Division of Public Health
Agreement Addendum
FY 22-23

	Chronic Disease and Injury / Cancer Prevention and Control
Local Health Department Legal Name	**DPH Section / Branch Name**
452 Breast and Cervical Cancer	Debi Nelson 919-707-5155 debi.nelson@dhhs.nc.gov
Activity Number and Description	**DPH Program Contact** (name, phone number, and email)
06/01/2022 – 05/31/2023	
Service Period	**DPH Program Signature** **Date** (only required for a negotiable Agreement Addendum)
07/01/2022 – 06/30/2023	
Payment Period	

☒ Original Agreement Addendum
☐ Agreement Addendum Revision # ___

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I. <u>Background</u>:

In the United States, breast cancer is the second most commonly diagnosed cancer in women. It is the leading cause of cancer death in Hispanic women and the second most common cause of cancer death among white, black, and Asian/Pacific Islander and American Indian/Alaska Native women.[1] In 2018, the U.S. incidence of breast cancer was 126.8 per 100,000 women and the mortality was 19.8 per 100,000 women.[2] In 2021, an estimated 281,550 new cases of invasive breast cancer are expected to be diagnosed among U.S. women, as well as an estimated 48,530 additional cases of in situ breast cancer. In 2021, approximately 43,600 U.S. women are expected to die from breast cancer. Only lung cancer accounts for more cancer deaths.[3] In North Carolina, an estimated 11,677 new female breast cancer cases will be diagnosed in 2021, resulting in 1,508 deaths.[4]

Cervical cancer, once the leading cause of death for women in the U.S., has significantly decreased in incidence and mortality since the mid-1970s due to an increase in Pap Tests being conducted. Between 2014 and 2018, the incidence of cervical cancer was 7.5 per 100,000 women and the mortality was 2.2 per 100,000 women in the U.S.[5] While cervical cancer incidence and mortality continue to decrease, both are considerably higher among Hispanic and non-Hispanic Black women. In 2021, an estimated 14,080 new cases are expected to be diagnosed, with an estimated 4,290 women were expected to die from cervical cancer.[1] In North Carolina, an estimated 406 cervical cancer cases will be diagnosed in 2020, resulting in 129 deaths.[2]

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[1] U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, 2020
[2] National Cancer Institute SEER Stat Fact Sheets, Female Breast Cancer, 2020, https://seer.cancer.gov/statistics/
[3] American Cancer Society Cancer Facts and Figures, 2020
[4] N.C. State Center for Health Statistics, 2020
[5] American Cancer Society Cancer Facts and Figures 2020
1 American Cancer Society Cancer Facts and Figures 2020
2 N.C. State Center for Health Statistics, 2020

The most recent available data[3] shows 72,010 women eligible for breast cancer screening and diagnostic follow-up and 293,509 women eligible for cervical cancer screening and diagnostic follow-up in North Carolina. These estimates do not include the thousands of women who are underinsured and may still be eligible for preventative cancer services.

The North Carolina Breast and Cervical Cancer Control Program (NC BCCCP) began in North Carolina in 1992 and continues to provide services to underserved North Carolina women. Funding is received through a competitive grant from the Centers for Disease Control and Prevention (CDC). This program was the first chronic disease screening program funded in the United States.

The NC BCCCP is a screening program and does not provide funds for treatment. However, women enrolled in NC BCCCP and provided with at least one screening and/or diagnostic service prior to diagnosis may be eligible to receive Breast and Cervical Cancer Medicaid (BCCM) to cover acute treatment services for breast and cervical cancers and eligible precancerous breast and cervical findings and for reconstruction surgeries. Additionally, women who are diagnosed outside of NC BCCCP with breast and/or cervical cancer and/or precancerous lesions and who meet NC BCCCP eligibility may apply for BCCM. Presumptive retroactive coverage of BCCM may not exceed three months.

II. Purpose:

The goal of the North Carolina Breast and Cervical Cancer Control Program (NC BCCCP) is to reduce the morbidity and mortality due to breast and cervical cancers in women by providing breast and cervical cancer screening, diagnostic services, and patient navigation services for eligible underserved women of North Carolina.

