cytology (1) wk after
completion of Estrogen Therapy
Negative
Abnormal
Repeat Cytology @ 6 mos
Abnormal
Colposcopy
Negative
Biopsy
confirmed
CIN of any
grade
Routine
Screening
Repeat Cytology
@ 6 mos
Negative
Abnormal
Repeat Colposcopy
Manage as per
biopsy diagnosis

RESCREENING SERVICES

Breast cancer screening, which includes a clinical breast examination and mammogram, is effective in identifying *existing cancerous conditions* and reducing mortality. However, in order for breast cancer screening to be most effective, the screening must be conducted at *regular intervals*, particularly as a woman ages and her risk for breast cancer increases.

Components of Breast Cancer Rescreening

Client Education – The contractor must provide and document screening information for every woman who is rescreened. The following information must be explained verbally to each woman in her primary language and may be supplemented with printed or audio-visual materials in the woman's primary language:

- importance of regular screening;
- possible results;
- eligibility requirements; and
- the shared responsibility of the client and the contractor in following through with regular screening.

Recall of Clients – Contractors must attempt to notify each woman in writing of her regular screening due date.

CASE MANAGEMENT SERVICES

A systematic approach of assessment, planning, and monitoring is necessary in order to overcome client and system barriers to timely diagnosis and treatment.

Goals of Case Management – The goal of case management for the BCCC is to ensure that women enrolled in the BCCC receive timely and appropriate services. Assessment of BCCC-enrolled women for case management services and the provision of such services when necessary can assist in attaining this goal. The outcome of case management and the progress toward reaching this goal is evaluated by the performance measures outlined in the BCCC contract and Policy Manual. Performance measures include:

- a shortened interval between screening, diagnosis and treatment;
- a reduction in the number of clients lost to follow-up or refusing further services; and
- the initiation of treatment within 30 days of the diagnosis of a pre-cancerous or cancerous condition.

Definition of Case Management – Case management is an individualized approach for each BCCC enrolled woman with abnormal screening and/or diagnostic results which involves establishing, brokering, and sustaining a system of available clinical and essential support services.

Case Management Components

Key elements of the case management components both at the BCCC and client level include assessment, planning, coordination, monitoring, evaluation, and resource development.

Case management begins with receipt of an abnormal screening result. The client must be informed and understand the screening and follow-up process. The case manager and client must discuss how diagnostic services will be arranged. Case management services conclude when a client initiates treatment or is no longer eligible for BCCC services.

Case managers are responsible for identifying and securing resources for cancer treatment services for BCCC-enrolled women in need, regardless of their ability to pay. In Texas, the Breast and Cervical Cancer Prevention and Treatment Act was implemented to provide full Medicaid benefits to uninsured women under age 65 who are diagnosed with cancer through the BCCC and require treatment for breast or cervical cancer.

Assessment – Assessment is a cooperative effort between the client and case manager to examine and document the client's need for services (screening, diagnostic, treatment, and essential support services) through a process of gathering critical information from the client. The assessment includes consent and assurance of confidentiality between the client, the case manager, and the contractor.

All clients with abnormal screening results must receive a BCCC needs assessment, using the Comprehensive Case Management Form (CCMF) or documenting in the client's progress notes, unless the client refuses. Assessment components include client information, including other contact information, social resources, other services the client has accessed, education and counseling issues, consent for case management and confidentiality. The assessment is to be conducted within 30 days from the date of referral for diagnostic procedures or prior to the initiation of the first diagnostic service. The assessment should be conducted in a face-to-face interview format.

Planning – Planning is a cooperative effort between the client and case manager to develop an individual service plan to meet the client's immediate, short-term and long-term needs as identified in the assessment.

The service plan must be documented on the CCMF or the client's progress notes and completed within 30 days of referral for diagnostic procedures and case management. The plan includes needs, services related to needs, timeframes for meeting the services, referral, outcome and follow-up. Timeframes must be consistent with BCCC required intervals.

Coordination – Coordination is the implementation of the service plan, and the linkage between the client and contractors, including the appropriate use of available resources to meet the needs of the client.

Implementation of planned services and ongoing case manager-client consultation is documented in the CCMF or the client's progress notes. Coordination of services may include scheduling appointments, making referrals, and obtaining and disseminating appropriate reports.

Monitoring – Monitoring occurs concurrently at the contractor and client levels and is key to ensuring attainment of required performance measures.

- **At the contractor level** – Monitoring is the tracking of abnormal screening/diagnostic results as they occur for the purpose of providing case management services. The contractor must establish a system to document the monitoring of abnormal screening/diagnostic results.
- **At the client level** – Monitoring is the ongoing assessment of the client's service plan to ensure that the client's needs are met. As additional needs are identified, they are recorded on the CCMF or the client's progress notes. The case manager must document that the diagnostic, treatment, or social service which was provided took place within 30 days of the planned service date.

Resource Development – Resource development happens concurrently at the contractor and client levels.

- **At the contractor level –** Resource development is the establishment of formal and informal agreements to maximize availability and access to essential screening, support, diagnostic and treatment services. Documentation must be maintained in a resource directory developed specifically for detailing services that support BCCC-enrolled women with unmet needs.
- **At the client level –** Case managers assure that clients gain the knowledge, skills and support needed to obtain necessary services. Documentation must be made in the CCMF or the client's progress notes.

Evaluation – Evaluation is the process of assessing the effectiveness of case management activities at the client, contractor and state levels.

- At the client level – client satisfaction surveys;
- At the contractor level – internal quality assurance reviews;
- At the state level – client data for case management performance measures.

Requirements For Case Management Compliance

- Contractors must assure the case management functions occur with each enrolled woman with abnormal results or diagnosis of cancer until treatment is initiated, if indicated.
- At a minimum, all clients with an abnormal result must receive a BCCC needs assessment within 30 days of receipt of the result or prior to the initiation of the first diagnostic service.
- The needs assessment must include client consent for case management services.
- Contractor must have a system in place to ensure that monitoring of abnormal screening/diagnostic results is conducted and documented at the contractor level.
- Contractor must contact the client with abnormal screening results no later than five working days following receipt of an abnormal screening result. All screening services must be documented.

- Contractor must contact the client with abnormal diagnostic results no later than two working days following the receipt of an abnormal diagnostic result. All diagnostic services and a procedure specific consent (if applicable) must be documented.
- All contact attempts can be made by office visit, telephone, and home visit or by mail. Attempts to contact the client must be written or presented verbally (when appropriate) in the client's primary language, including appropriate provisions for the visually and hearing impaired.
- The contractor must attempt to obtain in writing and document in the client record informed refusal from the client if the client fails to keep appointments or refuses recommended procedures. If the client cannot or will not sign an informed refusal, the contractor must document verbal refusal. Before closing the client record as a refusal, a thorough review of the client's plan, recommendations, and case manager's actions must be conducted to ensure proper closure.
- Before a contractor can consider a client "lost to follow-up," the contractor must have at least three documented separate attempts to contact the client, with the last attempt sent by certified mail.
- Within one month after the client and case manager complete the case management plan, the case manager must follow-up and document that the service was actually implemented; and that there is written validation of final diagnosis.
- As additional needs are identified, they are recorded on the plan and the accompanying services and time frames are indicated.
- Contractors must notify the BCCC state office in writing when diagnostic and/or treatment needs cannot be met due to non-availability of resources.

- Contractors must develop and maintain a resource directory containing information on services that could support women with unmet needs who are eligible for BCCC.

TREATMENT

- Contractors are required to provide follow-up of clients with abnormal results and to initiate treatment for clients with a diagnosis of cancer.
- The Breast and Cervical Cancer Treatment Act, provides Medicaid coverage for breast and/or cervical cancer treatment to eligible clients screened or diagnosed with BCCC funds. The Act allows BCCC contractors to determine presumptive Medicaid eligibility for clients in order to facilitate cancer treatment.
- BCCC contractors are required to submit clients' applications for Medicaid eligibility to the Department of State Health Services with a copy to the BCCC central office. Contractors or their subrecipients must be enrolled as Medicaid providers in order to apply for BCCC funds.

BREAST AND CERVICAL CANCER TREATMENT ACT

The Breast and Cervical Cancer Prevention and Treatment Act of 2000 (Act) gives states the authority to provide Medicaid eligibility to low income women previously not eligible under the Medicaid program. The Centers for Medicare and Medicaid Services (CMS) approved a Medicaid state plan amendment to allow Texas to provide full Medicaid benefits to uninsured women under age 65 who are screened or diagnosed through the CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and are in need of treatment for certain breast or cervical cancer.

In Texas, the NBCCEDP is administered by the DSHS Breast and Cervical Cancer Control (BCCC). BCCC contractors/providers are responsible for assisting with completion of the Health and Human Services Commission (HHSC) medical assistance application (Form 1034) and determining presumptive eligibility for qualified clients. It is HHSC's responsibility to enter the presumptive determination into the HHSC database, make a final Medicaid eligibility determination, and send the client notification.

Eligibility – To qualify for the Treatment Act, the woman:

- Must have been screened for breast or cervical cancer under the CDC Breast and Cervical Cancer Early Detection Program, and found to need treatment for one of the following biopsy-confirmed diagnoses for breast or cervical cancer: CINIII, severe dysplasia, carcinoma in-situ, invasive cervical cancer, or invasive breast cancer; and
- Must not be insured, that is, she must not otherwise have creditable coverage (including current enrollment in Medicaid). There is no requirement that there be a waiting period of prior uninsured status before a woman screened under BCCC can become eligible for Medicaid; and
- Must be under age 65; and
- Must be a citizen or qualified alien.

Screened Under the Program – In Texas a woman has been "screened under the program" if CDC funds paid for all or part of the cost of her screening services. The BCCC contractor/provider is responsible for providing DSHS with verification that the woman was screened under the CDC program.

A woman is considered screened under the BCCC and may be eligible for Medicaid services if she received a screening mammogram, clinical breast exam, or Pap test; or she received diagnostic services following an abnormal clinical breast exam, mammogram, or Pap test, which leads to a diagnosis of breast or cervical cancer.

Need Treatment – A woman is considered to "need treatment" if, in the opinion of the individual's treating health professional (i.e., the individual who conducts the screen or any other health professional with whom the individual consults), and diagnostic evaluation following the clinical screening indicates that the woman is in need of treatment services.

Presumptive Eligibility – Presumptive eligibility is a Medicaid option that allows states to enroll Medicaid applicants for a limited period of time before a Medicaid determination is completed, based on a determination by a Medicaid provider of likely Medicaid eligibility. Presumptive eligibility facilitates the prompt enrollment and immediate access to services for women who are in need of treatment for breast or cervical cancer.

Presumptive eligibility begins on the date that a provider determines that the woman appears to meet the eligibility criteria described above. If there is doubt as to whether a client qualifies for Medicaid services, the contractor/provider does not make a presumptive eligibility determination, but completes the medical assistance application and forwards it to DSHS with appropriate accompanying documentation.

Eligibility Period – A woman's eligibility for coverage under the Act begins on the date of diagnosis of breast or cervical cancer. A woman's eligibility for coverage under the Act may begin up to three months prior to the month in which she applies for Medicaid, if as of this earlier date she would have met all eligibility requirements under the state plan.

Eligibility for coverage ends when the woman no longer meets the criteria for this eligibility category (for example, because she has attained age 65 or has creditable coverage, or no longer needs treatment for breast or cervical cancer).

A woman is not limited to one period of eligibility. A new period of eligibility and coverage commences each time a woman is screened under BCCC, found to need treatment of breast or cervical cancer, and meets all other eligibility criteria.

