7.0 **INTRODUCTION**

Quality assurance is the activity of monitoring and evaluating, in an objective and systematic manner, the quality and appropriateness of client care. Quality can be viewed from three different perspectives: the consumer, payer and provider. Although all three may have different views on which they focus, all have a common interest. They all have a common goal of high quality breast and cervical cancer screening and diagnostic services. This standard applies to all women who receive services through IBCCP.

7.1 **DATA QUALITY STANDARDS**

7.1.1 **MINIMUM DATA ELEMENTS**

Data collected for women who qualify for the Federal (CDC) Program (women with income at or below 250% of the Federal Poverty Level) are included in the Minimum Data Elements (MDEs) submitted to CDC. The MDEs are a set of standardized data elements developed to ensure that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, and treatment information are collected on women screened or diagnosed with Program funds. MDEs are the single most important source of data for Program management and monitoring Program activities. (CDC, Data User's Manual, 2012.)

Semi-annual MDE submissions, a compilation of the data entered into Cornerstone by the IBCCP agencies, are used to monitor the completeness of the data collected and the timeliness and adequacy of the service delivered to women who participate in the Program. The MDE is comprised of three major sections: All Patients Section, Abnormal Pap Test Section, and Abnormal Mammogram/Clinical Breast Exam Section.

Prior to each MDE submission, the Data Manager mails reports to the Lead and Consortia Agencies for data review and correction. Lead Agencies are expected to make data corrections promptly upon receiving the reports. Lead Agencies with Consortia Agencies are responsible for disseminating the reports and monitoring the correction of data entry errors in the Consortia Agencies. The Data Manager or the Quality Assurance Nurse assigned to the Lead Agency will follow-up to determine that the appropriate data corrections have been made.

With the addition of Clinically Navigated Insured women, an additional set of MDE’s will be generated and submitted to CDC. They are entirely separate from your NBCCEDP/IBCCP MDEs. Although, the women included in the data set are insured, as a Clinical Patient Navigator (CM), the same standard and quality
of case management applies to these women. Clinical Navigated Insured MDEs will not be sent to Lead Agencies to correct. But the expectation is that you clinically navigate (CM) these women as robustly as if they were an NBCCEDP/IBCCP client.

CDC, using MDEs from all programs, sets benchmarks for comparison of program data across all states and territories. Individual program performance is also compared across reporting periods. Additionally CDC will now compare the MDEs of clinically navigated insured women with the MDEs of the women in the NBCCEDP/IBCCP Program.

MDE criteria and benchmarks (same for CNI) established by CDC for NBCCEDP are in the following tables:

**Pap Test Data:**

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>CDC BENCHMARK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of first funded Pap tests provided to women never or rarely screened.</td>
<td>≥ 20%</td>
</tr>
<tr>
<td>Percentage of abnormal Pap test results with diagnostic follow-up; includes ASC-H, High grade SIL, Squamous cancer, and Abnormal glandular cells results.</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of colposcopies that include a biopsy.</td>
<td>≥ 75%</td>
</tr>
<tr>
<td>Percentage of invasive cervical cancers with missing stage at diagnosis.</td>
<td>≤ 1%</td>
</tr>
<tr>
<td>Percentage of invasive cervical cancers with unknown stage at diagnosis.</td>
<td>≤ 10%</td>
</tr>
</tbody>
</table>

**Clinical Breast Exam and Mammogram Data:**

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>CDC BENCHMARK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of women ≥ 50 years of age receiving federally funded mammograms.</td>
<td>&gt; 75%</td>
</tr>
<tr>
<td>Percentage of abnormal CBE results with diagnostic follow-up; includes discrete palpable mass, bloody or serous nipple discharge, nipple or areolar scaliness, and skin dimpling or retraction results.</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of abnormal mammogram results with diagnostic follow-</td>
<td>100%</td>
</tr>
</tbody>
</table>
up; includes suspicious of abnormality, highly suggestive of malignancy, and assessment incomplete results.

| Percentage of invasive breast cancers with missing stage at diagnosis. | ≤ 1% |
| Percentage of invasive breast cancers with unknown stage at diagnosis. | ≤ 10% |
| Percentage of invasive breast cancers with missing tumor size. | ≤ 1% |
| Percentage of invasive breast cancers with unknown tumor size. | ≤ 15% |

Pap Test, Clinical Breast Exam, and Mammogram Data:

