

Iowa's Breast & Cervical Cancer Early Detection Program

A Manual for Healthcare Providers

Updated November 2019



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A LETTER FROM IOWA

Dear Healthcare Provider,

Thank you for participating in Iowa's Breast and Cervical Cancer Early Detection Program. If you are reading this manual, you know that screening and early cancer detection is an important step in helping live longer, healthier lives.

This manual will help you and your agency effectively participate in our program. It will help you understand the Breast and Cervical Cancer component of the Care for Yourself program.

Your work is important in helping underserved lowans receive the cancer screenings they need while reducing barriers to screening.

We wish you and your agency success in engaging with this program to increase the breast and cervical cancer screening rates in Iowa.

Regards,

Jill Myers Geadelmann, BS, RN Chronic Disease Prevention and Management Bureau Chief Iowa Department of Public Health



PROGRAM BACKGROUND

Since 1995, the Care for Yourself – Breast and Cervical Cancer Program (BCC Program) has served Iowans as part of the Center for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program.

The program's goal is to decrease cancer burden through prevention, early detection and timely follow-up.

Through a decentralized program structure, local Boards of Health across Iowa elect to participate in the program, providing patient navigation and service delivery for underserved Iowans. Every local program has at least one staff person trained on the Care for Yourself program. This person is called the *local program coordinator*. The local program coordinators find, recruit and refer individuals to direct screening at a local health system.

The priority focus of the program is to:

- Maintain a network of healthcare providers to support screening service availability and delivery
- Provide access to screening and diagnostic services for program-eligible individuals
- Provide patient navigation to guide participants through the healthcare continuum
- Reach individuals who have never or have rarely been screened for breast and cervical cancer
- Reduce over-screening for cervical cancer

THE PROGRAM PROVIDES SERVICES FOR:

- Individuals age 40 and over
- Individuals under age 40 with symptoms of breast cancer
- Transgender women taking hormones
- Transgender men who have not had a bilateral mastectomy or total hysterectomy
- All participants must have a household income less than 250 percent of the federal poverty level¹

ENROLLMENT PROCESS

To enroll a patient in the BCC Program, please contact your local program coordinator. A service area map with contact information can be found in Appendix I of this document or on the Care for Yourself website.²

¹ Current income guidelines are available at the program website: www.idph.iowa.gov/CFY

² Appendix I or Contact A Program Near You www.idph.iowa.gov/CFY/public.

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YOUR ROLE AS A HEALTHCARE PROVIDER

As a healthcare provider participating in the Breast and Cervical Cancer Program, you must:

- Review the Healthcare Provider Manual
- Be licensed or certified to practice in the state where participants are served
- Provide appropriate breast and cervical cancer screening, diagnostic and treatment services according to program policies and protocols
- Follow the evidence-based guideline for cervical abnormalities published by the American Society of Colposcopy and Cervical Pathology (ASCCP)³
- Immediately and confidentially report exam results and recommended follow-up to the Care for Yourself local program coordinator upon receipt of results⁴
- Ensure your Health System and/or Clinic is an enrolled facility

All laboratories must have current certification with the Commission on Office Laboratory Accreditation (COLA) or the Clinical Laboratories Improvement Act (CLIA). Pap test results should follow the current The Bethesda System of Pap test classification.

All mammography facilities must be certified by the US Food and Drug Administration-approved certifying body under the Mammography Quality Standards Act (MQSA) of 1992. The American College of Radiology (ACR) Breast Imaging Lexicon will be used to report the interpretation of mammography examinations.

BECOMING AN ENROLLED FACILITY

Every facility interested in participating in the Breast and Cervical Cancer Program must complete enrollment paperwork. Your organization, as defined by Tax ID number, must complete one Cooperative Agreement with the Iowa Department of Public Health. The Cooperative Agreement is valid for six years, after which it will need to be renewed. Each individual facility, as defined by address, must complete one Service Facility Application. This form includes facility and billing information necessary for claims processing and reimbursement. One clinic NPI number should be used for all claims; use of individual provider NPI numbers use should be avoided. In addition, a current W-9 and CLIA or COLA certificate should be included if applicable.

The Cooperative Agreement and Service Facility Application can be requested by emailing Gena Hodges at Gena. Hodges@idph.iowa.gov. For efficiency, please use a subject line of "BCC Application."