Coverage – A woman is entitled to full Medicaid coverage while in active treatment for breast or cervical cancer; coverage is not limited to coverage for treatment of breast or cervical cancer.

Verification of Citizenship and Identity – As part of Public Law 109-171, Deficit Reduction Act of 2005, individuals declaring to be a United States (U.S.) citizen or nationals of the U.S. must provide evidence of citizenship when applying for or receiving Medicaid benefits. Documented verification must establish both citizenship and identity. The new law does not affect current policy regarding qualifying immigrants/aliens and does not change the verification requirements to establish qualified alien status.

The Medicaid rules that govern citizenship and alienage apply to the Act. In general, to be eligible for Medicaid an individual must either be a citizen or a qualified alien. In Texas, legal permanent residents who arrived in the United States after August 21, 1996 are barred from receiving Medicaid. If the provider is uncertain if a woman meets citizenship and alienage status, the completed 1034 should be submitted for processing and determination. When citizenship and alienage is in question, the woman is not presumptively eligible.

BCCC Contractor/Provider Responsibilities – BCCC contractor/provider will be responsible for:

- determining BCCC eligibility;
- diagnosing qualifying condition for medical assistance;
- assisting in completing medical assistance application;
- determining client presumptive eligibility;
- faxing the following medical assistance application and documents to the BCCC case management coordinator at DSHS:
  - Form 1034
  - qualifying condition pathology report
  - citizenship and identity verification
  - BCCC data forms
- calling the BCCC case management coordinator to ensure/confirm that he/she has received the application and documents.

Timeframe – Medical assistance application and documents must be submitted to the BCCC case management coordinator at DSHS no later than 2 working days from the date the presumptive eligibility determination is made.

BCCC State Office Responsibilities – BCCC case management coordinator will be responsible for confirming BCCC eligibility; and, submitting application with required documentation to the Medicaid unit of HHSC.

Timeframe – Confirmed Medical Assistance Application must be submitted to HHSC Medicaid Unit within 2 workdays of receipt of the application.

HHSC Medicaid Unit Responsibilities – HHSC will be responsible for:

- routing the Medical assistance application (Form 1034) to designated certification staff;
- reviewing application for presumptive eligibility;
- manually completing data entry to certify presumptive client as an eligible recipient to initiate presumptive coverage;
- completing BCCC Medicaid Worksheet (Form 1105) to make final eligibility determination; and
- mailing notification of Medicaid eligibility to client.

Timeframe – Presumptive eligibility will be determined within 2 workdays of receipt of the application packet.

Eligibility for applications that are not “presumed eligible” will be determined within 45 calendar days of receipt of the application packet.

Contact Information – For additional information and/or questions regarding the Breast and Cervical Cancer Treatment Act contact:

BCCC Case Management Coordinator
Telephone Number: (512) 458-7796
Fax Number: (512) 458-7650

Email Address: isa.covio@dshs.state.tx.us
Web address: http://www.dshs.state.tx.us/bcccs/

For client eligibility determination questions, call:
Centralized Benefits Services
1-800-248-1078

COMMUNITY EDUCATION

Contractors must:

- implement strategies to enroll women in the BCCC including:
    - identifying the priority populations to receive information and
    - establishing relationships with internal and external partners to reach eligible women in the priority populations.
- provide information to each eligible woman in her primary language;
- provide access to information that is culturally sensitive, linguistically appropriate and also available to the visually and hearing impaired; and
- conduct outreach activities if less than 75% of all mammograms are provided to women ages 50-64, or the projected number of women to be screened is not reached.

Section III
Reimbursement, Data Collection and Reporting

Purpose: Section III provides policy requirements for submitting reimbursement, data collection and required reports.

REQUIREMENTS FOR REIMBURSEMENT

Billing Procedures for All BCCC Contractors – Purchase vouchers must be submitted at least monthly and within 30 days following the end of the month covered by the reimbursement request. All final claims for reimbursement must be submitted 90 days following the end of the contract period. Contractors must have payments direct deposited (as applicable) according to Government Code Section 403.016 (C) and may only bill for complete services. Complete services include complete breast cancer screening and cervical cancer screening according to standards and policies for breast cancer/cervical cancer screening. Contractors can charge only for "**satisfactory**" pap tests to BCCC.

Voucher Name: State of Texas Purchase Voucher-TDH Form B-13

Submission Date: Within 30 days following the end of the month

Submit Copy to:

Name of Unit/Branch	Original Required		Accepts Fax, Mail, or Email	# Copies
	Yes	No		
Contract Development & Support Branch (CDSB)		X	Fax, Mail, or Email	1
Accounting Section/Claims Processing Unit (CPU)		X	Fax, Mail, or Email	1

Instructions: Attach SUM Form to B-13

Clinical FFS, Support Fees, Case Mgm't Services, and Professional Education Travel for Contractors

A. The above listed services must be submitted on the Texas Purchase Voucher (Form B-13) with a BCCC Summary Billing form(SUM form) that provides detail backup that agrees with the B-13 Voucher. Each of the above categories must be broken out separately on the B-13 and a total provided for all categories

NOTE: Professional Education Travel must be SUBMITTED SEPARATELY ON A B-13.

If a voucher covers more than one month, each month must be broken out prior to calculating a total. The ser/del date on the B-13 represents all months that are covered by the SUM billing detail. The support fee cannot exceed 10% of the clinical services. It **MUST NOT** include Case Management Fee For Service.

Voucher Name: Summary Billing (SUM) Form				
Submission Date: Within 30 days following the end of the month				
Submit Copy to:				
Name of Unit/Branch	**Original Required**		**Accepts Fax, Mail, or Email**	**# Copies**
	Yes	**No**		
Contract Development & Support Branch (CDSB)		X	Fax, Mail, or Email	1
Instructions: Attach SUM Form to the B-13				
The Summary Billing form is the detail that backs up the dollars stated on the B-13. It should be grouped by				
each month, sub-totaled by month, page total and a Grand Total for all pages on the last detail page. The				
procedure fees must match the BCCC fee schedule for the current fiscal year. **PROFESSIONAL EDUCATION**				
Travel should be noted on the Summary Billing form if listed on the B-13. It should include number of				
persons traveling, inclusive dates of travel, and name of class attended.				

Additional Requirements for Reimbursement for Non Health Service Region Contractors

- Claims for reimbursement for clinical services, support services, and fee-for-service case management must be made using the State of Texas Purchase Voucher (Form B-13) and the BCCC Summary Billing (SUM) Form.
- Contractors must submit the B-13 and the SUM Form to:

  Department of State Health Services
  Fiscal Division-Accounts Payable
  1100 West 49th Street
  Austin, Texas 78756-3199

Additional Requirements for Reimbursement for Health Service Region 4/5 and South Texas Health Care System Providers

- Claims for reimbursement are billed using the budget number assigned by the Department of State Health Services.
- Contractors must submit the SUM Form directly to the BCCC state office at:

  Department of State Health Services
  Contract Development and Support Branch
  1100 West 49th Street, Mail Code 1914
  Austin, Texas 78756

Fee for Service Clinical and Case Management Services for Contractors – Claims for reimbursement of fee for service clinical and case management services must be submitted at least monthly using the State of Texas Purchase Voucher (Form B-13) and

a BCCC Summary Billing (SUM) form. Contractors must indicate separately on the voucher the respective amounts claimed for clinical services, support services, and fee-for-service case management. Support services may only be claimed in association with clinical procedures, and may not exceed ten percent of the amount of clinical services claimed on a voucher.

Case management services must be provided to a woman with abnormal results whether or not the contractor receives case management funds. Diagnostics are required in order to bill for case management. As long as a case management needs assessment has been completed, contractors can bill for case management services provided to women with abnormal results who are lost to follow-up or have refused further services. If billing for case management at 6-month follow-up, the case management needs assessment should be updated.

Professional Education Travel for Contractors – Claims for reimbursement must be submitted on the Texas Purchase Voucher (Form B-13) with a BCCC Summary Billing form (SUM form that provides detail backup that agrees with the B-13 Voucher.) Each of the above categories must be broken out separately on the B-13 and a total provided for all categories.

Professional Education Travel must be SUBMITTED SEPARATELY ON A B-13. If a voucher covers more than one month, each month must be broken out prior to calculating a total. The ser/del date on the B-13 represents all months that are covered by the SUM billing detail. The support fee cannot exceed 10% of the clinical services. It MUST NOT include Case Management Fee For Service.

Fee for Service Clinical and Case Management Services for Health Service Region 4/5 and South Texas Health Care System Providers – Claims for reimbursement are billed using budget number assigned by the Department of State Health Services and a BCCC Summary Billing (SUM) form is sent to the BCCC state office.

Instructions for completing the Summary Billing (SUM) form – Use the SUM form to itemize fee for service clinical and case management procedures to be billed to the BCCC. A SUM form must be submitted with a B-13 voucher form for payment to be authorized.

Review each completed BCCC data form (D-19b; D-19c; D-23; D-24) for women that received services in the billing month and identify services that are reimbursable with BCCC funds. Entries on the SUM Form must be grouped and sub-totaled by month. The total per month on the SUM form must equal the entries on the B-13.

To complete the SUM form:

- Print the unique identifying number of the client in the first column (CD Number).
- Print the procedure name and CPT code for the procedure in the second column (CPT Code/ Procedure); most women will have more than one billable procedure and more than one line will be used;

- Enter the date of the procedure (MM/DD/YY) in the third column (Date of Procedure);
- Enter the amount to be billed to CDC in the fourth column (Billing Amount (CDC)).
- Enter the subtotal for CDC billable procedures on the row for subtotals at the bottom of the page.
- Enter the "Grand Total" in the space provided (first page only). This is the sum of all subtotals on all pages submitted with voucher.
- Use as many pages as needed, following the same instructions for all pages, making sure to number each page.

Note: Procedures funded by a source other than CDC should <u>not</u> be reported on the SUM form (although they should still be reported on the appropriate D-23 or D-24 form).

DATA COLLECTION

To demonstrate the effectiveness of a breast and cervical cancer screening program, data collection is necessary. As a result, the Centers for Disease Control and Prevention (CDC) has established data collection as a program requirement.

Minimum Data Elements – The Minimum Data Elements (MDE's) is the set of data CDC has determined to be the basic elements necessary to effectively measure the quality of BCCC services and adherence to federal requirements. CDC uses the MDE's to measure BCCC performance.

Purpose – The purpose of data collection is to provide feedback to the CDC, the state office, and contractors on service delivery. Data is collected for each client until her screening cycle closes.

A **screening cycle** is the time period from the first screening exam until:
- Final diagnosis is reached or treatment is initiated.
- Client is lost to follow-up.
- Client refuses needed procedures.

How is this data used? – Data collection allows programs to:
- Better understand the population served.
- Monitor trends in service delivery.
- Demonstrate program success.
- Identify needed improvements.
- Contribute to the growing body of knowledge about breast and cervical cancer.

Data also is used in:
- **Outreach**: Are you reaching your priority population? Are women at higher risk for developing breast and/or cervical cancer being reached?
- **Quality assurance**: Does service delivery occur within established timelines? Are clients receiving appropriate services? Are results being received in a timely manner?
- **Case management**: Are BCCC clients getting lost in the health care system? Are too many clients refusing services?

How often do I submit forms?

- Normal Screening: Submit data forms within 30 days of the screening result date (CBE/mammogram or Pap, whichever is later).
- Abnormal Screening with Follow-up: Submit data forms within 30 days of the final diagnosis or treatment status date, whichever is later.
- Submit forms ***at least*** once a month.
- Include a completed "Batch Control" sheet with all data forms being submitted for the first time. This sheet records the quantity of data forms being submitted. You may use the sheet the state office provides or develop one on your own with the same content.
- Separate data forms with corrections from the forms being submitted for the first time. Data forms with corrections do not require a batch control sheet.