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>CDC BENCHMARK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Test Date to Diagnosis Date Interval</td>
<td></td>
</tr>
<tr>
<td>Total days between screening test with abnormal results and determination of diagnosis.</td>
<td>≤ 60 days</td>
</tr>
<tr>
<td>Percentage of diagnostic cycles with interval over 60 days.</td>
<td>≤ 25%</td>
</tr>
<tr>
<td>Diagnosis Date to Treatment Date Interval</td>
<td></td>
</tr>
<tr>
<td>Total days between determination of diagnosis and providing treatment.</td>
<td>≤ 60 days</td>
</tr>
<tr>
<td>Percentage of cycles that include diagnosis and treatment with interval over 60 days.</td>
<td>≤ 20%</td>
</tr>
</tbody>
</table>

Follow-up of Abnormal Screening Test Results Demonstrated by Thorough Data Entry:

| Percentage with complete follow-up. | ≥ 90% |
| Percentage lost to follow-up. | ≤ 3% |
| Percentage workup refused. | ≤ 2% |
| Percentage with incomplete follow-up. | ≤ 5% |

7.1.2 DATA STANDARDS – EXPANDED PROGRAM

Data collected for women who qualify only for the Expanded Program (women with income above 250% of the Federal Poverty Level) will not be submitted to CDC with the MDEs. Lead and Consortia Agencies are still responsible, however, for ensuring that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, and
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treatment information are collected on all women screened or diagnosed. Although the data for women enrolled in the Expanded Program will not be analyzed by CDC as part of the MDEs, the Data Manager will mail reports quarterly to the Lead and Consortia Agencies for data review and correction for these women. The Data Manager or the Quality Assurance Nurse assigned to the Lead Agency will follow-up to determine that the appropriate data corrections have been made.

Although the CDC-mandated criteria and benchmarks in the tables above do not specifically apply to the women enrolled in the Expanded Program, these criteria and benchmarks represent appropriate standards of care. Therefore, Lead and Consortia Agencies are required to comply with these criteria and benchmarks for all women screened.

7.2 PROFESSIONAL LICENSURE

As part of the Quality Assurance site visits, maintenance of current physician, nurse practitioner, physician’s assistant and nurse clinical patient navigator’s (case manager’s) licenses will be reviewed. It is the responsibility of the Lead Agency to maintain this information for themselves and the Consortia Agencies. Please also see Section 3.1.

7.3 BREAST CLINICAL SERVICES

A.) Clinical breast exam (CBE) results should be indicated on the Screening Summary/Office Visit Form.

B.) Screening mammogram results must include the radiology report. The IBCCP Mammogram and Abnormal Breast Screening Care Plan and Follow-up Report must be used by the local agency to track results from the mammography and ultrasound reports.

C.) For all diagnostic tests performed, the agency must obtain a written copy of the appropriate report prior to any data entry into Cornerstone (i.e.: radiology, ultrasound, pathology, cytology, etc.). Verbal reports require written verification prior to data entry.

D.) Abnormal results are to be followed-up according to Program protocol utilizing the appropriate algorithm.

E.) Contracted agencies will monitor the quality of all screening/diagnostic procedure(s) for breast cancer.
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F.) Medical providers must comply with the IBCCP protocol for screening, follow-up, and reporting requirements.

G.) Facilities conducting mammography procedures must have:

1.) American College of Radiology (ACR) accreditation;

2.) Certification issued under the Mammography Quality Standards Act (MQSA);

3.) Report findings using language from the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BIRADS).

7.4 CERVICAL CLINICAL SERVICES

Pelvic exam and Pap test results, which must include the cytology report, are to be included on the Screening Summary/Office Visit Form. Abnormal results are to be followed-up according to Program protocol.

A.) For all diagnostic tests performed, the agency must obtain a written copy of the appropriate report prior to any data entry into Cornerstone (i.e.: radiology, ultrasound, pathology, cytology, etc.). Verbal reports require written verification prior to data entry.

B.) Contracted agencies will monitor quality of all screening/diagnostic procedure(s) for cervical cancer.

C.) Medical providers must comply with the IBCCP protocol for screening, follow-up, and reporting requirements utilizing the appropriate algorithm.

D.) Laboratories must have Clinical Laboratory Improvement Act certification (CLIA).

E.) Results must be reported using the most recent guidelines of the American Society for Colposcopy and Cervical Pathology.

7.5 CHART REVIEWS AND SITE VISITS

Chart reviews determine if IBCCP screening, diagnosis, and treatment protocols are being followed and if complete information is being recorded. The purpose of chart reviews is to verify actual care compared to outcomes reported on data forms. Chart reviews are conducted to assess the adequacy of clinical services. The chart review
process allows Program staff to provide the participating clinic with valuable feedback on its delivery system, identify areas for improvement, develop a plan for making improvements, and offer an extended site visit. Clients chosen for chart reviews are selected from the Cornerstone Summary Statistics Report. Any client receiving services through IBCCP could be selected for the review process.