³ 2012 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities can be found at http://www.asccp.org/management-guidelines.

⁴ As a public health surveillance and intervention program according to Public Law 104-191, Sec 1178(b) the Iowa Care for Yourself Breast and Cervical Cancer Program is exempt from HIPAA regulations. See Appendix III.

PROGRAM SERVICES

SCREENING SERVICES

The BCC Program encourages individuals to obtain regular cancer screening services. All office visits for program participants must include appropriate breast and cervical cancer screening, including the following:

- Two blood pressure measurements taken at least two minutes apart
- Height and weight measurements
- Clinical breast exam
- Pelvic exam
- Mammography, as recommended by the provider⁵
- Pap test, per program protocol⁵
- Breast and/or cervical diagnostic services⁵, as recommended by the provider
- Referral for pre-cancer and cancer treatment, as recommended by the provider
- Tobacco cessation referral

Please reference the approved ICD-10 and CPT Service Codes⁶ listing for the current fiscal year. The BCC program will only pay for approved services.

FOLLOW-UP SERVICES

SHORT-TERM FOLLOW UP

Short-term follow-up is the repeat of an examination earlier than normally recommended by program guidelines.

The BCC Program protocol requires short-term follow-up for the following:

| Screening Service | Short-Term Follow Up |
|----------------------|---|
| Clinical Breast Exam | Based on healthcare provider recommendation |
| Mammogram | BIRADS Category III (probably benign) |
| Pap test | ASC-US, unless Reflex HPV testing is done |

⁵ See Appendix II- Program Screening Service Guidelines and Screening Follow-up Adequacy

⁶ Information for Healthcare Providers <u>www.idph.iowa.gov/CFY/information-for-healthcare-providers</u>

DIAGNOSTIC FOLLOW UP

Diagnostic follow-up refers to the examinations after abnormal screening results to determine a specific diagnosis. Program-eligible individuals over the age of 40 may be referred to the BCC Program after an abnormal screening result, even if they were not a program participant for the initial screening.

The BCC Program requires diagnostic testing for the following conditions:

• Clinical Breast Exam (CBE) Results

- Abnormality Suspicious for cancer (i.e., discrete mass [cystic or solid], bloody or serous nipple discharge, skin dimpling or retraction, nipple areolar scaliness). A diagnostic procedure(s) and final diagnosis must be reported.⁷
- A normal mammogram does not mean an abnormal CBE can be ignored. Further action must be taken.
- Mammogram Results BIRADS
 - Category IV Suspicious abnormality
 - o Category V Highly suggestive of malignancy
 - Category 0 Assessment Incomplete Need additional imaging evaluation
 Assessment Incomplete Film comparison needed
- <u>Pap Test Results</u> diagnostic follow-up should be done following the American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines⁸ for all cervical cytological results except negative.

DIAGNOSIC SERVICES

The BCC Program provides limited reimbursement for the following diagnostic services:

| Breast Diagnostics: | | |
|--|--|--|
| Surgical visit for repeat CBE Diagnostic mammogram Biopsy/lumpectomy Ultrasound | Fine needle/stereotactic/cyst aspiration biopsy Pathology consult during surgery Anesthesia time Breast MRI (preauthorization required) | |

Cervical Diagnostics:

- Specialty referral
- Colposcopy (with/without biopsy)
- LEEP (preauthorization required)
- Cold Knife Cone (preauthorization required)
- Endometrial biopsy (preauthorization required)
- Pathology

⁷ Follow diagnostic options for an abnormal CBE endorsed by the Commission on Cancer of the American College of Surgeons, the American College of Obstetrics and Gynecology or the National Cancer Institute.

⁸ 2012 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities can be found at http://www.asccp.org/management-guidelines.

REIMBURSEMENT FOR SERVICES AND CLAIM SUBMISSION

Federal law requires that reimbursement with federal funds may not exceed Iowa Medicare Part B rates. Medicare and BCC Program reimbursement rates are updated annually after the rates are released by the Centers for Medicare and Medicaid Services (CMS). Updated information is available on the Care for Yourself website. Program reimbursement rates are to be accepted as payment in full, and facilities will not bill individual patients or the BCC Program for any additional costs.