Where do I send forms?

Mark all submission packages containing client information **"Confidential."** Data form and batch control sheet submissions should be addressed to:

Texas Department of State Health Services
Preventive and Primary Care Unit
1100 W. 49th Street, Mail Code 1923
Austin, Texas 78756-3199
CONFIDENTIAL

Obtaining Forms and Supplies

The AG-30, Requisition for Office Supplies/Forms/Literature form is to be used for obtaining most items needed for the BCCC. The form can be found at: http://dbs.dshs.state.tx.us/mamd/litcat/AG-30.asp. Below are items that may be ordered using the AG-30 form.

Item	Description	Obtain Thru	Order option: Phone/Fax #	Order option: On-line address
*M-47	State Cytology laboratory form (for Pap specimens)	Women's Health Lab	ph: 210/531-4596 fax: 210/531-4506	http://dbs.dshs.state.tx.us/mamd/litcat/default.asp
*M-47	State Cytology laboratory form (for Pap specimens)	DSHS Warehouse	ph: 512/458-7761	http://dbs.dshs.state.tx.us/mamd/litcat/default.asp
Pap Supplies	Cytobrushes, slides, etc.	Women's Health Lab	ph: 210/531-4596;or 888/440-5002 fax: 210/531-4506	n/a
Pap Supplies	Cytobrushes, slides, etc.	DSHS Pharmacy	ph: 512/458-7500 fax: 512/458-7489	n/a
B-13	State Purchase Vouchers (reimbursement requests)	BCCC	ph: 512/458-7796 fax: 512/458-7650	n/a

***The M-47 State Cytology Laboratory forms used with Pap specimens are designated for contractors using the State Laboratory (Texas Center for Infectious Diseases-TCID) only**. Contractors using private labs will need to obtain laboratory forms through the Pap facility utilized. However, *all* contractors, regardless of the lab they are using, may obtain Pap supplies through the Texas Department of State Health Services (DSHS) Pharmacy or Women's Health Lab by requesting them on the AG-30 order form. Contractors using TCID may also request mailing labels for Pap specimens on the AG-30 order form. For your reference, please note the customer service telephone number for the Women's Health Laboratories: (888) 440-5002 or (210) 531-4596.

To order supplies from the DSHS Pharmacy complete the DSHS AG-30 form by filling out the "quantity" and "description" columns and the "ship to address" box. Sign the form in the "authorized signature" box and the mail the AG-30 form to the Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas 78156, attention Pharmacy or fax to (512) 458-7489.

BCCC Data Forms – The state office distributes data forms every six months (March and September). The shipments are based on the average number of individual screens conducted over the last six months and prior use for each contractor. A percentage of extra forms are included to allow for growth in caseload. Do not submit an AG-30 form to order data forms. Additional data forms may be requested by telephone at 512.458.7796 any time during the year. The state office will ship data forms to the main contractor site.

Breast and Cervical Cancer Screening Forms (D-19B, D-19C) – A Breast and/or Cervical Cancer Screening form should be initiated for every BCCC client prior to receiving screening services. The forms are initiated by completing the Patient Information section, the Breast Cancer History section, and the Cervical Cancer History section at the top of the form. The rest of the form is completed as screening services are provided.

These forms capture demographics, brief medical history, screening, and referral information. The D-19B is the data form used to collect breast cancer screening information and the D-19C is used to collect cervical cancer screening information.

Breast and Cervical Cancer Diagnostic Forms (D-23, D-24) – These forms capture procedures, dates, results, funding source, testing location, diagnosis, and treatment status of diagnostic evaluation clients.

Monthly Submission – Each BCCC contractor should send data forms to the BCCC state office **at least once every month.**

Medical Records – A copy of each screening and/or diagnostic form must be kept in the medical record of every woman who receives services through BCCC. The administrative office of each BCCC contractor must have immediate access to a copy of every screening and/or diagnostic form upon request.

BREAST AND CERVICAL CANCER SCREENING FORMS

PLEASE PRINT

Contractor No: ___	Clinic No: ____	Visit Date: __/__/____	Chart No: _____	CD Number: ___ __ ____

Contractor No. – This is the three-digit identification number **assigned to each BCCC contractor by the state office.**

Clinic No. – This is a **four digit identification number** to distinguish between individual clinic locations. (BCCC contractors may provide services through many different clinic sites.) The BCCC contractor assigns this number. If a client receives services at multiple clinic locations, this number should represent the clinic responsible for providing screening services.

Visit Date – This is the date of the first BCCC-funded service reported on the form. If the client received screening services from a non-BCCC funded source, the visit date is the day the client met with the BCCC contractor for diagnostic services. As with all dates on this form, the date should be written in the "mm/dd/yyyy" format, i.e., "February 15, 2003" is written in the format "02/15/2003."

Chart Number – This is the chart number or medical record number or client ID number assigned by the clinic or BCCC contractor. It may include up to ten (10) characters and contain letters, numbers, spaces, and dashes.

CD Number – The CD Number is a **nine digit number** used to uniquely identify all clients served by the BCCC. Please note the following:

- Clients are assigned one unique CD number upon enrollment into the program.
- Under no circumstances does a client's CD number change. Clients keep their originally assigned CD number through the life of the program (even if they transfer to another contractor within the BCCC).
- CD numbers are unique to each client, therefore CD numbers may not be shared or duplicated.

BCCC contractors are responsible for creating and assigning CD numbers. CD numbers are created according to the following rules:

1) The first three digits are the site number assigned to the BCCC contractor. The contractor number will always be 3 digits (include any leading zeros).

   For example, the first three digits of all CD numbers assigned by the provider whose site number is seven would be "007", not "7."

2) The next two digits represent the calendar year in which the CD number is assigned. All clients enrolled on or after 1/1/2000 will have the letter "A" in the first position,

and the number “0" in the second position. The “A” represents the new millennium and the “0" represents which year of the millennium.

For example, for a client enrolled in the year 2000, their two digits for the calendar year would be “A0". A client enrolled in the year 2001, would enter “A1" in these two digits. For the year 2003 enrollees, it would be “A3", etc....

3) The remaining four digits may be assigned by the contractor in any way desired. They must be in the range of 0001 through 9999. All four digits must be completed with numerals (letters, spaces, or dashes cannot be used).

For example, in the year 2002, site 007 could assign valid CD numbers such as: 007 A2 0025, 007 A2 0103 and 007 A2 8914.

The following would be **invalid** CD numbers:

7 A2 0200 leading zeros missing, making it a less than 9 digit CD#.
007 A2 025 one numeral missing in the last 4 digits, making it a less than 9 digit CD#.
007 A2 -123 no dashes allowed, numeral needed in its place.

PATIENT INFORMATION

<table>
<tr><th colspan="6">PATIENT INFORMATION</th></tr>
<tr><td colspan="2">Last</td><td colspan="2">First MI</td><td>Maiden</td><td rowspan="3">Hispanic/Latino Origin
☐1 Yes ☐2 No ☐3 Unknown

Race (mark all that apply)
☐1 White
☐2 Black/African American
☐3 Asian
☐4 Native Hawaiian/Pacific Islander
☐5 Am Indian/Alaskan Native
☐6 Other
☐7 Unknown

_____
(Specify Other)</td></tr>
<tr><td colspan="4">Address</td><td>Social Security Number
___ ___ ___ / ___ ___ / ___ ___ ___ ___</td></tr>
<tr><td>City</td><td>State</td><td>Zip</td><td>Birth Date
___/___/___</td><td>Age</td></tr>
<tr><td>Day Phone
( ) -</td><td colspan="2">Night Phone
( ) -</td><td colspan="2"></td></tr>
</table>

Last, First, MI, Maiden – Print the client's last name, first name, middle initial, and maiden name in the spaces provided. The last name is the client's current last name (or family name). The first name should be the client's full first name. Avoid nicknames and abbreviations. A client's maiden name is her family name prior to her first marriage.

Address, City, State, Zip – Print the client's address, city, state, and zip code in the spaces provided. If the client does not maintain a permanent residence, any address where the client can receive mail should be recorded. The city name should be written without abbreviation. For the state, print the two-letter postal code (i.e., Texas is "TX"). Write the client's zip code in the space provided, along with the four-digit extension, if known.

Social Security Number – Write the client's nine-digit social security number in this space provided. If the client does not have a social security number, print **"NONE"** in this space. **Do Not Leave Blank**.

Birth Date, Age – Write the client's date of birth in this space using the format "mm/dd/yyyy." Write the client's age at the time of her visit.

Day Phone – Write a telephone number (if any) where the client can be reached during the day. **Be sure to include the area code**. The number can be the telephone number of the client's residence, work place, friend or relative.

Night Phone – Write a telephone number where the client can be reached after 6 pm. **Be sure to include the area code**. Like the day phone field, this can be the telephone number of the client's residence, work place, friend, or relative.

Race – Indicate the client's race or ethnicity by checking **all appropriate boxes**. If none of the categories apply check the number six for "Other" and print the appropriate race in the space provided. If race is "Unknown" check number seven. If the client is multi-racial, you may mark multiple categories as appropriate. (Race is self-reported.)

BREAST CANCER SCREENING FORM
BREAST CANCER HISTORY

BREAST CANCER HISTORY
1. Has the client ever had a mammogram before? □1 Yes → Approximate Date: ____/____/____ □2 No
2 Did breast symptoms lead to this visit? □1 Yes □2 No □3 Unknown
3. Is this a short -term follow-up visit? □1 Yes □2 No
4. Has the client ever had breast cancer? □1 Yes □2 No □3 Unknown
5. Does the client have a breast implant? □1 Yes □2 No □3 Unknown

1. Has the client ever had a mammogram before?

If a client had a mammogram at any time prior to her current visit, check **"Yes"** and write the date of the most recent mammogram prior to the referring mammogram. If the exact date is unknown, estimate or provide as much information as possible (i.e., "around 1975"). If a client has never had a mammogram before, or if a client is not sure if they have ever had a mammogram or a "breast x-ray," mark **"No."**

2. Did breast symptoms lead to this visit?

Mark **"Yes"** if:

- A client detected symptoms that resulted in seeking breast cancer screening services; **OR**
- If they were referred to this program by a medical professional because of possible symptoms for breast cancer; **OR**
- If they are receiving breast screening services before their regular annual or biannual visit.

3. Is this a short-term follow-up visit?*

If a client is returning for a short- term follow-up visit, mark **"Yes."** If client is returning for an annual or biannual visit, mark **"No."**

4. Has the client ever had breast cancer?

If a client has ever had breast cancer, mark **"Yes."** If they have never had breast cancer, mark **"No."** If the attending clinician is unsure whether or not a client has had breast cancer, mark **"Unknown."**

5. Does The Client Have A Breast Implant?

If the client has had breast reconstruction or cosmetic breast augmentation, or if they have had any other kind of breast implant that might interfere with a normal screening mammogram, mark **"Yes."**

*To determine a **short-term follow-up**, consider the purpose of the follow-up. It is not the amount of time that passes between tests, but rather the reason that the amount of time passed. For example –

- A planned delay, such as a clinician wanting some time to pass before re-evaluating, would begin a new cycle.
- If the clinician wanted immediate diagnostic tests, but the woman or a scheduling problem delayed the tests, then the tests are a continuation of the abnormal screening cycle.