III. Scope of Work and Deliverables:

1. Provided Services. The Local Health Department (LHD) shall provide breast and cervical cancer screening services and/or diagnostic services and/or patient navigation only services to NC BCCCP-enrolled women according to the following table:

Number of NC BCCCP-Enrolled Women, by Service Period	State Funded	Federally Funded	Total
Breast and Cervical Cancer Screening and/or Diagnostic Services Provided			
June 1, 2022 – May 31, 2023	0	—	0
July 1, 2022 – May 31, 2023	—	0	0
Patient Navigation Services Only-Breast & Cervical Cancer Medicaid Application Completion			
July 1, 2022 – May 31, 2023	—	0	0

2. Priority Populations
   a. The priority population for **NC BCCCP mammography services** is women who are low-income (below 250% of federal poverty level), who have not been screened in the past year and:
      1. For **federally funded services**, the priority population is between the ages of 50 and 64.
      2. For **state-funded services**, the priority population is between the ages of 40 and 64.
   b. The priority population for **NC BCCCP cervical cancer screening services** is women who are low-income (below 250% of federal poverty level), who have not been screened in the past year and:
      1. For **federally funded services**, the priority population is between the ages of 21 and 64.

[3] SAHIE 2018

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2. For **state-funded services**, the priority population is between the ages of 21 and 64.

c. The priority population for **NC BCCCP services** is individuals who are defined as disproportionately burdened populations. While all segments of society are affected by cancer, there are certain populations that are disproportionately burdened by the increased risk of cancer or by the lack of adequate healthcare options for prevention and/or treatment. Special emphasis is placed on targeting efforts to achieve health equity by recruiting women disproportionately affected by cancer, including women of ethnic minorities.

   Disproportionately burdened populations may be defined by sex, race, ethnicity, disability, sexual orientation, gender identity, geographic location, or socioeconomic status. Among the populations that will benefit from this program are those living in rural and frontier geographic areas; culturally isolated women; incarcerated or institutionalized women; medically underserved women; women from minorities defined by race, religion, ethnicity, or culture, including African-Americans, Alaska Natives, American Indian, Asian Americans, Pacific Islanders and Hispanics; lesbian, gay, bisexual, or transgender individuals; and women with low literacy, non-English speaking language barriers, and disabilities.

3. Eligible Population

   a. Women 21 to 75 years of age with gross incomes that are below 250% of the federal poverty level, according to the Federal Poverty Guidelines, and who are uninsured or underinsured, may be eligible for breast and cervical services, subject to the limitations and exceptions listed below.
      1. Women enrolled in Medicare (Part B) and/or Medicaid programs are not eligible for NC BCCCP-funded services.
      2. Women receiving Family Planning (Title X of the Public Health Service Act) services are not eligible for NC BCCCP-funded services that are available through Title X funding.

   b. Documented citizenship is not required for screening and/or diagnostic services through NC BCCCP.

   c. Breast Services. **At least 75% of all initial mammograms provided through NC BCCCP using federal funds must be for women ages 50 to 64**; no more than 25% may be provided for symptomatic women under the age of 50.
      1. Symptomatic women under the age of 50
         a. NC BCCCP state funds or federal funds can be used to reimburse for diagnostic services for symptomatic women under the age of 50.
         b. Abnormal findings, including a discrete palpable mass, nipple discharge, and skin or nipple changes, a woman can be provided a diagnostic mammogram and a referral for a surgical consultation.
      2. Asymptomatic women ages 40 to 49
         a. NC BCCCP state funds may be used to reimburse for mammograms for women ages 40 to 49.
         b. NC BCCCP federal funds may only be used for mammograms in this population for women who are symptomatic, subject to the 25% limitation noted above.
      3. Asymptomatic women under the age of 40
         a. NC BCCCP state funds and federal funds can be used to screen asymptomatic women under the age of 40, if they are considered to be at high risk (see high risk defined below) for developing breast cancer.

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4. Asymptomatic or symptomatic women ages 65 to 75.
    a. NC BCCCP state funds may be used to reimburse for mammograms for women ages 65 to 75 if no other source of funding is available.
    b. NC BCCCP federal funds may be used for symptomatic women in this population.
5. All women should undergo a risk assessment to determine if they are at high risk for developing breast cancer.

d. Cervical Services. At least 20% of all enrolled women screened for cervical cancer shall meet the definition of never screened (greater than 10 years). The priority age for cervical cancer screening is women between the ages of 21 and 64. All women should undergo a risk assessment to determine if they are at high risk for developing cervical cancer.

e. Women diagnosed outside of NC BCCCP with breast and/or cervical cancer and/or pre-cancerous lesions with a diagnosis that is less than three months prior to the date of BCCM application, and who meet NC BCCCP eligibility criteria may receive Patient Navigation-only (PN-only) services to apply for BCCM.