7.5.1 LEAD AGENCY SITE VISITS

A.) At least one technical assistance site visit will be done as a result of noncompliance with IBCCP protocol discovered during chart review/site visit, based upon MDE errors and/or desk audits.

B.) For site visits, the Quality Assurance Coordinator will utilize the Quality Assurance Site Review Form (Appendix F).

C.) Full site visits will be done a minimum of once every three years at each Lead Agency.

D.) Utilizing the Quality Assurance Client Chart Review Form (Appendix F), the Quality Assurance Nurse Coordinator at IDPH will review a percentage of the caseload (new and re-screen clients) from the previous 12 months. The process includes extracting a sample within the time interval of interest from the 897 Report, usually an equal mix of breast and cervical charts are reviewed, with both normal and abnormal results.

   1. The usage of electronic medical records is acceptable; however, it is the responsibility of the Program Coordinator to ensure required documentation is available to the Quality Assurance Nurse during site visits via hard copy or staff must be made available to assist with viewing client’s records via the computer.

E.) An informal oral report of the findings from the client chart review and site visit will be shared with the contracted agency staff at the end of the visit. Administrative staff are invited to attend, if they choose to be involved.

F.) As part of the site visit, the Lead Agency’s Fiscal Officer will need to be available to meet with the Contract and Data Manager Section Supervisor or Data Manager for the fiscal review portion of the visit. The Fiscal Officer will then be required to provide documentation for a sample of expenses from Reimbursement Certification Forms submitted, answer questions about control activities and staffing, and complete, sign, and date the Quality Assurance Site Review Form (Appendix F, Form d),
certifying that the information in the questionnaires is true, accurate, correct, and complete. The Contract and Data Manager Section Supervisor or Data Manager may request a walkthrough of the Lead Agency office area.

G.) A formal report of the findings from the quality assurance site visit and chart review at the Lead Agency will be sent to the Lead Agency Administrator and Program Coordinator. A copy will also be remitted to the Quality Assurance Coordinator at IBCCP and a copy placed in the agency file.

H.) Each agency is then required to respond within 30 days with a written action plan addressing findings.

I.) The Quality Assurance Nurse will review the written action plan within 30 days of receipt from the Lead Agency and either approve or deny the plan. A formal letter either approving or denying the action plan will be sent to the Agency Administrator and Program Coordinator. If the plan is denied, additional documentation will be requested from the Lead Agency to ensure an effective action plan is in place.

J.) The Quality Assurance Nurse will conduct follow up with the Lead Agency after 90 days of approval of the written action plan to ensure the plan is being implemented as approved. Records and/or policies will again be reviewed to ensure compliance. Only records created since the time of approval of the written plan will be reviewed during subsequent monitoring or technical assistance visit.

K.) If any subsequent findings of noncompliance are identified during a subsequent monitoring or technical assistance visit, the Lead Agency may be referred for financial sanctioning.

### 7.5.2 CONSORTIA AGENCY SITE VISITS

A.) Each Lead Agency will perform a site visit at their respective Consortia Agencies annually. The visit may be scheduled based on noncompliance with IBCCP protocol discovered during a previous chart review or site visit or based upon MDE errors, 785 and 897B reports, or desk audits.

B.) A designated staff member at the Lead Agency will perform chart reviews of a minimum of 5% of the Consortia Agencies caseload attainment from the previous 12 months.
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C.) An informal oral report of the findings from the client chart review and site visit will be shared with the contracted agency staff at the end of the visit. Administrative staff are invited to attend, if they choose to be involved.

D.) A formal report of the findings from the quality assurance site visit and chart review at the Consortia Agency will be sent to the Consortium Agency Administrator and Program Coordinator. A copy will also be remitted to the Quality Assurance Coordinator at IBCCP and placed in the agencies files.

E.) The consortia agency is then required to respond within 30 days with a written action plan addressing findings.

7.5.3 SELF MONITORING AND MEDICAL PROVIDERS QUALITY ASSURANCE

A.) Lead Agencies and Consortia Agencies are required to annually monitor a minimum of 5% of their own IBCCP client charts (new and rescreen clients). Self-review is intended to monitor the quality of screening and diagnostic services in onsite clinics, where they exist, to determine compliance with the IBCCP protocols. This is the agency’s opportunity to review compliance of the contracted medical providers through a review of test results to determine trends of care that need correction or repeat education to enforce compliance with Program protocols.