BREAST CANCER SCREENING FORM
CLINICAL BREAST EXAM (CBE)

CLINICAL BREAST EXAM (CBE)	
6.	Did the client receive a clinical breast exam this screening cycle? □1 Yes □3 No, other □4 Yes, performed elsewhere
7.	If yes, when was the CBE performed? ____/____/____.
8.	What were the results of this CBE? □1 Normal/Benign findings * □2 Abnormal - Suspicious for cancer
*	*Referral for case management and diagnostic procedures required*

6. Did the client receive a clinical breast examination this screening cycle?

Mark **"Yes"** if the client received a clinical breast examination (CBE) in the current screening cycle.

Mark **"No other"** if the client did not require a CBE this visit (i.e. short term follow-up visit or referral).

Mark **"Yes, performed elsewhere"** if the client received a CBE elsewhere within the past 30 days.

Skip to question 9 if the client did not receive a CBE.

7. If yes, when was the CBE performed?

Write the date on which the client received a CBE.

8. What were the results of this CBE?

Mark **"Normal/Benign findings"** if there were no indications that the client might have breast cancer. Benign findings such as fibrocystic changes, diffuse lumpiness, etc. should be included in this category. If the CBE revealed possible symptoms of breast cancer, such as a palpable mass, skin changes, or bloody nipple discharge, mark **"Abnormal- suspicious for cancer."**

Note: *Number 7 & 8 above must be answered even if the CBE was performed elsewhere*.

BREAST CANCER SCREENING FORM
INITIAL MAMMOGRAM

INITIAL MAMMOGRAM
9. Did the client receive a mammogram this screening cycle? □1 Yes □3 No, other □4 Yes, performed elsewhere
10. When was the mammogram performed? ____/____/____
11. When were the results received? ____/____/____
(Continued next column)

9. Did the client receive a screening mammogram this screening cycle?

Mark **"Yes"** if the client received a screening mammogram funded through the BCCC or an outside source for this screening cycle.

Mark **"No, other"** if the client is ineligible for a BCCC funded mammogram, or if they do not need a screening mammogram this visit.

Mark **"Yes, performed elsewhere"** if the client received a mammogram elsewhere within the past 90 days.

Skip to question 16 if the client did not receive a screening mammogram.

10. When was the mammogram performed?

Write the date that the client received their screening mammogram.

11. When were the mammogram results received?

Write the date that the radiologist's report was received by the BCCC contractor.

Note: *Number 10 & 11above must be answered even if the mammogram was performed elsewhere*.

BREAST CANCER SCREENING FORM
INITIAL MAMMOGRAM (CONTINUED)

INITIAL MAMMOGRAM (continued)

12. Mammogram Type:

□ 76092 (Screen) □ 76091 (Bilateral) □ 76090 (Unilateral)

13. What were the results of the initial mammogram?

□1 Negative
□2 Benign
□3 Probably benign
* □4 Suspicious
* □5 Highly suggestive of malignancy
* □6 Incomplete: needs additional imaging evaluation

* *Referral for case management and diagnostic procedures required*

14. What was the funding source for the mammogram?
□1 CDC □2 Other_____

15. What radiology facility performed the mammogram?

Facility _____

City_____ State _____ Zip_____

12. What was the type of mammogram received?

Mark the type of mammogram received. In the case of a short-term follow-up requiring a diagnostic mammogram only and the diagnostic mammogram result is negative, the D-19B will be the only form required for documentation. If the diagnostic mammogram is abnormal and further testing is required or if the recommendation for short -term follow-up is an ultrasound, a D-23 data form will also be needed to complete documentation.

13. What were the results of the initial mammogram?

Mark the mammogram results in one of the “overall assessment of findings” classification of the Final Mammography Quality Standards Act Regulations.

See Appendix A for classifications.

BREAST CANCER SCREENING FORM
INITIAL MAMMOGRAM (CONTINUED)

INITIAL MAMMOGRAM (continued)

12. Mammogram Type:

□ 76092 (Screen) □ 76091 (Bilateral) □ 76090 (Unilateral)

13. What were the results of the initial mammogram?

	□1	Negative
	□2	Benign
	□3	Probably benign
*	□4	Suspicious
*	□5	Highly suggestive of malignancy
*	□6	Incomplete: needs additional imaging evaluation

* *Referral for case management and diagnostic procedures required*

14. What was the funding source for the mammogram?
□1 CDC □2 Other_____

15. What radiology facility performed the mammogram?

Facility _____

City_____ State _____ Zip_____

14. What was the funding source for the screening mammogram?

- Mark **"CDC"** if this was a BCCC-funded mammogram.
- If not, mark **"Other"** and specify the funding source (i.e., private insurance, gratis/donated, other funding source).

15. What radiology facility performed the mammogram?

Indicate the facility name, city, and zip code of the location where the mammogram was performed, **regardless of funding source**.

BREAST CANCER SCREENING FORM
BREAST CANCER SCREENING FOLLOW-UP STATUS

FOLLOW-UP STATUS
16. Was the client referred for case management and diagnostic procedures (dx mammogram/add'l views, ultrasound, breast biopsy, fine needle aspiration)? □1 Yes □ Date referred for procedure(s): ___/___/____ *(If yes, form D-23 must follow)* □2 No □ Date of next breast screening: ___/___/____
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16. Was the client referred for case management and diagnostic procedures (dx mammogram/add'l views, ultrasound, breast biopsy, fine needle aspiration)?

Mark **"Yes"** if:
- The client was referred for case management and diagnostic procedure(s); **OR**
- The client was referred into the program for diagnostic procedure(s).

Write the date the client was referred for diagnostic procedures. Report the details of the diagnostic evaluation on the Breast Cancer Diagnostic Evaluation Form (D-23).

Mark **"No"** if:
- Cancer was not detected, client will return for next annual breast screening; **OR**
- Short-term follow-up is recommended

Write the date of the client's next breast screening (this could either be her next annual screening, biannual screening; or a short term follow-up screening). The next screening date will initiate a new screening cycle and should be reported on a new Breast Cancer Screening Form (D-19B).

For scanning legibility, the shaded area located at the bottom of the form is to remain blank for the state office date stamp.

CERVICAL CANCER SCREENING FORM
CERVICAL CANCER HISTORY

CERVICAL CANCER HISTORY

1. Has the client ever had a Pap smear before?
   □1 Yes □2 No □3 Unknown

   If yes, specify date and result: ____/____/____
   - □0 Results not known
   - □1 Negative for intraepithelial lesion or malignancy
   - □2 Atypical squamous cells of undetermined significance *(ASC-US)*
   - □3 Low grade SIL *(including HPV changes)*
   - □4 Atypical squamous cells cannot exclude HSIL (ASC-H)
   - □5 High grade SIL (with features suspicious for invasion)
   - □6 Squamous cell carcinoma
   - □7 Abnormal glandular cells (including Atypical, Endocervical adenocarcinoma in situ and Adenocarcinoma)
   - □8 Other_____

2. Has the client had a history of cervical dysplasia/cancer, HIV, HPV, or are they immuno-compromised?
   □1 Yes □2 No □3 Unknown

3. Has the client had a hysterectomy?
   □1 Yes □2 No □3 Unknown

4. If yes, was the hysterectomy performed for either cervical cancer or neoplasia?
   □1 Yes □2 No □3 Unknown

1. Has the client ever had a Pap test before?

If a client has ever had a Pap test at any time prior to her current visit, mark **"Yes"** and record the date and result of her most recent Pap test prior to the referring Pap test. If the exact date is unknown, please provide as much information as possible. If a client has never had a Pap test before, mark **"No."**

2. Has the client had a history of cervical dysplasia/cancer, HIV, HPV or are they immuno-compromised?

Mark **"Yes"** if a client has a medical history of cervical dysplasia, CIN I, CIN II, CIN III, CIS, cervical cancer, HPV, HIV, or if they are immuno-comprised.

Mark **"No"** if they have no history of cervical dysplasia, cervical cancer, HPV, or HIV.

Mark **"Unknown"** if the client is unsure whether they have ever had cervical dysplasia, cervical cancer, HPV, or HIV.

(Questions 3 and 4 continued on page III-15)

3. Has the client had a hysterectomy?

Mark **"Yes"** if the client has ever had a complete or partial hysterectomy for any reason.

Mark **"No"** if a client has never had a hysterectomy.

Mark **"Unknown"** if the client is unsure if past medical history includes a hysterectomy.

4. If yes, was the hysterectomy performed for either cervical cancer or neoplasia?

Mark **"Yes"** if the hysterectomy was performed to treat cervical cancer or neoplasia.

Mark **"No"** if the hysterectomy was for some other purpose.

Note: BCCC services provided to women whose hysterectomies were for reasons other than cervical cancer or neoplasia are non-reimbursable.
Mark **"Unknown"** if the purpose of the hysterectomy is unknown.

CERVICAL CANCER SCREENING FORM
PAP TEST

PAP SMEAR

5. Was a CBE performed this year? □1 Yes □2 No
(If CBE was abnormal, complete breast screening form)

6. Did the client receive a pelvic exam this screening cycle?
□1 Yes □2 No

7. Was the Cervix present?
□1 Yes *(Cervical Pap)* □2 No *(Vaginal Pap)*

8. Did the client receive a Pap smear this screening cycle?
□1 Yes □3 No, client refused
□2 Yes, performed elsewhere □4 No, other

5. Was a CBE performed this visit?

Mark **"Yes"** if the client received a clinical breast examination.

Mark **"No"** if the client did not receive a clinical breast examination.

If the clinical breast examination is abnormal, complete a breast cancer screening form (D-19).

6. Did the client receive a pelvic examination this screening cycle?

Mark **"Yes"** if the client received a pelvic examination.

Mark **"No"** if the client did not receive a pelvic examination.

7. Was the cervix present?

Mark **"Yes"** if enough of the cervix was present to perform a cervical Pap test.

Mark **"No"** if the cervix was not present, necessitating a vaginal Pap test.

8. Did the client receive a Pap test this screening cycle?

Mark **"Yes"** if the client received a Pap test funded through the BCCC or another source this screening cycle.

Mark **"Yes, performed elsewhere"** if the client received a Pap test elsewhere.

Mark **"No, client refused"** if the procedure is needed but refused by the client.

Mark **"No, other"** if a Pap test was not necessary.

CERVICAL CANCER SCREENING FORM
PAP TEST (CONTINUED)

PAP SMEAR (continued)

9. Is this a follow-up visit for a previous abnormal pap?
   □1Yes □2 No

10. When was the Pap smear performed? ___/___/_____

11. Was this a liquid-based test? □1Yes □2 No

12. When were the results received? ___/___/_____

13. What was the specimen adequacy of the Pap smear?
    □1 Satisfactory □2 Unsatisfactory □4 Unknown

14. What were the results of the Pap smear?
    - □1 Negative for intraepithelial lesion or malignancy
    - □2 Atypical squamous cells of undetermined significance (ASC-US)
    - □ HPV tested? □1 Negative □2 Positive
    - □3 Low grade SIL
    - □4 Atypical squamous cells cannot exclude HSIL (ASC-H)
    - □5 High grade SIL
    - □6 Squamous cell carcinoma
    - □7 Abnormal glandular cells (including Atypical, Endocervical adenocarcinoma in situ and Adenocarcinoma)
    - □8 Other _____

    □ *Referral for case management and diagnostic procedures required*

15. What was the funding source for the Pap smear?

    □1 CDC □2 Other_____

16. At what facility was the Pap smear specimen obtained?

Facility: _____.

City: _____ State: _____ Zip: _____

(Questions 9-16: Refer to the instructions on the next page for an explanation of each column.)

9. Is this a follow up visit for a previous abnormal pap?

If a client is returning for a short-term follow-up visit, mark **"Yes."** If client is returning for an annual or biannual visit, mark **"No."**

10. When was the Pap test performed?

Write the date the Pap test was performed.