4. Clinical Protocols

a. Breast Screening
1. Protocols for breast screening and follow-up shall be in accordance with the *Breast Screening Manual: A Guide for Health Departments and Providers* (DHHS, December 2021) available on the website at: http://bcccp.nc.ncdhhs.gov/providers.htm.
2. Protocols for Mammography Facilities and follow-up shall be in accordance with the Federal Food and Drug Administration (FDA) regulations. When contracting with any mammography facility, the LHD shall assure that the facility is accredited under the Mammography Quality Standards Act (MQSA) regulations. *(*See *Breast Screening Manual: A Guide for Health Departments and Providers,* DHHS, 2021
3. All eligible women shall receive breast cancer screening services based on the guidelines under Section III, Subsection C. Eligible Population. The vertical strip method for CBE services is endorsed.
4. All women should undergo a risk assessment to determine if they are at high risk for developing breast cancer. NC BCCCP state funds and federal funds can be used for annual screening among women who are considered high risk for developing breast cancer. "Women at high risk" includes those who have a known genetic mutation such as BRCA 1 or 2, first-degree relatives with premenopausal breast cancer or known genetic mutations, a history of radiation treatment to the chest area before the age of 30 (typically for Hodgkin's Lymphoma), or a lifetime risk of 20% or more for development of breast cancer based on risk assessment models that are largely dependent on family history. These women should be screened with both an annual mammogram and an annual breast MRI.

b. Cervical Screening
1. Protocols for cervical screening and follow-up shall be in accordance with *The Cervical Screening Manual: A Guide for Health Departments and Providers* (DHHS, December 2020), available on the website at http://bcccp.ncdhhs.gov/providers.htm.
2. Laboratories processing cervical cytology and HPV testing samples must be certified under the most recent version of Clinical Laboratory Improvement Amendments. The latest version of the Bethesda System is required for reporting the results of cervical

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cytology. (See *The Cervical Screening Manual: A Guide for Health Departments and Providers.* DHHS, 2020.)

3. For patients under age 30 with no abnormal findings, the screening interval for cervical cytology is every three years. For women ages 30-65, the patient may opt for co-testing with cervical cytology alone every three years, co-testing with cervical cytology and HPV testing every five years, or primary hrHPV testing alone every five years.
4. All women should undergo a risk assessment to determine if they are at high risk for developing cervical cancer. Women who are at high risk for cervical cancer need to be screened more frequently than average-risk women. NC BCCCP funds can be used for annual screening among women who are considered high risk for cervical cancer. This includes women with HIV infection, who have had an organ transplantation, who may be immunocompromised from another health condition, or who had diethylstilbestrol (DES) exposure in utero.
5. NC BCCCP funds cannot be used for cervical cancer screening in women with total hysterectomies (i.e., those without a cervix), unless the hysterectomy was performed because of cervical neoplasia or invasive cervical cancer, or if it was not possible to document the absence of neoplasia or reason for the hysterectomy. (A one-time pelvic exam is permitted to determine if a woman has a cervix.)
6. Women who have had a total hysterectomy for Cervical Intraepithelial Neoplasia (CIN) disease should undergo cervical cancer screening for 20 years even if it goes past the age of 65.
7. Women who have had cervical cancer should continue screening indefinitely as long as they are in reasonable health.
8. Women who have had a supracervical hysterectomy remain eligible for cervical cancer screening.
9. With the exception of Subparagraph 5 above, a pelvic exam should not be provided using NC BCCCP funds in the absence of cervical cancer screening.

c. Clinical Records
   1. The LHD shall maintain clinical records for each woman receiving NC BCCCP services as a part of the patient's individual medical record.
   2. The LHD shall audit a random sample of at least five NC BCCCP patient records at least once annually to check for compliance with program requirements

d. Tobacco Screening and Cessation. The LHD is required to assess the smoking status of every woman screened by NC BCCCP and refer those who smoke to a tobacco cessation program such as QuitlineNC.

e. Colorectal Cancer Screening Status. The LHD shall assess each patient ages 45 and above for her colorectal cancer screening status. (See *NC BCCCP Colorectal Cancer Screening Information and Assessment Policy*, effective May 29, 2015, revised June 2, 2021.)

f. Insurance Status. The LHD shall assess all women seeking to be enrolled in BCCCP for insurance status at each visit. Uninsured women must be referred to available insurance options, such as the Health Insurance Marketplace (i.e., HealthCare.gov). If the woman's visit does not occur during open enrollment, she must be provided information about how to enroll at the next opportunity.

g. Follow-up Services and Patient Navigation
   1. Patient Navigation is defined as "individualized assistance offered to clients to help overcome health care system barriers and facilitate timely access to high-quality

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screening and diagnostics as well as initiation of treatment services for women who are diagnosed with cancer."