7.6 TECHNICAL SITE VISITS AND DESK AUDITS

Technical Site Visit

A.) Problematic site visits are scheduled with sites that do not meet the Minimum Data Elements (MDE) described in Section 7.1.1. The Program reviews the site data and tries to identify contributing problems. The Program then suggests corrections or improvements.

Routine site visits occur on an as needed basis, usually at least once per year. Activities include review of enrollment numbers; review of diagnostic cases; discussion about unusual cases/problematic cases; discussion of administrative issues (e.g., policy, billing, and discussion of promotion plan development) for the coming year.
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Non-routine visits also may be conducted more frequently to review management reports if enrollment suddenly drops, (2) when there is an increase in the number of follow-up or billing issues/concerns, (3) when changes in staff require training, (4) coalition and partnership activities, and (5) on request.

B.) Topics reviewed on a technical site visit may include, but are not limited to, the following topics.
   a. Cornerstone Reports
   b. Abnormal Chart Findings
   c. MDE Errors
   d. Caseload Achievement
   e. Outreach Activities
   f. Coalition Formation
   g. Additional Staff Training
   h. Other Guidance and Suggestions

Mid-Year Desk Audit

A.) A mid-year desk audit is a comprehensive quality assurance audit that is mailed to IBCCP agencies annually. The desk audit response is due annually. The desk audit consists of three or four main focus areas with minimal questions for each area. The focus areas vary each year but are selected from key elements or requirements from the CDC Grant Agreement.

Agencies are sent a listing of clients from their agencies selected for review. The focus is dependent on Program objectives, but may look at the diagnosis and referral of women diagnosed with breast or cervical cancer or a precancerous condition, screening to diagnosis within 60-days, diagnosis to treatment within 60-days, completion of case notes, Abnormal Breast and/or Cervical Screening Care Plan and Follow-up Reports, as well as appropriate data entry of procedures into Cornerstone. During the review of Cornerstone data entry, a brief review of billing requests is completed to determine situations where duplicate billing, over billing, or inappropriate use of CPT codes has occurred. These situations are brought to the Agencies attention as part of the written report received by the Agency.

In addition to the clinical component of the desk audit, all Lead Agencies are required to respond to a fiscal component. This fiscal component includes the annual completion of Internal Control/Accounting System Questionnaires by each Lead Agency’s Fiscal Officer. These questionnaires will be kept on file and will be reviewed during future Lead Agency site visits. In addition, Lead Agencies may be required to submit documentation for specific expenses as part of the
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fiscal component each year.

The desk audit is designed to take the place of an onsite visit. Program staff review the audit responses submitted by the Lead Agencies. A formal written report is sent to each agency. If corrective actions are indicated for any client, these are noted and the agency is expected to respond. All information is maintained in the agencies file at the Illinois Department of Public Health. Technical assistance and/or full site visits may be scheduled if indicated during the mid-year audit.

7.7 SATISFACTION SURVEYS

A.) Satisfaction surveys are required by CDC as an indicator of the overall quality of the Program.

B.) Lead and Consortia Agencies are to develop and disseminate both client and provider satisfaction surveys. Medical providers are to be given the opportunity to complete a satisfaction survey on an annual basis. This type of survey can identify training and technical assistance needs as well as necessary infrastructure improvements that will contribute to provider satisfaction.

C.) A random sampling of participating clients must receive a client satisfaction survey. The agency can choose a variety of options to achieve this random sampling. Suggestions are: every 10th client that receives services; all clients in an identified quarter of a grant year; all clients every third month. The minimum acceptable return rate for client satisfaction surveys is 10% of those surveyed. This type of survey can identify concerns with provider services as well as public and client education needs, which if met could improve the screening experience for Program-funded women.

D.) A compilation of the results from both the client and provider surveys must be on file for review during technical assistance and quality assurance site visits.

7.8 IBCCP MEDICAL ADVISORS

The IBCCP Medical Advisors play an important role advising the Program in the establishment of quality standards for screening and diagnostic services related to breast and cervical cancer. Physicians working directly with IBCCP, in laboratory and radiological settings, as well as academia provide medical expertise to IBCCP staff for clinical issues dealing with screening and follow-up services. This collaborative effort assists the Program staff with the goal of reducing cancer morbidity and mortality through early detection and diagnosis.
The IBCCP Medical Advisors consist of practicing physicians and nurse practitioners working to screen and diagnose breast and/or cervical cancer in the clinical setting and other medical professionals.

Key components IBCCP may refer to Medical advisors:

- clinical protocols and algorithms;
- medical practice issues pertaining to the care and treatment of breast and cervical cancer patients;
- review of policies and procedures;
- medical provider concerns;
- professional staffing issues; and
- professional education needs.