11. Specimen type for Pap test?

Note if a conventional or liquid-based Pap was used.

12. When were the results received?

Write the date the Pap test results became available to the BCCC contractor. If the Pap test was performed elsewhere, record the date that the outside agency communicated the results to the provider.

13. What was the specimen adequacy of the Pap test?

This information is located on the cytopathology report from the laboratory. Unsatisfactory Pap tests are not reimbursable.

14. What were the results of the Pap smear?

Mark the results of the Pap test using the Bethesda classification system. If more than one classification applies, mark the highest. For example, if **"Negative for intraepithelial lesion or malignancy"** and **"Low grade SIL"** are noted, mark **"Low grade SIL."**

15. What was the funding source for the Pap test?

Mark **"CDC"** if this was a BCCC-funded Pap test. If not, mark **"Other"** and specify the funding source for the Pap test (i.e., private insurance, donated, etc.).

16. At what facility was the Pap test specimen obtained?

Indicate the facility name, city, and zip code of the location where the Pap test was performed, **regardless of income**.

***Note**: Number 10 thru 16 of this section should be answered even if the Pap test was performed elsewhere.*

CERVICAL CANCER SCREENING FORM
CERVICAL CANCER SCREENING FOLLOW-UP STATUS

FOLLOW-UP STATUS
17. Was the client referred for case management and diagnostic procedures (colposcopy, cervical biopsy, etc.)? ☐ 1 Yes Date referred for procedure(s): ____/____/____. ☐ 2 No Date of next cervical screening: ____/____/____ *(If yes, form D-24 must follow)*
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17. Was the client referred for case management and diagnostic procedures (colposcopy, cervical biopsy, etc.)?

Mark "Yes" if:
- The client was referred for case management and diagnostic procedure(s); **OR**
- The client was referred into the program for diagnostic procedure(s)

Write the date the client was referred for diagnostic evaluation. Report the details of the diagnostic evaluation on the Cervical Cancer Diagnostic Evaluation Form (D-24).

Mark "No" if:
- Cervical cancer was not detected, client will return for next annual/biannual screening; **OR**
- Short-term follow-up is recommended

Write the date of the client's next cervical screening (this could be her next annual screening, or a short term follow-up screening). The next screening date will initiate a new screening cycle and should be reported on a new Cervical Cancer Screening Form (D-19C).

For scanning legibility, the shaded area located at the bottom of the form is to remain blank for the state office date stamp.

All Cervical Screening Referrals Require A Diagnostic Form (D-24)

BREAST CANCER DIAGNOSTIC EVALUATION FORM (D-23)

WHEN TO COMPLETE THIS FORM

A Breast Cancer Diagnostic Evaluation Form is initiated upon referring a breast client for diagnostic treatment. This is designated at question #16 on the Breast Cancer Screening Form. The diagnostic form is to be completed as procedures are provided until a final diagnosis is reached. At that time, the form is completed and sent to the state office. The state office must receive the Breast Cancer Diagnostic Evaluation Form within 60 days of the referral date.

REMEMBER TO SUBMIT YOUR FORMS MONTHLY TO THE CENTRAL OFFICE WITH BATCH CONTROL SHEET AND UNDER CONFIDENTIAL COVER.

BREAST CANCER DIAGNOSTIC EVALUATION FORM PATIENT INFORMATION

Contractor No:	Clinic No:	Chart No:	CD Number:
__ __ __	__ __ __ __	_____	__ __ __ __ __ __ __ __ __

PATIENT INFORMATION				
Last	First MI	Social Security Number __ __ __/__ __/__ __ __ __	Birth Date __ __/__ __/__ __	Age

Patient Information

Write the contractor number, clinic number, chart number, CD number, client's name, social security number, date of birth, and age at the top of the form. This information can be obtained from the Breast Cancer Screening Form completed for the client.

Don't Forget Client's CD Number OR Your Contractor Number

BREAST CANCER DIAGNOSTIC EVALUATION FORM
DIAGNOSTIC PROCEDURES

DIAGNOSTIC PROCEDURES					
1. Mammogram Type 1 Unilateral 76090 2 Bilateral 76091	**2. Ultrasound** 76942 76645	**3. Breast Biopsy** Aspiration 19000 Needle Core 19100 Excisional 19120 With rad mkr 19125 Add'l lesion 19126 Preop Loe wire 19290	**4. Fine Needle/ Cyst Aspiration** 10021	**5. Physician Consultation** 99241 99242 99243 99244 *Exam performed by surgeon/other breast specialist*	**6. Add'l Diagnostic Procedures** ***Without*** **Results (mark all completed procedures)** Date Performed Procedure /Fund Source Mammographic guidance for needle placement (76096) __/__/__ 1 CDC 3 Other Surgical Pathology (88305) __/__/__ 1 CDC 3 Other Anesthesia (00400) __/__/__ 1 CDC 3 Other Stereotactic Localization (76095) __/__/__ 1 CDC 3 Other **Add'l Diagnostic Procedures *With* Results** For each procedure listed below, use the ***Results*** in the previous columns to record the appropriate result(s). _____ ___/___/___ CPT Code Date Results:_____ Fund: 1 CDC 3 Other _____ ___/___/___ CPT Code Date Results:_____ Fund: 1 CDC 3 Other
Procedure Status: 1 performed 2 refused	**Procedure Status:** 1 performed 2 refused	**Procedure Status:** 1 performed 2 refused	**Procedure Status:** 1 performed 2 refused	**Procedure Status:** 1 performed 2 refused	
Date Performed ____/_____/__ _____ ___ (Site)	**Date Performed** ____/_____/____ _____ (Site)	**Date Performed** ____/_____/____ _____ (Site)	**Date Performed** ____/_____/____ _____ (Site)	**Date Performed** ____/_____/____ _____ (Site)	
Results Received ____/____/____	**Results Received** ____/____/____	**Results Received** ____/____/____	**Results Received** ____/____/____	**Results Received** ____/____/____	
Results: 1 Negative 2 Benign 3 Probably benign 4 Suspicious 5 Highly suggestive of malignancy 6 Incomplete: needs add'l imaging evaluation	**Results:** 1 Negative 2 Cystic 3 Solid 4 Suspicious or Indeterminate	**Results:** 1 Benign 2 Malignant	**Results:** 1 Normal 2 Abnormal 3 Indeterminate	**Results:** 1 Normal 2 Abnormal 3 Other benign findings	
Funding Source: 1 CDC 3 Other	**Funding Source:** 1 CDC 3 Other	**Funding Source:** 1 CDC 3 Other	**Funding Source:** 1 CDC 3 Other	**Funding Source:** 1 CDC 3 Other	

(Questions 1-6: Refer to the instructions on the next page for an explanation of each column.)

Procedure

- These columns are used for indicating the procedures a client receives.
- If a client receives a diagnostic procedure not listed, specify that procedure under column #6 “Additional Diagnostic Procedures”. Print the name of the procedure, the date performed and the five digit CPT (Current Physician's Terminology) code.
- If a client receives two of the same procedures, list one in its appropriate column and the other under column #6,“Additional Diagnostic Procedures.”

See Appendix C for more information on breast cancer diagnostic procedure definitions.

Procedure Status

Mark **“1"** in the status column for each procedure that was performed.
Mark **“2"** if the procedure is needed but has been refused by the client.

Date Performed/Site

For each procedure that was performed (Status marked "1") write the date that the service was performed in this column. An optional line is provided to record the site where the service was performed.

Results Received

Write the date that the contractor received the results of the diagnostic procedure in this column. This date must be on or after the date performed.

Results

Mark the appropriate diagnostic result for each procedure performed.
***Note**: Diagnostic mammogram results should be indicated by using the overall final assessment classifications.*

Funding Source

Mark **"1"** in this column if the procedure was funded by the CDC.
Mark **"3"** if the procedure was funded by some other source (donated, private insurance, other funding source).

BREAST CANCER DIAGNOSTIC EVALUATION FORM
DIAGNOSTIC EVALUATION STATUS

DIAGNOSTIC EVALUATION STATUS

7. What date was the client referred for a diagnostic evaluation for possible breast cancer? _____/_____/_____

NOTE: This date will match the date on the corresponding D-19B Screening Form (#16).

8. What is the status of the diagnostic evaluation?

☐ **1 Evaluation complete; a final diagnosis has been reached**

☐ **2Client refused needed procedures before a final diagnosis could be reached**

☐ **3Client is lost to follow-up**

9. When was the evaluation completed (date of determining procedure), refused, or the client lost to follow-up? (*see 8*)

____/_____/_____

10. If the evaluation is complete, was breast cancer detected?

☐ **1 Yes ⏩ *(staging info required)***

☐ **2 No ⏩ specify next visit interval:**

____ **recommend short term follow-up** ***(skip to #14)***

____ **recommend return to annual screening** ***(skip to #14)***

7. What date was the client referred for a diagnostic evaluation for possible breast cancer?

Write the date that the client was referred for diagnostic procedures. This date must match the referral date under question # 16 of the Breast Cancer Screening Form.

8. What is the status of the diagnostic evaluation?

- **Evaluation complete**: Mark if a final diagnosis has been reached.
- **Client refused needed procedures before a final diagnosis could be reached**: Mark if a final diagnosis cannot be reached because a client refused needed procedures.
- **Client is lost to follow-up**: Mark if three attempts to contact the client have failed, with the third attempt being by certified mail.

*Refer to Appendix D for diagnostic evaluation status definitions***.**

BREAST CANCER DIAGNOSTIC EVALUATION FORM
DIAGNOSTIC EVALUATION STATUS (CONTINUED)

DIAGNOSTIC EVALUATION STATUS

7. What date was the client referred for a diagnostic evaluation for possible breast cancer? ____/____/____
NOTE:This date will match the date on the corresponding D-19B Screening Form (#16).

8. What is the status of the diagnostic evaluation?
- ☐ **1 Evaluation complete; a final diagnosis has been reached**
- ☐ **2 Client refused needed procedures before a final diagnosis could be reached**
- ☐ **3 Client is lost to follow-up**

9. When was the evaluation completed (date of determining procedure), refused, or the client lost to follow-up? (*see 8*) ____/____/____

10. If the evaluation is complete, was breast cancer detected?
- ☐ **1 Yes ⏩ *(staging info required)***
- ☐ **2 No ⏩ specify next visit interval:**

____ **recommend short term follow-up** ***(skip to #14)***
____ **recommend return to annual screening** ***(skip to #14)***

9. When was the evaluation completed, refused, or the client lost to follow-up?

If the evaluation is complete, write the date of determining procedure.

If the client refused needed procedures before a diagnosis could be made, write the date the client refused procedures.

If the client is lost to follow-up, write the date that you mailed the certified letter.

10. If the evaluation is complete, was breast cancer detected?

Mark "**Yes**" if question 9 is marked "Evaluation complete" and breast cancer was detected. Answer questions 11 through 13. *Staging information consisting of discharge summary (if applicable), operative report and surgical pathology is required.*

Note: Send staging information to:

Texas Department of State Health Services
Preventive and Primary Care Unit
1100 W. 49th Street, Mail Code 1923
Austin, Texas 78756-3199

Mark "**No**" if breast cancer was not detected and specify next visit interval - then skip to question 14.