2. LHDs should establish services:
    a. To assist women eligible for NC BCCCP-paid clinical services in overcoming barriers to complete screening, diagnostic services, and initiation of cancer treatment; and
    b. To support low-income women (the priority populations) but who have other payment sources (e.g., state funds, Medicaid) for screening in overcoming barriers to complete screening, diagnostics, and initiation of cancer treatment.
3. Patient Navigation for women served by the NC BCCCP must include the following activities:
    a. Assessment of individual patient barriers to cancer screening, diagnostic services, and initiation of cancer treatment;
    b. Patient education and support;
    c. Resolution of identified patient barriers (e.g., transportation, translation services);
    d. Patient tracking and follow-up to monitor patient progress in completing screening, diagnostic testing, and initiating cancer treatment;
    e. A minimum of two (but preferably more) contacts with the patient, due to the centrality of the patient-navigator relationship;
    f. Collection of data and reporting to NC BCCCP to evaluate the primary outcomes of cancer screening and/or diagnostic testing, final diagnosis, and treatment initiation if needed.
4. Women in need of screening shall receive assessment of their need for patient navigation and assistance to access screening services, whether by enrollment in BCCCP or referral to a non-BCCCP provider.
5. When follow-up services are required, NC BCCCP funds are to be used to pay for or provide the diagnostic services listed on the most current NC BCCCP Fee Schedule up to a maximum of $2,000 per woman. All fee schedules are sent via email to the LHD BCCCP navigators and are found at http://bcccp.ncdhhs.gov/providers.htm. The LHD must hold sufficient NC BCCCP funds to complete screening, follow-up, and/or diagnostic services for each woman served.
6. The LHD shall assure that a referral system for the diagnosis and treatment of all abnormal findings is in place. The LHD shall designate a primary person who shall be responsible for implementing a protocol that ensures all patients receive follow-up services or medical treatment when required. Cross-training is strongly encouraged. Follow-up of an abnormal screening test must be completed within 60 days of the patient's screening visit for breast cancer screening and within 90 days for cervical cancer screening.
7. Women having an abnormal breast or cervical cancer screening result shall receive Patient Navigation and be referred for assessment of the following findings:
    a. Clinical breast exam results of discrete palpable mass, serous or bloody nipple discharge, nipple or areolar scaliness, or skin dimpling or retraction;
    b. Mammogram result of Category IV (suspicious abnormality, biopsy should be considered) or Category V (highly suggestive of malignancy);
    c. Cervical cytology result of low-grade squamous intraepithelial lesion (LSIL), atypical squamous cells of undetermined significance (ASC-US) with positive

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Human Papilloma Virus (HPV), atypical squamous cells- cannot exclude high-grade lesions (ASC-H), high-grade squamous intraepithelial lesion (HSIL), squamous cell carcinoma (SCC), abnormal glandular cells (AGC) including atypical glandular cells of undetermined significance (AGUS) or adenocarcinoma.

8. At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be made by certified letter. Written documentation of all attempts to inform the patient must be included in the patient's medical record.
9. For all abnormal mammograms, clinical breast examinations, and cervical cancer screening results, the following information shall be documented in the patient's medical record:
    a. Patient contact information (number and date of attempts made to follow-up);
    b. Follow-up appointment information (date, follow-up provider, and follow-up location);
    c. Date the referral was made;
    d. Results of all referrals, including the report from the follow-up provider.
10. The LHD shall assist eligible women with a breast or cervical cancer diagnosis with applying for BCCM. Providers are no longer required to provide a screening or diagnostic work-up for patients to apply for BCCM. Women diagnosed outside of NC BCCCP with breast and/or cervical cancer and/or pre-cancerous lesions with a diagnosis that is less than three months prior to the date of BCCM application, and who meet NC BCCCP eligibility criteria may receive Patient Navigation-only (PN-only) services to apply for BCCM. Patients who receive PN-only services to apply for BCCM will count as a PN-only target and the LHD will be eligible to receive $50 *per capita* reimbursement for providing this service. LHDs are not allowed to draw down funding for Patient Navigation-only services in addition to screening/diagnostic service target funding.