Reimbursement of claims will be processed up to one year (12 months) from the date of service. Claims exceeding the 12-month period from the date of service will be denied. As a reminder, no participant in the BCC Program should be billed for any covered service; however, the participant may be billed for services not covered by the BCC Program. The participant must be made aware before the service is provided that the screening program will not cover the procedure and that the cost will be the participant's responsibility.

Medical Billing Services (MBS) processes and reimburses claims for the Breast and Cervical Cancer Program. All reimbursements for the Breast and Cervical Cancer Program will be paid by MBS doing business as "lowa Screening Programs." Questions regarding claims should be directed to MBS at 515-237-3974.

Electronic claim submission is encouraged, and only **837p** (professional claims) will be accepted electronically. Please provide your clearinghouse with the following information:

The payer ID information is: TriZetto Provider Solutions One Financial Plaza 501 N. Broadway, 3rd Floor, St. Louis, MO 63102

More information can be found on the Care for Yourself website.9

⁹ Information for Healthcare Providers <u>www.idph.iowa.gov/CFY/information-for-healthcare-providers</u>

ADDITIONAL PROGRAM COMPONENTS

MEDICAL ADVISORY BOARD

A Medical Advisory Board offers guidance and assistance to the IA BCC Program. Members represent various program specialties, including breast surgeon, oncologist gynecologist, pathologist, mammography technician, women's health and family practice. Please contact the program at **1-866-339-7909** if you are interested in becoming a member of this board.

TECHNICAL ASSISTANCE AND PROFESSIONAL EDUCATION

State and local BCC Program staff are available to provide orientation and training about this program for healthcare facilities' staff. Contact your local BCC Program coordinator or call **1-866-339-7909**.

Program changes and updates can be found on the Care for Yourself website 10.

QUALITY ASSURANCE AND QUALITY IMPROVEMENT

Quality assurance and quality improvement are integral components of the BCC Program and contribute to the program's success. The purpose of quality assurance and improvement is to:

- Ensure the quality of services delivered through the program
- Monitor performance and identify opportunities for improvement
- Plan effective strategies for improving services

Program requirements and monitoring activities include:

- Reporting standards for radiological, laboratory and pathology reports must be reported according to national standards
- Standards for adequacy of follow-up data reports track appropriate and timely diagnostic, short-term and rescreening services
- Patient navigation services local program staff evaluate needs, implement plans and refer participants who need additional services
- Accurate data and documentation Specific data elements are reported to Centers for Disease Control and Prevention (CDC) semi-annually
- Evaluation reports are completed routinely and as needed to assess how well the BCC Program is meeting CDC goals
- Adherence to CDC policies and guidelines

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¹⁰ www.idph.iowa.gov/CFY

BREAST AND CERVICAL CANCER TREATMENT

Eligibility for Referral to the IA Breast and Cervical Cancer Treatment (BCCT) Option of Medicaid

- 1. An individual is eligible for the BCCT option of Medicaid if they:
 - a. Are not covered by a mandatory category of Medicaid
 - b. Have not reached age 65
 - c. Received breast or cervical cancer screenings or related diagnostic services provided or funded by:
 - i. a National Breast and Cervical Cancer Early Detection Program
 - ii. family planning centers
 - iii. community health centers
 - iv. non-profit organizations
 - d. Do not have creditable insurance coverage for breast or cervical cancer or pre-cancer treatment
- 2. The individual must meet the income eligibility requirements established by the BCC Program.
- 3. The individual must be diagnosed with a pre-cancerous/cancerous breast or cervical condition and require treatment for the cancer.

Responsibilities of Healthcare Providers

- 1. Notify local or state BCC Program staff of the diagnosis.
- 2. Validate that the enrolled/referred individual is diagnosed with pre-cancerous or cancerous breast or cervical condition(s).
- 3. Send a copy of the pathology report with the breast or cervical diagnosis to the BCC Program staff at the same time as the notification.
- 4. Provide Department of Human Services (DHS) staff with appropriate participant information upon request.
- ** Steps 1 and 3 facilitate participant referral for treatment coverage under the BCCT option of Medicaid. The quicker these steps are accomplished the quicker an individual without creditable insurance can start breast or cervical cancer treatment.