BREAST CANCER DIAGNOSTIC EVALUATION FORM
BREAST CANCER TREATMENT STATUS

BREAST CANCER TREATMENT STATUS

COMPLETE #11-#13 ONLY IF THE CLIENT IS DIAGNOSED WITH BREAST CANCER

11. What is the treatment status for breast cancer?
- ☐ **1 Treatment initiated or complete**
- ☐ **2 Client refused treatment**
- ☐ **3 Client is lost to follow-up**
- ☐ **4 Treatment scheduled or pending**

12. What date was treatment initiated, refused, or client lost to follow-up? (*see 11*) _____/_____/_____

13. Where was treatment initiated?
Hospital/Facility: _____
City:_____ **Zip:**_____

14. When is the client's next breast screening? _____/_____/_____

Answer questions 11 through 13 only if the client has breast cancer.

11. What is the treatment status for breast cancer?

- Mark "**Treatment initiated or complete**" if treatment for breast cancer has begun. This category may also be marked if the removal of the breast mass was considered treatment by the physician.
- Mark "**Client refused treatment**" if the client refused needed treatment.
- Mark "**Client is lost to follow-up**" if three attempts to contact the client have failed with the third attempt being by certified mail, if the client moved out of the state, or if the client died.
- Mark "**Treatment is scheduled or pending**" if breast cancer treatment is being arranged, but there will be a delay of 90 days or more before treatment actually begins.

See Appendix E for treatment status definitions.

BREAST CANCER DIAGNOSTIC EVALUATION FORM
BREAST CANCER TREATMENT STATUS (CONTINUED)

BREAST CANCER TREATMENT STATUS
COMPLETE #11-#13 ONLY IF THE CLIENT IS DIAGNOSED WITH BREAST CANCER
11. What is the treatment status for breast cancer? ☐ **1 Treatment initiated or complete** ☐ **2 Client refused treatment** ☐ **3 Client is lost to follow-up** ☐ **4 Treatment scheduled or pending**
12. What date was treatment initiated, refused, or client lost to follow-up? (*see 11*) _____/_____/_____
13. Where was treatment initiated? **Hospital/Facility:** _____ **City:**_____ **Zip:**_____
14. When is the client's next breast screening? _____/_____/_____
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12. What date was treatment initiated, refused, or the client lost to follow-up?

Write the date the client began to receive breast cancer treatment (this might be the same as the biopsy date). If the client refused treatment, write the date the client refused treatment. If the client is lost to follow-up, record the date that certified letter was mailed.

See Appendix E for treatment status definitions.

13. Where was treatment initiated?

Document the name of the principal hospital or facility at which the client received breast cancer treatment. Document the name of the city and the zip code in which the hospital or facility is located.

14. When is the client's next breast screening?

Write the date of the client's next annual/biannual or short-term follow-up visit.

For scanning legibility, the shaded area located at the bottom of the form is to remain blank for the state office date stamp.

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM

WHEN TO COMPLETE THIS FORM

A Cervical Cancer Diagnostic Evaluation Form is initiated upon referring a cervical client for diagnostic treatment. This is designated on question #18 on the Cervical Cancer Screening Form. The diagnostic form is to be completed as procedures are provided until a final diagnosis is reached. At that time, the form is completed and sent to the state office. The state office must receive the Cervical Cancer Diagnostic Evaluation Form within 60 days of the referral date.

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM PATIENT INFORMATION

Contractor No:	Clinic No:	Chart No:	CD Number:	
_ _ _	_ _ _ _	_____	_ _ _ _ _ _ _ _	
PATIENT INFORMATION				
Last	**First** **MI**	**Social Security Number**	**Birth Date**	**Age**
		_ _ _/_ _/_ _ _ _	_ _/_ _/_ _	

Patient Information

Write the contractor number, clinic number, chart number, CD number, client's name, social security number, date of birth; and age at the top of the form. This information can be obtained from the Cervical Screening Form.

THE CD NUMBER ON THE DIAGNOSTIC EVALUATION FORM MUST BE THE SAME AS ON THE SCREENING FORM.

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM
DIAGNOSTIC PROCEDURES

DIAGNOSTIC PROCEDURES				
1. Colposcopy Only **57452**	**2. Colposcopy & Biopsy** **57454**	**3. Other/CPT Code** _____ _____	**4. Other/CPT Code** _____ _____	**5. Other/CPT Code** _____ _____
Procedure Status: ☐ **1 performed** ☐ **2 refused**	**Procedure Status:** ☐ **1 performed** ☐ **2 refused**	**Procedure Status:** ☐ **1 performed** ☐ **2 refused**	**Procedure Status:** ☐ **1 performed** ☐ **2 refused**	**Procedure Status:** ☐ **1 performed** ☐ **2 refused**
Date Performed _____/_____/_____ _____ ***(Site)***	**Date Performed** _____/_____/_____ _____ ***(Site)***	**Date Performed** _____/_____/_____ _____ ***(Site)***	**Date Performed** _____/_____/____ _____ ***(Site)***	**Date Performed** _____/_____/_____ _____ ***(Site)***
Results Received _____/_____/_____	**Results Received** _____/_____/_____	**Results Received** _____/_____/_____	**Results Received** _____/_____/_____	**Results Received** _____/_____/____
Results: ☐ **1 Normal** ☐ **2 Abnormal**	**Results:** ☐ **1 Negative/Benign** ☐ **2 HPV/Atypia** ☐ **3 CIN I** ☐ **4 CIN II** ☐ **5 CIN III/CIS** ☐ **6 Invasive cancer** ☐ **7 Other**	**Results:** ☐ **1 Normal** ☐ **2 Abnormal** ☐ **3 Indeterminate** ☐ **4 Not Applicable**	**Results:** ☐ **1 Normal** ☐ **2 Abnormal** ☐ **3 Indeterminate** ☐ **4 Not Applicable**	**Results:** ☐ **1 Normal** ☐ **2 Abnormal** ☐ **3 Indeterminate** ☐ **4 Not Applicable**
Funding Source: ☐ **1 CDC** ☐ **3 Other**	**Funding Source:** ☐ **1 CDC** ☐ **3 Other**	**Funding Source:** ☐ **1 CDC** ☐ **3 Other**	**Funding Source:** ☐ **1 CDC** ☐ **3 Other**	**Funding Source:** ☐ **1 CDC** ☐ **3 Other**

(Questions 1 – 5: Refer to the instructions on the next page for an explanation of each column.)

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM DIAGNOSTIC PROCEDURES (CONTINUED)

Procedure

- These columns are used for indicating the procedures that a client receives.
- If a client receives diagnostic procedure(s) not listed, specify those procedure(s) under the “Other/CPT Code” columns (#3, #4, and #5). In the column heading, print the name of the procedure and the five digit Current Physician's Terminology (CPT) code underneath.
- If a client receives two of the same procedures, list one in its appropriate column and the second one under the “Other/CPT Code” column.

See Appendix F for cervical diagnostic procedure definitions.

Procedure Status

Mark **"1"** in the status column for each procedure that was performed.
Mark **"2"** if the procedure is needed but has been refused by the client.

Date Performed/Site

For each procedure that was performed (Status marked "1") write the date that the service was performed in this column. An optional line is provided to record the site where the service was performed.

Results Received

Write the date that the contractor received the results of the diagnostic procedure in this column. This date must not come on or before the date performed.

Results

Mark the appropriate diagnostic result for each procedure performed.

Funding Source

Mark **"1"** in this column if the procedure was funded by the CDC.
Mark **"3"** in this column if the procedure was funded by another source (donated, private insurance, other funding source).

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM
DIAGNOSTIC EVALUATION STATUS

DIAGNOSTIC EVALUATION STATUS

6. What date was the client referred for a diagnostic evaluation for possible cervical cancer? _____/_____/_____
NOTE: This date will match the date on the corresponding D-19C Screening Form (#17).

7. What is the status of the diagnostic evaluation?
- ☐ **1Evaluation complete; a final diagnosis has been reached**
- ☐ **2 Client refused needed procedures before a final diagnosis could be reached**
- ☐ **3 Client is lost to follow-up**

8. What date was the evaluation completed (date of determining procedure), refused, or the client lost to follow-up? (*see #7*) _____/_____/_____

9. If the evaluation is complete, what is the final diagnosis?
- ☐ **1 Normal/Benign Reaction/Inflammation**
- ☐ **2 HPV/Condylomata/Atypia**
- ☐ **3 CIN I/Mild Dysplasia**
- ☐ **4 CIN II/Moderate Dysplasia**
- ☐ **5 CIN III/Severe Dysplasia/Carcinoma in situ**
- ☐ **6 Invasive Cervical Carcinoma *(staging info required)***
- ☐ **7 Other**_____

6. What date was the client referred for a diagnostic evaluation for possible cervical cancer?

Write the date that the client was referred for diagnostic procedures. This date must match the date under question #17 of the Cervical Cancer Screening Form.

7. What is the status of the diagnostic evaluation?

- **Evaluation complete**: Mark if a final diagnosis has been reached.
- **Client refused needed procedures before a final diagnosis could be reached**: Mark if a final diagnosis cannot be reached because a client refused needed procedures.
- **Client is lost to follow-up**: Mark if three attempts to contact the client have failed, with the third attempt being by certified mail.

8. What date was the evaluation completed, refused, or the client lost to follow-up?

- If the evaluation is complete, write the date of determining procedure.
- If the client refused needed procedures before a diagnosis could be made, write the date the client refused procedures.
- If the client is lost to follow-up, write the date that the certified letter was mailed.

See Appendix D for evaluation status definitions.

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM
DIAGNOSTIC EVALUATION STATUS (CONTINUED)

DIAGNOSTIC EVALUATION STATUS

6. What date was the client referred for a diagnostic evaluation for possible cervical cancer? _____/_____/_____
NOTE: This date will match the date on the corresponding D-19C Screening Form (#17).

7. What is the status of the diagnostic evaluation?
- ☐ **1Evaluation complete; a final diagnosis has been reached**
- ☐ **2 Client refused needed procedures before a final diagnosis could be reached**
- ☐ **3 Client is lost to follow-up**

8. What date was the evaluation completed (date of determining procedure), refused, or the client lost to follow-up? (*see #7*) _____/_____/_____

9. If the evaluation is complete, what is the final diagnosis?
- ☐ **1 Normal/Benign Reaction/Inflammation**
- ☐ **2 HPV/Condylomata/Atypia**
- ☐ **3 CIN I/Mild Dysplasia**
- ☐ **4 CIN II/Moderate Dysplasia**
- ☐ **5 CIN III/Severe Dysplasia/Carcinoma in situ**
- ☐ **6 Invasive Cervical Carcinoma *(staging info required)***
- ☐ **7 Other_____**

9. If the evaluation is complete, what is the final diagnosis?

Mark the final diagnosis using the categories provided.

Normal/Benign Reaction/Inflammation:
- Mark if the client does not have cancer or a pre-cancerous condition.
- **HPV/Condylomata/Atypia**: "HPV" refers to human papillomavirus.
- **CIN I/Mild Dysplasia**: CIN means cervical intraepithelial neoplasia.
- **CIN II/Moderate Dysplasia**
- **CIN III/Severe Dysplasia/Carcinoma in situ**: Mark for "High Grade SIL."
- **Invasive Cervical Carcinoma**: Staging information required.
- **Other**: Specify any cancerous or pre-cancerous conditions that do not fit the above categories

If multiple categories apply, mark the most serious diagnosis. Do ***not*** specify treatment or diagnostic procedures in this space.

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM
CERVICAL CANCER TREATMENT STATUS

CERVICAL CANCER TREATMENT STATUS

COMPLETE THIS SECTION AFTER *ANY* FINAL DIAGNOSIS

10. What is the treatment status?
- ☐ **1 Treatment not needed**
- ☐ **2 Treatment initiated or complete**
- ☐ **3 Client refused treatment**
- ☐ **4 Client is lost to follow-up**
- ☐ **5 Treatment scheduled or pending**

11. What date was treatment initiated, refused, the client lost to follow-up, or a determination made that treatment was not needed? (*see #10*) _____/_____/_____

12. Where was treatment initiated?
Hospital/Facility: _____

City:_____ **Zip:**_____

13. When is the client's next cervical screening? _____/_____/_____

Answer questions 10 through 13 after any final diagnosis.