h. Standing Orders. All standing orders or protocols developed for nurses in support of this program must be written in the North Carolina Board of Nursing format. All local health departments shall have a policy in place that supports nurses working under standing orders. https://www.ncbon.com/vdownloads/position-statements-decision-trees/standing-orders.pdf

5. Recruitment, Outreach and Professional Education

a. Recruitment and Outreach

1. To enhance internal LHD referrals to NC BCCCP, the LHD shall provide in-reach activities. These activities are to ensure that staff in all LHD clinics are aware of the NC BCCCP eligibility guidelines and know how to refer a potentially eligible patient to the appropriate contact person.
2. The LHD shall conduct appropriate recruitment and outreach strategies to reach women who have never been screened for breast and/or cervical cancer as well as populations who are most at risk.
3. The LHD shall return all recruitment data and surveys by the required deadline as requested by the NC BCCCP Program Consultant.

b. Professional Development

1. The LHD shall participate in educational opportunities provided or recommended by NC BCCCP as appropriate.

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2. The LHD's NC BCCCP staff must attend:
    a. The NC BCCCP Biennial Update meeting.
    b. Scheduled statewide conference calls as indicated.
    c. At least one of the NC BCCCP trainings offered twice a year. For newly hired staff, the staff member must attend the first biannual NC BCCCP training following the date of hire. Web-based trainings and/or traditional face-to-face trainings will be available.
3. All registered nurses without advanced practice certification who perform clinical examinations for the NC BCCCP must enroll in and complete the Physical Assessment of Adults Course. This course is conducted by the University of North Carolina Gillings School of Global Public Health and is co-sponsored by the North Carolina Division of Public Health. Evidence of the satisfactory completion of a comparable course of study may be substituted for this requirement with the approval of the Public Health Nursing and Professional Development Unit (PHNPDU). Proof of this certification must be on file with the LHD.
4. Policies and procedures must be in place for assuring the competency of nurses and the documentation of competency for each nurse performing the clinical examinations. (See *North Carolina Nurse Practice Act* at https://www.ncleg.net/enactedlegislation/statutes/html/byarticle/chapter_90/article_9a.html.
5. All staff performing clinical breast examinations (CBE) are encouraged to use the vertical strip method. Training is available through NC BCCCP and Mammacare.com.

IV. <u>Performance Measures / Reporting Requirements</u>:

1. Performance Measures—Indicators and Benchmarks

Funding to the LHD for NC BCCCP in FY 22-23 will be based on the LHD's FY 21-22 performance (if available) in all areas listed in the following table**. Failure to comply with these indicators in FY 22-23 may result in loss of funding in FY 23-24.**

Indicator Type	Program Performance Indicator	Minimum Standard
Screening Goal	Total number of women served for FY 22-23	100%
Expenditures	Allocated BCCCP funds expended for each woman served	100%
Breast Cancer Screening Performance Indicators	Initial screening mammograms provided to women ≥ 50 years of age (applies to federal funds only)	≥ 75%
	Abnormal screening results with complete follow-up	≥ 90%
	Abnormal screening results; Time from screening to diagnosis > 60 days	≤ 25%
	Treatment started for breast cancer	≥ 90%
	Breast cancer; Time from diagnosis to treatment > 60 days	≤ 20%
Cervical Cancer Screening Performance Indicators	Initial program cervical cancer screening; never screened	≥ 20%
	Abnormal screening results with complete follow-up	≥ 90%
	Abnormal screening results - time from screening to diagnosis > 90 days	≤ 25%
	Treatment started for diagnosis of HSIL, CIN 2,3, CIS, Invasive Carcinoma	≥ 90%
	HSIL, CIN 2,3, CIS; Time from diagnosis to treatment > 90 days	≤ 20%
	Invasive carcinoma; Time from diagnosis to treatment > 60 days	≤ 20%

