

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

**Proposing rule making related to the Iowa care for yourself program
and providing an opportunity for public comment**

The Public Health Department hereby proposes to amend Chapter 8, “Iowa Care for Yourself (IA CFY) Program,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 135.11(1) and 135.39.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 135.

Purpose and Summary

The proposed amendments include changes to clarify statements, match medical definitions, and allow for cervical cancer services to be provided by the IA CFY program to an expanded population of persons 21 to 39 years of age who do not have access to other programs providing these services. The IA CFY program will also now be able to provide breast cancer services to asymptomatic persons under 40 years of age who are identified as at high risk for breast cancer.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department’s waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on December 7, 2021. Comments should be directed to:

Jill Myers Gadelmann
Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Email: jill.myers-gadelmann@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule 641—8.1(135) as follows:

641—8.1(135) Definitions. For purposes of this chapter, the following definitions apply:

“*Abnormal screen*” means a suspicion of breast or cervical cancer or laboratory values of total cholesterol or blood glucose and average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

1. A suspicion of breast cancer includes clinical breast examination 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 breast imaging reporting and data systems (BI-RADS) category 4 (suspicious abnormality suggesting need for biopsy) or category 5 (highly suggestive of malignancy) (ICD-10 R92.0, R92.1, R92.2, R92.8), breast biopsy result of ductal cancer in situ (ICD-10 D05.10, D05.11, D05.12), lobular cancer in situ (ICD-10 D05.00, D05.01, D05.02) or breast or lymph node (or other) biopsy result of breast cancer.

2. Suspicion of cervical cancer is a Pap test result of atypical squamous cells cannot exclude high-grade squamous intraepithelial lesions (ASC-H) (ICD-10 R87.611 or ~~R87.622~~ R87.621), atypical glandular cells (AGC) (ICD-10 R87.619 or R87.629), low-grade squamous intraepithelial lesions (LSIL) (ICD-10 R87.612 or R87.622), or high-grade squamous intraepithelial lesions (HSIL) (ICD-10 R87.613 or R87.623), leukoplakia of the cervix (ICD-10 N88.0), or cervical biopsy result of cervical intraepithelial neoplasia II (ICD-10 N.87.1) or III (ICD-10 D06.0, D06.1, D06.7 or D06.9), or cancer in situ (ICD-10 D06.0, D06.1, D06.7 or D06.9).

3. Abnormal value means laboratory values of total cholesterol or blood glucose (HbA1c if diagnosed diabetic) and average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

“*ACR*” or “*American College of Radiology*” means one of the Food and Drug Administration-recognized accreditation bodies for minimum quality standards for personnel, equipment, and record keeping in facilities that provide breast imaging.

“*Advanced registered nurse practitioner*” means an individual licensed to practice under 655—Chapter 7.

“*Alert value*” means laboratory values of total cholesterol, blood glucose or average blood pressure reading in the range defined by the CDC according to National Heart, Lung and Blood Institute guidelines.

“*BCCPTA*” or “*Breast and Cervical Cancer Prevention and Treatment Act of 2000*” means a federal law that provides each state with the option of extending Medicaid eligibility to individuals who were diagnosed with breast or cervical cancer through the National Breast and Cervical Cancer Early Detection Program.

“*BCCT option of Medicaid*” or “*breast and cervical cancer treatment option of Medicaid*” means the optional program of medical aid designed for individuals who are unable to afford regular medical service

and are diagnosed with breast or cervical precancer or cancer through the National Breast and Cervical Cancer Early Detection Program or through funds from family planning centers, community health centers, or nonprofit organizations. The individuals who receive screening or services meet eligibility requirements established by the Iowa care for yourself program. The BCCT option of Medicaid is financed by federal and state payment sources and is authorized by Title XIX of the Social Security Act.

“*Benign*” means a noncancerous condition that does not spread to other parts of the body.

“*Biopsy*” means the removal of a sample or an entire abnormality for microscopic examination to diagnose a problem. Examples of a sampling would be a core biopsy or incisional biopsy; an example of entire removal would be an excisional biopsy.

“*BI-RADS*” or “*breast imaging reporting and data systems*” means a standardized reporting system for mammography, breast ultrasound and breast magnetic resonance imaging (MRI) reports.

“*Blood glucose*” means a simple sugar found in the blood that is an important energy source in living organisms and is a component of many carbohydrates.

“*Blood pressure*” means the force of blood against the circulatory system. The systolic blood pressure is the force caused when the heart contracts and pushes out the blood. The diastolic blood pressure is when the heart relaxes and fills with blood.