10. What is the treatment status?

- Mark **"Treatment not needed"** if the client's condition does not require treatment.
- Mark **"Treatment initiated or complete"** if any treatment has begun.
- Mark **"Client refused treatment"** if the client refused needed treatment.
- Mark **"Client is lost to follow-up"** if three attempts to contact the client have failed with the third attempt being by certified mail.
- Mark **"Treatment is scheduled or pending"** if treatment is being arranged, but there will be a delay of 90 days or more before treatment actually begins.

11. What date was treatment initiated, refused, the client lost to follow-up, or a determination made that treatment was not needed?

Write the date the client began to receive treatment. If the client refused treatment, write the date the client refused. If the client is lost to follow-up, write the date that the certified letter was mailed. If treatment was not needed, write the date of that determination.

See Appendix E for treatment status definitions.

CERVICAL CANCER DIAGNOSTIC EVALUATION FORM
CERVICAL CANCER TREATMENT STATUS (CONTINUED)

CERVICAL CANCER TREATMENT STATUS

COMPLETE THIS SECTION AFTER *ANY* FINAL DIAGNOSIS

10. What is the treatment status?
- ☐ **1 Treatment not needed**
- ☐ **2 Treatment initiated or complete**
- ☐ **3 Client refused treatment**
- ☐ **4 Client is lost to follow-up**
- ☐ **5 Treatment scheduled or pending**

11. What date was treatment initiated, refused, the client lost to follow-up, or a determination made that treatment was not needed? (see #10) _____/_____/_____

12. Where was treatment initiated?
Hospital/Facility: _____

City:_____ **Zip:**_____

13. When is the client's next cervical screening? ___/___/___

12. Where was treatment initiated?

Document the name of the principal hospital or facility at which the client received treatment. Document the name of the city and the zip code in which the hospital or facility is located.

13. When is the client's next cervical screening?

Write the date of the client's next annual/biannual; or short-term follow-up visit.

APPENDIX A: OVERALL ASSESSMENT OF FINDINGS CLASSIFICATIONS

Negative
- There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.

Benign
- This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat containing lesions such as oil cysts, lipomas, galactoceles, and mixed density hamartomas all have characteristic appearances, and may be labeled with confidence. The interpreter may describe intramammary lymph nodes, implants, etc. while still concluding that there is no mammographic evidence of malignancy.

Probably benign
- A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data are becoming available that shed light on the efficacy of short interval follow-up. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.

Suspicious
- These lesions do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant probabilities should be cited so that the patient and her physician can make the decision on the ultimate course of action.

Highly suggestive of malignancy
- These lesions have a high probability of being cancer. Appropriate action should be taken.

Incomplete: needs additional imaging evaluation
- This is almost always used in a screening situation and should rarely be used after a full imaging work up. A recommendation for additional evaluation should be made including the use of spot compression, magnification, special mammographic views, ultrasound, etc.
- Whenever possible, the present mammogram should be compared to previous studies. The radiologist should use judgment in how vigorously to pursue previous studies.

Unsatisfactory, film could not be interpreted by radiologist
- Mammogram was technically flawed.

Source: Final Mammography Quality Standards Act (MQSA) Regulations: Effective April 28, 1999.

APPENDIX B: BETHESDA CATEGORY DEFINITIONS

Negative (within normal limits)
- There is nothing to comment on.

Atypical squamous cells (ASC)
- SC-US- atypical squamous cells of undetermined significance.
- SC-H – atypical squamous cells of undetermined significance, cannot exclude HSIL.

Low grade SIL (including HPV changes)
- Low-grade squamous intraepithelial lesion, encompassing: Cellular changes associated with HPV, mild (slight) dysplasia/cervical intraepithelial neoplasia grade 1 (CIN I).

High grade SIL
- High-grade squamous intraepithelial lesion, encompassing: moderate dysplasia/CIN II, severe dysplasia/CIN III, carcinoma in situ/CIN III.

Squamous cell cancer
- Invasive Cervical Carcinoma.

AGUS
- Atypical endocervical, endometrial, or glandular cells.

Source: The Bethesda 2001 Reporting System for Pap Test Results

APPENDIX C: PROCEDURES FOR THE BREAST CANCER DIAGNOSTIC EVALUATION FORM

Diagnostic Mammogram

- **Unilateral Diagnostic Mammogram** - CPT 76090. Mammography of either the left or right breast.
- **Bilateral Diagnostic Mammogram** - CPT 76091. Mammography of both left and right breasts.
  Note: Also includes the following descriptions - work up mammogram, spot compression, additional views of the breast via mammography, magnification views, compression views, cone compression, spot magnification.

Ultrasound

- Ultrasound of the breast(s) - CPT 76645, either unilateral or bilateral, B-scan and/or real time with image documentation.
- Ultrasound - CPT 76942. Ultrasonic guidance for needle placement, radiological supervision, and interpretation.
  Note: Alternative terms include - Sonogram, sonography or echography.

Breast Biopsy

- Needle Core - CPT 19100. A needle used to sample a suspicious piece of breast tissue.
- Excisional - CPT 19120. Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion.
  Note: Also includes - Lumpectomy, nodule removed, cyst removed, lump removed, removed mass (unless the breast is excised), excisional biopsy and biopsy.
- Incisional - CPT 19101. Different from excisional biopsy because the surgeon does not remove the entire mass.
- With radiological marker - CPT 19125. Metallic marker that shows up on x-ray to serve as landmarks or to identify areas of suspicion.
- Additional lesion - CPT 19126.
- Pre-opt. placement of local wire - CPT 19290.

Fine Needle/Cyst Aspiration - CPT 88173

- Fine needle aspiration with or without preparation of smears; superficial tissue, and fine needle biopsy.

Office Consultation - CPT 99241

- New or established patient office consultation which requires three key components: a) a problem focused history; b) problem focused examination; and c) straightforward medical decision-making. Physician typically spends 15 minutes face-to face with patient. **For BCCC purposes, an office consultation must include a breast exam by a surgeon or other breast specialist.**

APPENDIX C (CONTINUED): PROCEDURES FOR THE BREAST CANCER DIAGNOSTIC EVALUATION FORM

Office Consultation - CPT 99242
- New and established patient office consultation which requires three key components: a) an expanded problem focused history; b) an expanded problem focused examination; and c) straightforward medical decision-making. Physician typically spends 30 minutes face-to-face with patient.

Office Consultation - CPT 99243
- New and established patient office consultation which requires three key components; a) a detailed history; b) a detailed examination; and c) medical decision making of low complexity. Physician typically spends 40 minutes face-to face with patient.

Office Consultation - CPT 99244
- New and established patient office consultation which requires three key components; a) a comprehensive history; b) a comprehensive examination; and c) a medical decision making of moderate complexity. Physician typically spends 60 minutes face-to-face with patient.

Additional Diagnostic Procedures
- Can include but is not limited to: Mammographic guidance for needle placement, breast, each lesion, radiological supervision and interpretation, CPT 76096; surgical pathology, CPT 88305; stereotactic localization, CPT 76095.

DO NOT REPORT PRIVATE PHYSICIAN/CLINIC HOSPITAL; MASTECTOMY; OR TREATMENT INFORMATION AS DIAGNOSTIC PROCEDURES.

APPENDIX D: DIAGNOSTIC EVALUATION STATUS CATEGORY DEFINITIONS

Evaluation Complete

- Diagnostic testing is completed, AND;
- The final diagnosis and date of final diagnosis are known.

Work-Up Refused

- The client explicitly states that they will not consent to further diagnostic services.
- BCCC recommends that the patient sign a refusal statement.

Lost To Follow-Up

- Three documented attempts to contact the client to arrange diagnostic services have failed. These three attempts were by telephone, mail, or home visit, and the final attempt was by certified letter.

APPENDIX E: TREATMENT STATUS CATEGORY DEFINITIONS

Treatment Not Needed - **Cervical diagnostic form only**
- The client does not have cervical cancer or severe cervical dysplasia; AND
- The client does not require immediate medical intervention.

Treatment Initiated or Completed - Both breast and cervical diagnostic forms
- A written plan for the treatment of cancer or a precancerous lesion has been developed and started; AND
- Other obstacles to treatment have been identified and plans have been established to overcome them.

Treatment Refused - Both breast and cervical diagnostic forms
- The client explicitly states that they will not consent to treatment for breast or cervical cancer or moderate to severe cervical dysplasia. BCCC recommends that a signed refusal be obtained if possible.

Lost To Follow-Up - Both breast and cervical diagnostic forms
- At least three documented attempts to contact the client to arrange cancer treatment services have failed. The three attempts were by telephone, mail, or home visit, and the final attempt was by certified letter.

APPENDIX F: PROCEDURES FOR THE CERVICAL CANCER DIAGNOSTIC EVALUATION FORM

Colposcopy Only - CPT 57452
- Colposcopy (vaginoscopy); **without** biopsy

Colposcopy and Biopsy - CPT 57454
- Colposcopy (vaginoscopy) **with** biopsy(s) of the cervix
  Note: The following terms also fit this category - endocervical curettage (ECC), biopsy, cervical biopsy.

Additional Diagnostic Procedures
- Can include but is not limited to: pathology CPT 88305, office visits CPT 99203, 99212, 99213, 99214
- Other procedures not funded by BCCC: Pelvic ultrasound - CPT 76856.

DO NOT REPORT CRYOTHERAPY, CRYOSURGERY, MEDICATIONS FOR TREATMENT OF SYMPTOMS/DISEASE, BIOPSY UNRELATED TO CERVIX, LAPAROSCOPY, HYSTERECTOMY AS DIAGNOSTIC PROCEDURES.

REPORTING

Request for Advance or Reimbursement Form 270 – Form 270 is to be submitted within 60 days of the completion of the contract year to the Claims Processing Unit and to the Contract Development and Support Branch (CDSB). A copy of the form may be found at the following website: http://www.dshs.state.tx.us/grants/forms.shtm

Report Name: Form 270 - Request for Advance or Reimbursement (TDH GC-10)				
Submission Date: No later than sixty (60) days after the end of the contract term				
Submit Copy to:				
Name of Unit/Branch	**Original Required**		**Accepts Fax, Mail, or Email**	**# Copies**
	Yes	**No**		
Contract Development and Support Branch (CDSB)	X		Mail only	1
Accounting Section/Claims Processing Unit (CPU)	X		Mail only	1
Instructions: Form 270 requires an original signature				

Fax Numbers:	Contract Development and Support Branch	(512) 458-7235
	Accounting Section/Claims Processing Unit	(512) 458-7442
	Preventive and Primary Care Unit	(512) 458-7203
Mail Codes:	In order to ensure timely and accurate delivery of Department of State Health Services mail, please use the following mail codes when submitting vouchers and reports.	
	Contract Development and Support Branch	1914
	Accounting Section/Claims Processing Unit	1940
	Preventive and Primary Care Unit	1923
Mailing Address:	1100 W. 49th Street, Austin, Texas 78756-3199	
Claims Process Unit Email Address	Invoices@dshs.state.tx.us	

Staging of Cancers – Contractors must contact health care providers to obtain stage of disease information. Stage of disease information includes copies of pathology report; operative reports; discharge summary; or a tumor node metastasis form signed and dated by a physician or Certified Tumor Registrar.