2. Reporting Requirements-Screening Data

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Frequency and Due Dates: All BCCCP data, including initial screening or diagnostic service, follow-up of abnormal results, and treatment disposition shall be recorded by the LHD in a data system compatible with the North Carolina state data system and transferred to the state through the LHD-HSA (Health Services Analysis, located at the State Center for Health Statistics) as follows:

a. The LHD shall enter BCCCP patient data into a data system compatible with the North Carolina state data system, transfer the data to the state. All screening data for each month shall be entered and transferred by the 10th of the following month.

b. All test results, including follow-up, diagnosis, and treatment, shall be updated as soon as received and according to NC BCCCP timelines.
   1. Diagnostic disposition must be entered within 60 days of the breast screening date and within 90 days of the cervical screening date.
   2. Treatment disposition must be entered within 60 days of the diagnostic disposition date for breast or cervical cancer and within 90 days of the diagnosis date for HSIL, CIN2,3, or CIS of the cervix.

c. The LHD shall never withhold inputting data on any patient. The LHD shall not wait for the completion of follow-up to enter data, even if there are abnormal findings that require follow-up.

d. The LHD shall separately report the total women screened on the monthly expenditure report and fax the signed report before funding is drawn down in ATC for the previous month's screenings.

e. The LHD shall provide the required screening and patient navigation data by completing Patient Navigation-Only Form for each woman who receives Patient Navigation-only services and submitting the completed form by fax to the NC BCCCP office at 919-870-4812. This form must be submitted to NC BCCCP before the LHD requests reimbursement.

f. The LHD shall notify NC BCCCP Staff of any LHD NCBCCCP Staff changes (including the Health Director, Nursing Director/Supervisor, NC BCCCP Navigator, Health Educator, or Financial Contact), the state's NC BCCCP is to be advised of the name and contact information of that person within one month using the *Staff Change Notification Form,* available for download at https://bcccp.ncdhhs.gov/linksandresources/Manuals/Section10-Forms/1001-Staff-Change-Notification-Form.pdf.

3. **Reporting Requirements-Performance and Financial Data**

Complete the following reports via the Smartsheet dashboard, which can be accessed at https://app.smartsheet.com/b/publish?EQBCT=82018408e7b44ef9b44e113b6e536ffb. All the due dates for these reports are posted on the Smartsheet dashboard.

a. **Monthly Financial Reports**: These monthly financial reports will report on the prior month. The first financial report is for June 2022 and is due by July 22, 2022.

b. **Quarterly Performance Reports**: These quarterly performance reports will detail the prior quarter's progress. The first report is to report for June, July and August 2022 and is due by September 15, 2022. The quarterly periods for these reports are defined as:
   - June–August 2022
   - September–November 2022
   - December 2022–February 2023
   - March–May 2023

4. **Process and Outcome Evaluations**

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The LHD shall respond to NC BCCCP evaluation requests in a timely manner. This includes completing evaluations, surveys, focus groups, interviews, and other data collection methods as outlined in the CDC and NC BCCCP Evaluation Plans.

V. Performance Monitoring and Quality Assurance:

1. The LHD shall monitor by:
   a. Maintaining clinical records for each woman receiving NC BCCCP services as a part of the patient's individual medical record.
   b. Auditing a random sample of at least five NC BCCCP patient records at least once annually to check for compliance with program requirements.

2. NC BCCCP Program staff shall monitor by:
   a. Reviewing the data entered into the LHD-HSA by the LHD in order to determine whether the LHD is meeting contract targets and performance measures.
   b. Conducting a risk assessment of the LHD and determining the LHD's risk category prior to the release of this Agreement Addendum. Each LHD will be categorized as low or high risk. An LHD's risk category can change at any time and will be reassessed at least annually and if irregularities are noted. The frequency and intensity of monitoring techniques applied will be directly proportional to the level of risk assigned. An LHD categorized as low risk will receive a detailed monitoring event at least once every three years. An LHD categorized as high risk will be notified by letter of the high-risk assessment. A specific date for corrective action and details about the monitoring plan will be defined in the letter. For LHDs categorized as high risk, the site visit for a detailed monitoring event will occur at least annually.
      1. The purpose of the monitoring event is to verify and document timeliness and adequacy of follow up, quality of services, efficiency of operations, and compliance with program requirements.
      2. The monitoring event will be conducted on-site at the LHD if possible. Alternatively, a remote monitoring event may be conducted if travel to the LHD site is not possible. NC BCCCP staff will provide advance notice to the LHD of the date and time of the monitoring event.
   c. Reviewing the LHD's Program Performance Indicators in the program data system monthly.
      1. Technical assistance is provided as needed.
      2. If the LHD is not meeting monthly performance indicators at the time of the mid-year performance evaluation, NC BCCCP Program staff will notify the LHD that it has been placed on "high-risk status" and will require a Corrective Action Plan (CAP). The CAP will be submitted and implemented within 30 days.
      3. If the LHD is placed on high-risk status, NC BCCCP Program staff will notify LHD by letter of high-risk status and a specific date for corrective action and details about the monitoring plan will be identified in the letter.
   d. Providing progress reports to the LHD to report performance and identify individual cases requiring follow-up or correction by the LHD. All patients with abnormal findings or data errors are to remain listed on the monthly data reports for two program years, or until follow-ups are completed or errors are corrected, whichever is earlier.
   e. Providing the LHD with more frequent technical assistance if there are indications of problems meeting performance requirements or if requested by the LHD.

