

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
TITLE 566. COMPREHENSIVE BREAST AND CERVICAL CANCER DETECTION
TREATMENT [REVOKED]**

SUBCHAPTER 1. GENERAL PROVISIONS [REVOKED]

310:566-1-1. Purpose [REVOKED]

This Chapter implements O.S.L. Chapter 210 "Oklahoma Breast Cancer Prevention and Treatment" and Public Law 101-354, Title XV, Public Service Act, "Breast and Cervical Cancer Mortality Prevention" authorized by Congress in 1990 and amended in 2000. State statutes established a breast and cervical cancer prevention, treatment and research program advised by a group of predetermined individuals. The federal law established a comprehensive population based statewide breast and cervical cancer early detection program with an additional amendment establishing the treatment program. The purpose of both laws is to reduce the mortality of breast and cervical cancer by providing statewide early detection, diagnosis and treatment of breast and cervical cancer.

310:566-1-2. Definitions [REVOKED]

"Abnormal screen" means a suspicion of breast or cervical cancer. A suspicion of breast cancer includes clinical breast exam findings of: palpable breast mass, breast dimpling, nipple retraction, bloody nipple discharge, palpable lymph nodes around clavicle or axilla, nipple erythema and scaliness, a mammography result of BiRads 4 (Suspicious Abnormality suggesting need for biopsy) or 5 (Highly Suggestive of Malignancy) (ICD 793.8), breast biopsy result of Ductal Cancer in situ, Lobular Cancer in situ (ICD 233.0), or breast or lymph node (or other) biopsy result of breast cancer. Suspicion of cervical cancer is a Pap test result of Atypical Squamous Cells (ASC), Atypical glandular cells (AGC), Low grade squamous intraepithelial lesions (LSIL), or High grade squamous intraepithelial lesions (HSIL) (ICD 622.1), leukoplakia of the cervix, (ICD 622.2), or cervical biopsy result of Cervical intraepithelial neoplasia II or III, or Cancer in situ (ICD 233.1).

"ACR" means American College of Radiology. The ACR is the FDA recognized approved accreditation body for minimum quality standards for personnel, equipment, and record keeping in facilities that provide mammography.

"Benign" means a non-cancerous condition that does not spread to other parts of the body.

"Bethesda System" means a specified system of reporting cervical cytology findings.

"Biopsy" means removal of an entire abnormality (excisional biopsy) or a sampling or portion of abnormality (core and incisional biopsy) for microscopic examination in order to diagnose a problem.

"BiRads" means Breast Image Reporting and Data System.

"Breast and Cervical Cancer Program Treatment Act (BCCPTA)" means a Medicaid plan amendment creating a new categorically needy group consisting of women screened for breast and/or cervical cancer under the BCCEDP and found to be in need of treatment.

"Breast carcinoma in situ" means breast changes in which malignant cells are localized and confined to breast ducts or lobules and may press against adjoining breast tissue but have not penetrated or spread beyond the breast.

"BSE" means breast self examination. This is inspection and palpation of a woman's breasts by the woman herself.

"Cancer" means a general term for more than 100 diseases characterized by abnormal and uncontrolled growth of cells.

"CBE" means clinical breast examination. A complete examination of the breast and axilla with palpation by a health professional, including examination of the breast in both the upright and supine positions.

"Case management" means a program component of the Oklahoma Breast and Cervical Cancer Early Detection Program that involves establishing, brokering, and sustaining a system of available clinical and essential support services for all women enrolled in the program.

"Certified provider" means a healthcare professional who has signed a memorandum of understanding with the Oklahoma Breast and Cervical Cancer Early Detection Program certifying that the woman received breast or cervix screening, was found to be in need of treatment, and meets eligibility criteria for referral to the Medicaid Breast and Cervical Cancer Treatment Program.

"CLIA" means the Clinical Laboratory Improvement Act which establishes minimum quality standards for personnel and quality assurance methods which monitor patient test management and assess quality control, proficiency testing and personnel handling of laboratory and pathology specimens.

"Colposcopy" means examination of the cervix with a high-powered microscope.

"Creditable coverage" means any insurance that pays for medical bills incurred for the screening, diagnosis, or treatment of breast and cervical cancer. Creditable coverage includes, but is not limited to, group health plans, health insurance coverage consisting of medical care under any hospital or medical service policy, or health maintenance organization, Medicare Part A and B, Medicaid, Armed Forces Insurance, and/or state health risk pool. A woman having creditable coverage will not be eligible to apply for Medicaid coverage of breast and cervical cancer screening or treatment.