The stage of disease must be reported within ninety (90) days of the date the cancer diagnosis was made, as reported in the data collection form submitted to BCCC.

If an initial reported diagnosis of cancer turns out to be benign, the contractor must record the new information and submit a revised diagnostic data form to the BCCC.

Match Report – Matching funds refer to non-Federal resources (money and/or in-kind contributions). The CDC requires the BCCC to provide $1 in match for every $3 awarded. See page 3 - 2 for examples of acceptable match items. All BCCC contractors must identify, secure, ensure, budget and submit non-Federal match. Match reports are submitted to the BCCC on a quarterly basis; see below for instructions on completing the report. Contractors must maintain and submit back-up documentation to support matching contributions.

Report Name: Quarterly Matching Contribution Report				
Submission Date: Quarterly, within 30 days following the end of each quarter				
Submit Copy to:				
Name of Unit/Branch	**Original Required**		**Accepts Fax, Mail, or Email**	**# Copies**
	Yes	**No**		
Contract Development and Support Branch (CDSB)		X	Email only	1
Instructions: Quarter Matching Contribution report does not require original signature				

Instructions for completing the Quarterly Match Report

1. The contractor organization name must appear as it does on the DSHS contract.

2. Indicate the current budget period (07/01/YY – 06/30/YY)

3. Indicate the reporting quarter

Match Report Quarters:	Due Dates
1st Jul 1 – Sep 30	30 days following end of qtr.
2nd Oct 1 – Dec 31	30 days following end of qtr.
3rd Jan 1 – Mar 31	30 days following end of qtr.
4th Apr 1 – Jun 30	30 days following end of qtr.

4. Indicate the base award, all supplemental awards (if applicable) and total funding for reporting year.

5. Indicate the match projected for the approved base award. If your organization received additional funding, indicate the match projected for supplemental funds.

Indicate "N/A" if no supplemental funds were awarded. Total match projected for both base award and supplemental awards and note it on the "Total Match."

6. Signature must be of the person authorized to verify the match information (i.e., that reported match is correct and auditable).

7. List each item by category (program component), detailed description of service provided, funding source (e.g., another (non-federal) grant, local government, donation from individual or organization), and amount of each match item. Items must be those that would be paid by the BCCC, are directly allocable to BCCC activities, and cannot include indirect or overhead costs. Indicate total amounts for each quarter and cumulative totals.

Examples of acceptable match items by category (not all-inclusive)

Screening/Diagnostic Services:
- clinical breast and pelvic examinations;
- office visits and/or breast consultations
- clinical procedures approved for reimbursement by the program
- difference between usual and customary charges and Medicare reimbursement rates approved by the program.

Case Management Services:
- staff time conducting face-to-face and telephone contact with clients who have abnormal breast or cervical findings to provide case management activities such as assessment, planning, and monitoring; and local travel required for follow-up of individual clients.

Public Education/Information:
- staff time conducting breast and/or cervical cancer media campaigns;

Client Education:
- staff time spent providing breast and cervical cancer education to program clients
- educational materials provided to individual clients such as videotapes, and pamphlets

Outreach:
- staff time spent conducting outreach and recruitment activities to increase the number of women screened by the program
- staff's local travel necessary to conduct outreach and recruitment activities

Data Collection:
- staff time for data collection and reporting
- costs of local program data tracking software and other tools

Quality Assurance:
- staff time to review client records to assess compliance with program requirements.

Professional Development/Professional Education:
- expenses paid by contractor to attend breast/cervical cancer-related training, workshops, or conferences. (Break out travel, per diem, conference fees, and CEU fees)

Costs associated with the above activities (e.g., staff time, postage, supplies) may be reported as match if they are directly allocable to those activities. Such items that are not directly allocable to program activities and that would be defined as overhead or indirect costs are not allowable as match. Treatment costs are not allowable as match.

Supporting information must be included on the form or attached separately to document the method used to calculate match amounts. See examples on next page.

Category	Description of Services	Funding Source(s) and Amount of Each	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Cumul. Total Qtrs. 1-4
1. Screening and Diagnostic Services	Difference between usual and customary charges and BCCC Medicare rates	N/A	$20,000	$30,000	$35,000	$40,000	$125,000
	Facility charges for excisional breast biopsies	Memorial Hospital	$7,000	$5,500	$2,000	$4,000	$18,500
2. Case Management Services	Case management of clients with abnormal screening and/or diagnostic results	X funding source 10 clients x $100 each	$500	$800	$700	$1,000	$3,000
3. Public Information and Outreach	Breast cancer pamphlets for quarterly health fair	Komen Foundation 1,000 pamphlets@ $.50 ea.	$500	$500	$500	$500	$2,000
4. Client Education	Staff time to conduct face-to face-interviews with clients	Y funding source Health Educator salary = $30,000 x 10% = $3,000 x 20% fringe = $20+$3,000 = $3,020	$1,200	$2,400	$2,000	$3,020	$8,620
5. Data Collection	Staff time to conduct data collection and reporting	Kellogg Foundation Office assistant salary = $25,000 x 10% = $2,500 x 20% fringe = $500 = $3,000	$3,000	$3,000	$3,000	$3,000	$12,000
6. Quality Assurance	Staff time for reviewing BCCC client records	Client Fees R.N. salary =$50,000 x 5% = $2,500 x 20% fringe = $500 +$2,500 = $3,000	$3,000	$2,500	$3,000	$3,000	$11,500
7. Professional Education	Attendance at breast cancer conference	City Funding Source Travel expenses for 1 nurse				$500	$500
8. Program Management	Staff time processing billing	County Funds Accountant salary = $40,000 x 5% = $2,000 x 20% fringe = $400+$2,000 = $2,400	$2,400	$2,400	$2,400	$2,400	$9,600
Grand Total			$37,600	$47,100	$48,600	$57,420	$190,720

BREAST AND CERVICAL CANCER CONTROL
QUARTERLY MATCH REPORT

1. Contractor _____2. Budget Period _____ 3. Quarter ____1 ____ 2 ____ 3 ____ 4

4. Total Funding Award for Current Budget Period: Base Award _____ Additional Funding Award _____ Total Award _____

5. Total Match Projected for Current Budget Period: Base Match _____ Match for Additional Funding: _____ Total Match _____

6. Date Match Report Submitted _____ Name of Person Submitting Report _____

7. In the table below, list your actual match contributions for each quarter. Describe each service, the funding source(s) for each service, and the total match for each quarter. Indicate the cumulative totals in the appropriate spaces. Use additional pages if necessary.

Category	Description of Services	Funding Source(s) and Amount of Each (Federal Funds are not approved for as a match source)	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.	Cumul. Total Qtrs. 1-4
1. Screening and Diagnostic Services							
2. Case Management							
3. Public Information and Outreach							
4. Client Education							
5. Data Collection							
6. Quality Assurance							
7. Professional Education							
8. Program Management							
Grand Total							

REPORTS FROM DSHS

BCCC Quarterly Reports

Purpose – The BCCC prepares and disseminates the BCCC Administrative Report to each contractor on a quarterly basis. The purpose of the report is to assist contractors to monitor their progress throughout the year as it relates to BCCC performance measures. The report also guides the technical assistance needs of each contractor.

Components of BCCC Administrative Report – The Administrative Report is based on the BCCC performance measures and includes:

- Number of women served;
- Mean days from abnormal result to diagnosis;
- Mean days from cancer diagnosis to treatment;
- Percent of clients refusing diagnostic services;
- Percent of clients lost to follow up for diagnostic services;
- Percent of clients refusing treatment;
- Percent of clients lost to follow up for treatment;
- Percent of clients rescreened for breast cancer;
- Percent of BCCC-funded mammograms provided to clients age 50-64; and
- Percent of women receiving BCCC-funded cervical cancer screening services who have not been screened within the previous five (5) years.

Monthly Packet

Purpose – The BCCC sends a monthly packet to each contractor. The purpose of the Monthly Packet is to provide feedback to contractors regarding pending data and services. The report also guides the technical assistance needs of each contractor.

Components of Monthly Packets – The packet can include any or all of the items listed below:

Item	Description
Error reports	data form errors/cd number errors
Billing summary	percent of funds spent
Pending list	abnormal cases pending diagnosis/treatment
Staging list	cancer cases pending staging information
Submission table	data form submission information
Rescreening list	summary of clients to be rescreened

Rescreening List of Eligible Women – two months prior to the target month, the BCCC will distribute to each contractor a list of names of women due to be rescreened in the target month. The BCCC will monitor the proportion of women rescreened for each contractor. The BCCC may require a screening plan from contractors that consistently fail to achieve rescreening requirements.

Review of Monthly Packets – The BCCC mails the monthly packets to the contractor's designated contact person on a monthly basis. Contractors are required to review monthly packets and respond to the BCCC within ten (10) working days of receipt. The BCCC will follow-up with contractor upon receipt of contractors corrected items.

PERFORMANCE MEASURES

Contractors are required to meet BCCC performance measures. The following performance measures are used to assess, in part, the contractor's effectiveness in providing BCCC services:

- The mean number of days between abnormal CBE or abnormal initial mammography results (includes suspicious abnormality, highly suggestive of malignancy and assessment incomplete) and final diagnosis must be less than or equal to 60 days.
- The mean number of days between final diagnosis of breast cancer (in situ or invasive) and treatment must be less than or equal to 30 days.
- At least 90% of abnormal breast screenings or cases with a diagnostic work-up planned must have a completed diagnosis with no more than 3% lost to follow-up, 2% refused, and 5% pending. Abnormal breast screening includes mammograms with a final assessment of suspicious abnormality, highly suggestive of malignancy, or assessment incomplete, or abnormal CBE.
- The mean number of days between abnormal Pap test results (ASC-H, LSIL, HSIL, AGUS, or squamous cell cancer) and final diagnosis must be less than or equal to 60 days.
- The mean number of days between diagnosis of CIN II, CIN III/CIS, or invasive cancer of the cervix and treatment must be less than or equal to 30 days.
- At least 90% of abnormal cervical screenings or cases with a diagnostic work-up planned must have a completed diagnosis with no more than 3% lost to follow-up, 2% refused, and 5% pending. Abnormal cervical screening includes a Pap test result of ASC-H, LSIL, HSIL, AGUS, or squamous cell cancer.
- *Percent of clients rescreened for breast cancer is greater than or equal to 30% of clients screened during the previous year.
- Percent of BCCC-funded mammograms provided to clients age 50-64 is a minimum of 75%.
- **Assure no more than 25% of the BCCC-funded diagnostic mammograms are provided to women under age 50.
- Percent of women receiving BCCC-funded cervical cancer screening services who have not been screened within the previous five years is a minimum of 20%.
- Assure that 75% of the women that have had three consecutive normal annual BCCC-funded Pap tests within a 5 year period (as documented in the BCCC database) do not receive a fourth annual Pap test. Once there is documentation of three normal/benign results within a five-year period, BCCC funds may be used to reimburse for Pap tests once every three years.
- Provide breast and/or cervical cancer screening and diagnostic services to a minimum of 250 unduplicated clients.
- Expend at least 95% of the BCCC budget.
- BCCC Quarterly Match Reports must be submitted within 30 days following the end of each quarter.
- Submission of BCCC billing and client data on a monthly basis.

- 12% of women screened for breast cancer with BCCC funds will be African-American.

*The proportion of women rescreened is incorporated into the performance indicators for each screening and diagnostic contract in the next budget period.

**Contractors should consult with the BCCC case management coordinator before enrolling women younger than 40 for diagnostic assessment to ensure 75% requirement of BCCC-funded mammograms to women ages 50-64 is being met.