Once BCC Program staff are notified, they will:

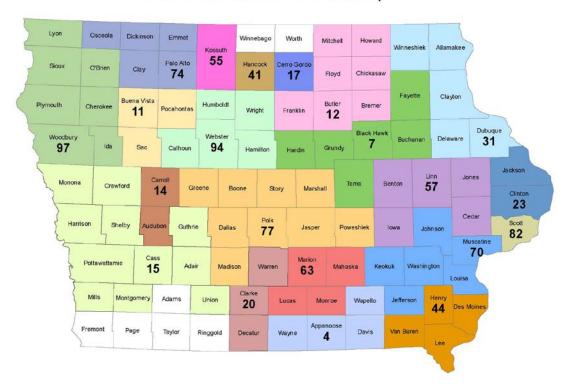
- 1. Assess the individual for eligibility for the BCCT Medicaid option.
- 2. Assist the eligible individual to apply for the BCCT option of Medicaid.
- 3. Provide DHS staff the necessary documentation. *DHS staff are responsible for making the final determination of eligibility.*

An individual enrolled in the BCCT option of Medicaid will receive full Medicaid benefits for the duration of the breast or cervical pre-cancer or cancer treatment period.

APPENDIX I

SERVICE AREA MAP

Iowa Care for Yourself Service Area Map



| 4 Appanoose | 15 Cass | 41 Hancock | 70 Muscatine | 97 Woodbury |
|------------------------------------|----------------------------|--------------------------|-----------------------|-----------------------|
| Jerilyn Lasley | Victoria Means | Kelly Hutcheson | Melissa Bell | Lori Jackson |
| 209 E Jackson St | 1408 E 10 th St | 545 State Street | 1609 Cedar St | 1014 Nebraska St |
| Centerville, IA 52544 | Atlantic, IA 50022 | Garner, IA 50438 | Muscatine, IA 52761 | Sioux City, IA 51105 |
| 641.437.4332 | 712.243.7443 | 641.923.3676 | 563.263.0122 | 712.279.6119 |
| 7 Black Hawk | 17 Cerro Gordo | 44 Henry | 74 Palo Alto | |
| Gabbi DeWitt | Karen Crimmings | Angie Rhum | Candace Bisenius | |
| 1407 Independence Ave | 22 N Georgia St Ste 300 | 106 N Jackson St Ste 103 | 3201 W 1st St | |
| Waterloo, IA 50703 | Mason City, IA 50401 | Mount Pleasant, IA 52641 | Emmetsburg, IA 50536 | |
| 319.292.2225 | 641.421.9323 | 319.385.0779 | 712.852.5419 | |
| 11 Buena Vista | 20 Clarke | 55 Kossuth | 77 Polk | White service areas |
| Beth Rix | Stephanie Shields | Josie Bjustrom | Louanne Williams | represent areas |
| 1709 E Richland St | 144 W Jefferson St | 1515 S Phillips St | 1907 Carpenter Ave. | overseen by IDPH. |
| PO Box 663 | Osceola, IA 50213 | Algona, IA 50511 | Des Moines, IA 50314 | Contact Jolene Carver |
| Storm Lake, IA 50588 | 641.342.3724 | 515.295.2451 | 515.286.2095 | 1-866-339-7909 |
| 712.749.2548 | | | | |
| 12 Butler | 23 Clinton | 57 Linn | 82 Scott | |
| Nancy Hemann | Diane Koster | Amber Straw | Diane Koster | |
| 428 6 th St, PO Box 325 | 1227 E Rusholme St | 4251 River Center Ct NE | 1227 E Rusholme St | |
| Allison, IA 50602 | Davenport, IA 52803 | Cedar Rapids, IA 52402 | Davenport, IA 52803 | |
| 319.267.2934 | 563.244.4925 | 319.730.7332 | 563.244.4925 | |
| 14 Carroll | 31 Dubuque | 63 Marion | 94 Webster | |
| Beth Hacker | Cathy Tieskoetter | Open Position | Sadie Trueblood | |
| 318 S Maple St Ste 3 | 1454 Iowa Street | 2003 N Lincoln | 723 1st Ave South | |
| Carroll, IA 51401 | Dubuque, IA 52001 | PO Box 152 | Suite 220 | |
| 712.794.5436 | 563.556.6200 | Knoxville, IA 50138 | Fort Dodge, IA, 50501 | |
| | | 641.828.2238 | 515-573-4107 | |