"Creditable coverage circumstances" means there are some circumstances where a woman has creditable coverage but is not actually covered for treatment of breast or cervical cancer. In an instance such as pre-existing condition exclusions, or when the annual or lifetime limit on benefits has been exhausted, a woman is not considered to have creditable coverage for this treatment. If the woman has limited coverage, such as limited drug coverage or limits on number of outpatient visits or high deductibles, the woman is still considered to have creditable coverage and is not eligible to apply for Medicaid coverage of breast and cervical cancer treatment. If the woman has a policy with limited scope of coverage such as only dental, vision, or long term care, or a policy that covers only a specific disease or illness, she is not considered having creditable coverage, unless the policy provides full coverage for breast and cervical cancer treatment. For the purposes of this program eligibility for IHS or Tribal health care is not considered creditable coverage.

"Diagnostic mammography" means radiologic examination used to evaluate a patient with a breast mass(es), other breast signs or symptoms (spontaneous nipple discharge, skin changes, of special cases such as a history of breast cancer with breast conservation or augmented breasts).

"FDA" means the United States Food and Drug Administration. The FDA certifies that a mammography facility meets minimum quality standards for personnel, equipment, and record keeping.

"Follow-up" means a program component of the Oklahoma Breast and Cervical Cancer Early Detection Program that involves a system for seeking information or reviewing an abnormal condition, rescreening, and/or recall for annual visits.

"Infrastructure" means sufficient staff and adequate supporting systems to plan, implement, and evaluate the program components of the Oklahoma Breast and Cervical Cancer Early Detection Program.

"In need of treatment" means an abnormal screen determined as a result of a screening for breast and/or cervical cancer under the Oklahoma Breast and Cervical Cancer Early Detection Program.

"Medicaid" means a combined federal and state payment source for health care benefits for certain eligible women who are disabled or who have dependent children. Health care benefits must be a part of the state plan for health services.

"Medicare" means a federal payment source for health benefits for certain eligible women.

"Minimum data elements" means a set of standardized data elements developed by the Centers for Disease Prevention and Control, Division of Cancer Prevention and Control, to ensure that consistent and complete information on screening location, demographic characteristics, screening results, diagnostic procedures, tracking and follow-up, and treatment information are collected on women screened and/or diagnosed with federal funding.

"Never screened" means women who have never been screened for breast and/or cervical cancer or who do not utilize preventive health services.

"Oklahoma Breast and Cervical Cancer Early Detection Program (BCCEDP)" means a comprehensive breast and cervical cancer program established and funded under Title XV of the federal Public Health Service Act with delegated responsibility of implementation and evaluation to the Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, and administered by the Oklahoma State Department of Health.

"Oncologist" means a specialist who treats or studies the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment.

"Outreach" means a program component of the Oklahoma Breast and Cervical Cancer Early Detection Program that involves recruiting high-risk populations, targeted populations or persons who never or rarely utilize preventive health services.

"Pap smear" means a screening test for the detection of abnormal cells from the cervix. The Pap smear can detect abnormal cells or pre-cancerous cells before cancer develops.

"Pathologist" means a specialist in pathology; a physician who practices, evaluates, or supervises diagnostic tests, using materials removed from living or dead patients, and functions as a laboratory consultant to clinicians, or who conducts experiments or other investigations to determine the causes or nature of disease changes.

"Physician" means any person who has completed a course of medical training, has received a medical degree and is licensed by the Oklahoma State Board of Medical Licensure or the Oklahoma Osteopathic Board of Examiners to practice medicine.

"Pre-cancerous lesions" means poorly differentiated cells that could progress to cancer.

"Program and fiscal management" means a program component of the Oklahoma Breast and Cervical Cancer Early Detection Program that conducts planning, organizing, directing, coordinating, managing, budgeting, and evaluating program activities.

"Radiologist" means a physician skilled in the diagnostic and/or therapeutic use of x-rays and other forms of radiant energy.

"Rarely screened" means women who have not had breast and/or cervical cancer screening within the last five (5) years.

"Referral" means a program component of the Oklahoma Breast and Cervical Cancer Early Detection Program that involves directing women with abnormal screens to appropriate resources for action.