3. Consequences of Inadequate Performance

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a. Failure to meet targets, expend funds, submit data, and other required reporting as expected may result in reduced current and/or future targets and funding.

b. Failure to submit data in a timely manner could result in the LHD being deemed as out of compliance. If the LHD is deemed out of compliance, program staff will provide technical assistance and the LHD shall be requested to cease drawing down funds in ATC until the LHD is back in compliance with deliverables. If technical assistance does not prove beneficial, the agreement may be terminated.

c. If monthly or triennial monitoring uncovers deficits, NC BCCCP staff will work with the LHD to correct these deficits.

   1. Ongoing deficits will require development and implementation of a Corrective Action Plan
   2. Persistent failure to meet program requirements will result in termination of the Agreement Addendum.

d. If the LHD terminates or is terminated from the NC BCCCP, the following procedures shall be followed:

   1. If the LHD chooses to terminate, it shall notify the NC BCCCP Program Director of the reason and intent to terminate in a letter written on the LHD's letterhead and signed by the health director, which includes the effective date of the termination.
   2. Identify resources in the community and refer women who have abnormal findings found prior to termination of the LHD's NC BCCCP activity.
   3. Notify all current NC BCCCP participants of closure of the program and offer them assistance to find alternative providers of screening services.
   4. Continue to monitor monthly data reports and provide follow up or corrected information until all cases are closed out.
   5. Maintain all NC BCCCP records and program manuals according to the local record retention schedule.

e. With termination, all remaining NC BCCCP funds will revert to DPH.

VI. Funding Guidelines or Restrictions:

4. Requirements for pass-through entities: In compliance with 2 CFR §200.331 – *Requirements for pass-through entities*, the Division of Public Health provides Federal Award Reporting Supplements to the Local Health Department receiving federally funded Agreement Addenda.

   a. Definition: A Supplement discloses the required elements of a single federal award. Supplements address elements of federal funding sources only; state funding elements will not be included in the Supplement. Agreement Addenda (AAs) funded by more than one federal award will receive a disclosure Supplement for each federal award.

   b. Frequency: Supplements will be generated as the Division of Public Health receives information for federal grants. Supplements will be issued to the Local Health Department throughout the state fiscal year. For federally funded AAs, Supplements will accompany the original AA. If AAs are revised and if the revision affects federal funds, the AA Revisions will include Supplements. Supplements can also be sent to the Local Health Department even if no change is needed to the AA. In those instances, the Supplements will be sent to provide newly received federal grant information for funds already allocated in the existing AA.

5. Financial

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a. The LHD will be reimbursed at a capitated rate of $325 per woman who receives at least one NC BCCCP-funded clinical service (mammogram, clinical breast exam, Pap test, Pap test with HPV co-test, primary hrHPV testing, or diagnostic service).

b. The LHD will be reimbursed at a rate of $50 for each unduplicated woman who receives Patient Navigation-only services to apply for Breast and Cervical Cancer Medicaid (BCCM). Women diagnosed with cancer not more than three (3) months prior to applying for BCCM can be navigated by a BCCCP provider to apply for BCCM up to the total number of women specified in Section III, Paragraph A of the Agreement Addendum. **LHDs cannot request reimbursement for providing PN-only services ($50) in addition to screening/diagnostic service target funding ($325) for the same patient**.

c. The total funds awarded from NC BCCCP shall be maintained by the LHD in a separate budget cost center to assure proper auditing of expenditures. Funding allocations are based on performance measures as stated in Section IV-Performance Measures/Reporting Requirements.