APPENDIX II

BCC PROGRAM SCREENING SERVICES GUIDELINE

| lowa Care For Yourself - BCC Program Screening Services | | | | |
|--|---|---|--|--|
| Age | Blood Pressure, Height, Weight | Clinical Breast Exam | Mammogram | Pelvic/Pap test ¹¹ |
| Under 40 | ONLY if reporting symptoms of breast cancer ¹² | ONLY if reporting symptoms of breast cancer | ONLY if CBE is abnormal | ONLY if reporting symptoms of breast cancer |
| 40 – 49 | Annually | Asymptomatic Annually Symptomatic As needed | Asymptomatic Per BCC program protocol Symptomatic As indicated | Asymptomatic Per BCC program protocol Symptomatic As indicated |
| 50 – 64 | Annually | Asymptomatic Annually Symptomatic As needed | Asymptomatic Annually Symptomatic As indicated | |
| Over 64 Participants over age 64 who do not have Medicare Part B and meet income guidelines will receive services as above for ages 50 – 64 years. | | | delines will receive | |

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 $^{^{\,11}\,}$ Refer to: Recommendations and Rationale for Cervical Cancer Screening Protocol.

¹² Examples of breast cancer symptoms include but are not limited to an abnormal CBE, breast skin dimpling or retraction, palpable mass or nipple discharge, inversion or scaliness.

ALGORITHM FOR BREAST CANCER SCREENING FOLLOW-UP ADEQUACY¹³

| CBE RESULT | MAMMOGRAM RESULT | DIAGNOSTIC PROCEDURES REQUIRED FOR ADEQUACY ¹⁴ |
|--|---|--|
| Normal/Benign (including fibrocystic, lumpiness or nodularity) | Negative Benign Probably Benign (Short term follow-up indicated) | No work-up required If work-up is planned, at least one diagnostic procedure must be done and a final diagnosis recorded |
| | Suspicious Abnormality | One or more of the following: Surgical consult for repeat breast exam Ultrasound Biopsy/Lumpectomy Fine Needle/Cyst Aspiration |
| | Assessment Incomplete | One or more of the following: Additional mammography views Ultrasound |
| | Highly Suggestive of Malignancy | One or more of the following: Biopsy/Lumpectomy Fine Needle/Cyst Aspiration |
| | Negative Benign Probably Benign (Short term follow-up indicated) Assessment Incomplete | One or more of the following: |
| Abnormal (suspicious for cancer) | Suspicious Abnormality Highly Suggestive of Malignancy | One or more of the following: Biopsy/Lumpectomy Fine Needle/Cyst Aspiration |
| | Highly Suggestive of Malignancy | One or more of the following: Biopsy/Lumpectomy Fine Needle/Cyst Aspiration |

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¹³ This algorithm is inappropriate as a tool for clinical decision-making for individuals to determine whether certain providers are performing according to accepted national practices.

¹⁴ Clinical interventions based on clinical guidelines endorsed by the Commission on Cancer of the American College of Surgeons, the American College of Obstetrics and Gynecology and the National Cancer Institute.

ALGORITHM FOR CERVICAL CANCER SCREENING FOLLOW-UP ADEQUACY¹⁵

NOTE: Pap Specimen Adequacy must be "Satisfactory" for Pap test results to be recorded.

| PAPANICOLAOU (PAP) TEST RESULT BETHESDA (TBS) 2001 | DIAGNOSTIC PROCEDURES REQUIRED FOR ADEQUACY ¹⁶ | |
|---|---|--|
| Negative for Intraepithelial Lesion or Malignancy | No work-up required | |
| ASC-US (Atypical Squamous Cells – Undetermined Significance) | No work-up required, but follow-up at one year required If HPV test negative, co-testing follow-up at 3 years If HPV test positive, colposcopy required If work-up is planned, colposcopy must be done | |
| Low Grade SIL encompassing: HPV Mild Dysplasia/CIN 1 | One or more of the following: Negative HPV, repeat co-testing at 1 year Negative HPV, colposcopy (with or without biopsy) No or Positive HPV, colposcopy (with or without biopsy) | |
| ASC-H (Atypical Squamous Cells – Cannot exclude High Grade Squamous Intraepithelial Lesion [SIL]) | One or more of the following: | |
| High Grade SIL encompassing (with features suspicious for invasion): • Moderate & Severe Dysplasia • CIS/CIN 2 & CIN 3 | One or more of the following: Colposcopy Colposcopy with biopsy Loop Electrode Excision Procedure ¹⁷ Conization ¹⁷ | |
| Squamous Cell Carcinoma | One or more of the following: Colposcopy Colposcopy with biopsy | |
| Abnormal Glandular Cells Adenocarcinoma in situ (AIS) Adenocarcinoma | One or more of the following: Colposcopy Colposcopy with biopsy Cold knife Conization 17 Endometrial Biopsy 17 | |