"Screening mammography" means x-ray of the breasts of asymptomatic women in an attempt to detect abnormal lesions of the breast when they are small, non-palpable, and confined to the breast.

"Service delivery" means providing either directly or through contractual arrangements for comprehensive breast and cervical cancer services of screening, diagnosis, and treatment through client tracking of screening intervals, timeliness of diagnosis and timeliness of treatment.

"Surgeon" means a physician who treats disease, injury, and deformity by operation or manipulation.

"Surveillance" means a program component of the Oklahoma Breast and Cervical Cancer Early Detection Program that involves the systematic collection, analysis, and interpretation of health data.

"Ultrasound of the breast" means the use of sonic energy to produce a pictorial representation of the internal structure of the breast. The image is produced by pulse-echo techniques with detection and display of tissue interfaces rather than densities.

[Source: Added at 22 Ok Reg 400, eff 12-21-04 (emergency); Added at 22 Ok Reg 2409, eff 7-11-05]

310:566-1-3. Agreement with Oklahoma Health Care Authority [REVOKED]

—The Oklahoma State Department of Health, the Oklahoma Health Care Authority, and the Department of Human Services have coordinated to develop procedures for women who are residents of Oklahoma, are in need of treatment, meet eligibility criteria. (BCCPTA)

310:566-1-4. Eligibility for Breast and/or Cervical Cancer Treatment (BCCPTA) [REVOKED]

~~—A woman who is an Oklahoma resident is able to apply for Medicaid coverage for treatment of breast or cervical cancer including breast carcinoma in situ or precancerous conditions of the cervix if:~~

- ~~(1) She is currently enrolled in the Oklahoma Breast and Cervical Cancer Early Detection Program (OKBCCEDP). To be considered enrolled in OKBCCEDP she must meet program age guidelines and have at least one of the basic screening services (pap test or CBE) paid by the OKBCCEDP and be in need of treatment due to an abnormal screen which is suspicious for breast or cervical cancer, and/or breast and cervical pre-cancerous conditions; or~~
- ~~(2) She is referred by an OKBCCEDP certified provider and is documented to be in need of treatment due to an abnormal screen which is suspicious for either breast or cervical cancer, and/or breast or cervical pre-cancerous condition.~~
- ~~(3) Have a family income that is at or below one hundred eighty-five percent (185%) of the federal poverty income level.~~
- ~~(4) Have not attained the age of sixty five (65) years.~~
- ~~(5) Have no or have inadequate creditable health insurance or health benefit coverage.~~
- ~~(6) Is an Oklahoma and US Citizen or qualified alien.~~
- ~~(7) Has an abnormal breast or cervical cancer screening test result, or has been diagnosed with breast or cervical cancer and is still in need of treatment.~~

310:566-1-5. Coverage for treatment (BCCPTA) [REVOKED]

~~—Medicaid shall provide full payment coverage throughout the period of time required for treatment of the individual's breast or cervical cancer. Reimbursement rates for the treatment of breast and cervical cancer will be consistent with established Medicaid rates.~~

310:566-1-6. Loss of eligibility (BCCPTA) [REVOKED]

~~—A woman will no longer meet eligibility criteria for this program when her health care provider deems she is cancer free and will not require continued cancer treatment and/or therapy.~~

310:566-1-7. Criteria for certified screening provider [REVOKED]

~~—Physicians (M.D., D.O.), advanced practice nurses, physician assistants, and Certified Nurse Midwives who have signed a memorandum of understanding with the Oklahoma Breast and Cervical Cancer Early Detection Program can be a certified provider. The provider in signing the memorandum of understanding certifies that the woman received breast or cervix screening, was found to be in need of treatment, and meets eligibility criteria for referral to the Medicaid Breast and Cervical Cancer Treatment Program. Eligibility criteria includes that the woman is between the ages of 19 and 64, is a US Citizen or qualified alien and a resident of Oklahoma, has an income at or below 185% of the current Federal Poverty Level, has provided a social security number, does not have creditable coverage for breast or cervical cancer treatment, and has an abnormal finding following a breast or cervical cancer screening service. Suspicious findings for breast includes clinical breast exam findings of: palpable breast mass, breast dimpling, nipple retraction, bloody nipple discharge, palpable lymph nodes around clavicle or axilla, nipple erythema and sealiness, a mammography result of BiRads 4 (Suspicious Abnormality suggesting need for biopsy) or 5 (Highly Suggestive of Malignancy) (ICD 793.8), breast biopsy result of Ductal Cancer in situ, Lobular Cancer in situ (ICD 233.0), or breast or lymph node (or other) biopsy result of breast cancer. Suspicion of cervical cancer is a Pap test result of Atypical Squamous Cells (ASC), Atypical glandular cells (AGC), Low grade squamous intraepithelial lesions (LSIL), or High grade squamous intraepithelial lesions (HSIL) (ICD 622.1), leukoplakia of the cervix, (ICD 622.2), or cervical biopsy result of Cervical intraepithelial neoplasia II or III, or Cancer in situ (ICD 233.1). Certified screening providers need not be BCCEDP contractors, and will not be reimbursed by the BCCEDP nor by Medicaid for the screening services provided to the woman.~~