d. Patients who receive clinical services using state funds need to be tracked and reported separately in a data system compatible with the North Carolina state data system from those who receive clinical services using federal BCCCP funds.

e. Monies shall be allocated to ensure achievement of contracted target numbers and payment for NC BCCCP approved services rendered by outside medical providers through subcontracts. These may include, but are not limited to, surgical consultations, follow-up for abnormal results, and diagnostic procedures. (Refer to the most current NC BCCCP Project Fee Schedule at http://bcccp.ncdhhs.gov/providers.htm.) As of June 1, 2022, the LHD must hold sufficient NC BCCCP funds to complete the screening, follow-up and/or diagnostic services for each woman served. Only services listed on the NC BCCCP Fee Schedule are reimbursable with Program funds unless prior authorization is obtained from NC BCCCP Nurse Consultants.

f. At the end of the program year, NC BCCCP funds held by the LHD in excess of the provider's actual costs of providing the initial screening and any necessary follow-up/diagnostic procedure may be used to cover staff providing indirect services or expenses such as salaries and fringes (e.g., data entry clerk or indirect personnel involved with screening services), travel, office supplies, medical supplies, postage, mailings, and fliers. These listed items are not inclusive of every indirect cost a LHD may incur.

g. The LHD shall adhere to the monthly deadlines for the Aid-to-Counties Database (ATC) Report submission to the State's Controller's Office when requesting reimbursement for services rendered in the preceding month. The LHD shall submit the required Local Health Department Monthly Expenditure report on total number served in the preceding month and the total funds requested before requesting funds in ATC.

h. **State funds** used for screening by May 31, 2023, must be requested by June 2023, in accordance with the "Last Day Local Health Department Expenditure Reports Due" referenced on the Aid-to-Counties Payment Schedule, Calendar Year 2023 established by the North Carolina Department of Health and Human Services Controller's Office.

i. **Federal funds** are allocated based on the federal grant. Federal funds used for **screening in the eleven months between July 1, 2022 and May 31, 2023** must be requested by June 2023, in accordance with the "Last Day Local Health Department Expenditure Reports Due" referenced on the Aid-to-Counties Payment Schedule, Calendar Year 2023 established by the North Carolina Department of Health and Human Services Controller's Office.

j. All reimbursement must be requested by the date determined by the State Controller's Office.

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k. NC BCCCP funds shall not be used to reimburse for treatment services. Payment to a subcontractor using NC BCCCP funds is limited to those screening and diagnostic follow-up services listed in the current NC BCCCP Services Fee Schedule and those that have been pre-authorized by NC BCCCP Nurse Consultants.

6. Payment for Services

   a. The payment to subcontractors for any service described in Section III may not exceed the prevailing Medicare-allowable fee for the service. The most current fee schedules shall be provided to the participating subcontractor by the LHD.

   b. NC BCCCP funds shall only be used for payment after all other third-party payment sources (private insurance but not Medicare [Part B] and Medicaid) provide evidence of partial or non-payment of eligible services. NC BCCCP funds may be used to reimburse for a deductible and/or co-payment required of the patient, provided that the total payment (including the deductible and co-payment) to the subcontractor or subcontractors does not exceed the prevailing Medicare-allowable fee.

   c. Women whose gross incomes are less than or equal to 100% of the federal poverty level shall not be charged for any services covered through NC BCCCP. However, ancillary costs and non-NC BCCCP covered fees may be charged to the NC BCCCP participant. Participants shall be notified of any possible charges prior to committing to the procedure.

   d. A flat fee may not be charged for NC BCCCP services to any woman enrolled in NC BCCCP.

   e. Sliding fee scales may be used for women whose gross incomes are between 101% and 250% of the federal poverty level.

7. Agreement Addendum Funding Allocation Adjustments

   a. As of June 1, 2022, the number of women served in compliance with performance indicators will be determined by the number of women who have a screening and/or diagnostic service paid partially or in full with NC BCCCP funds.

   b. To retain the baseline budget for the following fiscal year, the LHD must screen a minimum of 100% of their allocated number of women and expend a minimum of 100% of the funds awarded each year.

   c. Funding adjustments may be made in the baseline budget of the LHD. State accessible data shall be reviewed in November 2022 to determine if budget adjustments are indicated based on compliance with performance indicators and patient targets.

   d. Technical assistance will be provided to the LHD if it is unable to meet allocated targets.

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