| PRIMARY HUMAN PAPILLOMAVIRUS (HPV) SCREENING ALGORITHM | | |
|--|--|--|
| HPV TEST RESULT | DIAGNOSTIC PROCEDURES REQUIRED FOR ADEQUACY | |
| Negative | Routine Screening | |
| 12 Other High Risk HPV (hrHPV) Positive | Cytology Required If Pap test negative, HPV test in 12 months If Pap Test greater than or equal to ASC-US, colposcopy required | |
| Type 16/18 Positive | • Colposcopy | |

¹⁵ This algorithm is inappropriate as a tool for clinical decision making for individuals or to determine if certain providers are performing according to accepted national practices.

¹⁶ Clinical interventions based on the American Society for Colposcopy and Cervical Pathology's 2012 Algorithms from the Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities.

¹⁷ Must be preauthorized with BCC program state staff.

APPFNDIX III

HIPAA PRIVACY RULES AND THE RELEASE OF INFORMATION

THOMAS J. MILLER ATTORNEY GENERAL

HEATHER L. ADAMS
ASSISTANT ATTORNEY GENERAL



John Department of Instice

ADDRESS REPLY TO: Ucensing & Administrative Law 1305 E. Walnut Street Des Moines, IA 50319 Telephone: 515/ 515-281-3441 Fax: 515/281-7551 hadamsiliga, state Js us

HIPAA PRIVACY RULES AND THE RELEASE OF INFORMATION TO THE IOWA CARE FOR YOURSELF PROGRAM

The Health Insurance Portability and Accountability Act (HIPAA) regulations contain several major components. The Privacy Rule requires covered entities to obtain consent or authorization from an individual for certain uses and disclosures of identifiable health information. However, the Privacy Rule expressly permits covered entities to release identifiable health information to public health authorities under certain circumstances without obtaining consent or authorization from the patient.

First, although the requirements of HIPAA generally preempt state law, HIPAA provides for certain exceptions to this general preemption rule. One such exception applies when state statute and state administrative rules provide for "the reporting of disease or injury, . . . or for the conduct of public health surveillance, investigation, or intervention." 45 CFR 160.203. Iowa Code chapter 135 and 641 Iowa Administrative Code chapter 8 authorize the Iowa Care For Yourself Program (ICFYP) to have access to information from hospital records, physician records, and clinical charts for the purpose of ensuring service delivery and program and fiscal management. These provisions of law are not preempted by HIPAA and therefore a hospital, clinic, or health care provider is not required to obtain consent or authorization from a patient prior to releasing this information to the ICFYP.

HIPAA also provides for a number of "permitted disclosures," i.e. those disclosures of protected health information for which consent or authorization is not required. HIPAA authorizes such disclosures "to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law." 45 CFR 164.512(a). HIPAA further authorizes disclosures for public health activities to "a public health authority that is authorized by law to collect or receive such information for the purposes of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions[.]" 45 CFR 164.512(b)(1)(i). Hospitals, clinics, and health care providers are authorized by lowa law to allow the ICFYP to have access to information about patients for purposes of preventing cancer. Hence, HIPAA does not require that covered entities obtain consent or authorization prior to releasing such information to the ICFYP. Additionally, ICFYP participants execute a release which authorizes health care providers, laboratories, and hospitals to provide the ICFYP with results of the screening and follow-up examinations and treatment.

In short, HIPAA provides no legal basis for hospitals, clinics, or health care providers to prohibit the ICFYP from obtaining information for the purpose of ensuring that women receive appropriate screening tests, confirmatory testing, and treatment.