SUBCHAPTER 3. SCREENING SERVICE PROVISION [REVOKED]

310:566-3-1. Service provision of the Oklahoma Comprehensive Breast and Cervical Cancer Early Detection Program [REVOKED]

—The Oklahoma Comprehensive Breast and Cervical Cancer Early Detection Program shall include the following key components:

- (1) ~~Program and Fiscal Management will be conducted by ensuring strategic planning, implementation, coordination, integration, and evaluation of all programmatic activities and administrative systems, as well as the development of key communication channels and oversight mechanisms to aid in these processes. Program Management will ensure that infrastructure adequately supports service delivery.~~
- (2) ~~Service Delivery directly provided or provided through contractual arrangements of specific and appropriate clinical procedures to detect breast and/or cervical abnormalities for women enrolled in the Oklahoma Breast and Cervical Cancer Early Detection Program. In the Oklahoma Breast and Cervical Cancer Early Detection Program appropriate clinical screening procedures include clinical breast examinations (CBE), mammograms, screening pelvic exams and pap tests. Appropriate clinical diagnostic procedures include diagnostic mammography, ultrasound of the breast, surgical consultation, biopsy of the cervical or breast, colopseopy of the cervix, and electrical loop excisional biopsies of the cervix. Women should receive patient education directed toward breast self-examination (BSE) and risk reduction.~~
- (3) ~~Referral, Tracking and Follow up will be conducted utilizing a data system to monitor an enrolled woman's receipt of screening/re-screening, diagnostic, and treatment procedures. The enrolled woman will be notified of the results of the service delivery whether the results are normal, benign, or abnormal. The data system will provide tracking of appropriate and timely clinical services following an abnormal test result and/or diagnosis of cancer. Enrolled women with abnormal Pap smears or breast screening procedures will be provided comprehensive referral directing the woman to appropriate additional diagnostic or treatment services. The comprehensive referral will be written. Follow up will be conducted to seek information about whether services were timely, completed, or met.~~
- (4) ~~Case Management will be provided and involve establishing, brokering, and sustaining a system of available clinical (screening, diagnostic, and treatment) and essential support services for all Oklahoma Breast and Cervical Cancer Early Detection Program enrolled women, and assisting clients diagnosed with cancer through the Program to obtain needed diagnostic and treatment services.~~
- (5) ~~Quality Assurance and Improvement will be conducted utilizing established standards, systems, policies and procedures to monitor, assess and identify practical methods for improvement of the program and its components. Quality assurance tools will include utilizing FDA and ACR minimum standards for mammography facilities and CLIA minimum standards for cytopathology and pathology laboratories. Quality assurance contributes to the identification of corrective actions to be taken to remedy problems found as a result of investigating quality of care.~~
- (6) ~~Professional Education will be provided through a variety of channels and activities that enable professionals to perform their jobs competently, identify needs and resources, and contribute to ensuring that health care delivery systems provide positive clinical outcomes.~~
- (7) ~~Population Based Public Education and Outreach will be provided that involves the systematic design and delivery of clear and consistent messages about breast and cervical cancer and the benefits of early detection, using a variety of methods and strategies to reach priority populations. Outreach activities should focus on women who have never been screened or rarely been screened and work toward the removal of barriers to care, i.e.: the need for childcare, respite care, interpreter services and transportation through collaborative activities with other community organizations.~~
- (8) ~~Coalitions and Partnerships will be developed to bring together groups and individuals who establish a reciprocal agreement for sharing resources and responsibilities to achieve the common goal of reducing breast and cervical cancer mortality.~~

~~(9) Surveillance will be conducted utilizing continuous, proactive, timely and systematic collection, analysis, interpretation and dissemination of breast and cervical cancer screening behaviors, incidence, prevalence, survival, and mortality of breast and/or cervical cancer. Epidemiological studies will be conducted utilizing Minimum Data Elements and other data sources to establish trends of disease, diagnosis, treatment, and research needs. Program planning, implementation, and evaluation shall be based on the epidemiological evidence.~~

~~(10) Evaluation will be conducted through systematic documentation of the operations and outcomes of a program, compared to a set of explicit or implicit standards or objectives. The Oklahoma Breast and Cervical Cancer Prevention and Treatment Advisory Committee shall review the service delivery contractual agreements as to their outcomes. The Oklahoma Breast and Cervical Cancer Prevention and Treatment Advisory Committee shall make recommendations based on the evaluation in its annual report.~~

310:566-3-2. Eligibility criteria for the early detection program [REVOKED]

~~(a) Women who are Oklahoma residents and who meet the following criteria are eligible for breast and cervical cancer early detection services:~~

~~(1) Women 19-65 years of age whose incomes are less than 185% of poverty and lack creditable health insurance coverage are eligible with the following criteria.~~

~~(2) Women 50-65 years of age will be the priority population to receive annual breast and cervical cancer screening.~~

~~(3) Women 40-49 years of age who are symptomatic of breast cancer will receive breast cancer diagnostic work up and cervical cancer screening if appropriate.~~

~~(4) Women 35-65 years of age with an intact cervix who have not had a pap test in 5 or more years will be the priority population to receive cervical cancer screening.~~

~~(5) Women 35-65 years of age who have had a hysterectomy due to cervical cancer or pre-cancerous conditions of the cervix may receive Pap smears.~~

~~(6) Women 19-35 years of age will be eligible for cervical cancer screening depending on appointment availability.~~

~~(b) All enrolled women will receive annual recall for screening.~~

~~(c) Women who have creditable medical insurance, including Medicare Part B and Medicaid shall be referred to their primary care provider or facility for services.~~

310:566-3-3. Criteria for screening services contractors [REVOKED]

~~Criteria for contractors to provide services include the following:~~

~~(1) Contractors shall ensure approved services are performed by board certified radiologists, pathologists, GYN physicians, surgeons, and oncologists.~~

~~(2) Contractors agree that procedures and services provided shall not exceed the amount that would be paid under Medicare Part B rates of Title XVIII of the Social Security Act.~~

~~(3) Mammography contractors shall ensure current FDA certification and ACR accreditation; be Medicare and Medicaid approved facilities; their participating physicians/providers be Medicare and Medicaid approved providers; and their services must be delivered with personnel and equipment in accordance with the Mammography Quality Standards Act.~~

~~(4) Mammography facilities shall utilize the Breast Image Reporting and Data System (BIRADS) and follow the ACR guidelines for mammography report content.~~

~~(5) A board certified radiologist must be immediately available to determine selection of views, and readings when a diagnostic mammogram is performed.~~

~~(6) Cytology and pathology specimens obtained shall be submitted to a CLIA approved laboratory for processing. The laboratory will provide cytological reading and analysis of cervical and vaginal Pap smears by Certified/Registered Cytotechnologists. And cytology (Pap) smears will be reported using the current Bethesda classification system. The laboratory will provide board certified pathologists or experienced certified cytotechnologists to re-screen all Pap smears with specified~~

~~abnormal diagnosis. The Laboratory will provide surgical pathology analyses and readings of cervical and breast biopsies.~~

~~(7) Contract physicians shall practice according to the current standards of medical care for breast and cervical cancer early detection, diagnosis and treatment.~~

~~(8) Service delivery can be provided by a variety of settings. Service delivery must include:~~

~~(A) Providing screening services for a specific geographic area.~~

~~(B) Providing a point of contact for scheduling appointments.~~

~~(C) Providing age and income eligibility screening.~~

~~(D) Providing comprehensive breast and cervical cancer screening to eligible women.~~

~~(E) Providing referral and follow up for women with abnormal screening results.~~

~~(F) Providing required reporting system for screening and follow up activities.~~

~~(G) Providing population based education, out reach, and recruitment activities.~~