“*BMI*” or “*body-mass index*” means an index for relating weight to height a person’s weight in kilograms divided by the square of the person’s height in meters. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems.

“*Breast ultrasound*” means an imaging technique commonly used to screen for tumors and other breast abnormalities. The breast ultrasound uses high-energy sound waves to produce a detailed image of the inside of the breast.

“*Cancer*” means a group of diseases involving abnormal cell growth with the potential to invade or spread to other parts of the body.

“*Carcinoma in situ*” means a group of abnormal cells found only in the place where they first formed in the body.

“*Cardiologist*” means a physician licensed to practice under Iowa Code chapter 148 who specializes in the study or treatment of the heart and its action and diseases.

“*Cardiovascular disease*” means a broad term used to describe a range of diseases that affect the heart and, in some cases, blood vessels.

“*Cardiovascular disease risk factors*” means identifiable factors that make some people more susceptible than others to cardiovascular disease. Cardiovascular disease risk factors include:

1. Obesity.
2. Physical inactivity.
3. High blood pressure.
4. High blood cholesterol.
5. Diabetes.
6. Tobacco use.

Risk factors that cannot be changed are age, gender and family history. The more cardiovascular disease risk factors a person has increases the person’s chance of developing cardiovascular disease.

“*Case management*” means the IA CFY program component that involves establishing, brokering, and sustaining a system of available clinical and essential support services for all individuals enrolled in the program.

“*CBE*” or “*clinical breast examination*” means complete examination of an individual’s breast and axilla with palpation by a health care provider trained to recognize many different types of abnormalities and warning signs.

“*CDC*” means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services, a federal agency that conducts and supports health promotion, prevention and preparedness activities in the ~~U.S.~~ United States, with the goal of improving overall public health.

“*Cholesterol*” means a waxy, fat-like substance made in the liver and other cells and found in certain foods, such as foods from animals, for example, dairy products, eggs and meat. Types of cholesterol are as follows:

1. Low density lipoprotein or LDL, also called “bad” cholesterol. LDL can cause buildup of plaque on the walls of arteries. The more LDL there is in the blood, the greater, which narrows the arteries and increases the risk of cardiovascular disease.

2. High density lipoprotein or HDL, also called “good” cholesterol. HDL helps the body get rid of bad cholesterol in the blood. If levels of HDL are low, risk of cardiovascular disease increases.

3. Very low density lipoprotein or VLDL. VLDL is similar to LDL cholesterol in that it contains mostly fat and not much protein. It differs in that VLDL carries triglycerides, whereas LDL carries mainly cholesterol.

4. Total cholesterol means the sum of the very low, low and high density lipoproteins.

“*CLIA*” or “*Clinical Laboratory Improvement Acts of 1988*” means the federal regulatory standards that apply to all clinical laboratory testing performed on humans in the U.S United States. These standards establish minimum quality standards for personnel and quality assurance methods that monitor patient test management and assess quality control, proficiency testing, and personnel handling of laboratory and pathology specimens.

“*CLIA-waived tests*” means simple laboratory examinations and procedures that are cleared by the federal government for home use, that employ methodologies that are so simple and accurate that erroneous results would be negligible, or that pose no reasonable risk of harm to the patient if the test is performed incorrectly.

“*CMS*” or “*Centers for Medicare and Medicaid Services*” is a federal agency within the United States Department of Health and Human Services that administers health care programs, including Medicare, Medicaid, the children’s health insurance program (CHIP) and health insurance exchanges, in partnership with state governments.

“*Colposcopy*” means a medical procedure that allows close examination of the surface of the cervix with a high-powered microscope.

“*Community referral*” means to direct individuals elsewhere to obtain needed information, mutual support or community resources through help lines or other methods.

“*Community resource*” means a source of information, service or expertise that is available within the community, including respite care services, health and mental health services and other social services.

“*Cooperative agreement*” means a signed contract between the department and another party, for example, a health care facility, which allows the ~~department~~ department’s IA CFY program to pay the health care facility for providing services to IA CFY program participants.

“*CPT*” or “*current procedural terminology*” is means a listing of descriptive terms and identifying codes for uniform language to report medical services and procedures performed by qualified health care professionals and allows clinicians, statisticians, politicians, health insurance programs, health planners and others to speak a common language.

“*Creditable coverage*” means any insurance that pays for medical bills incurred for the screening, diagnosis, or treatment of breast and cervical cancer. Creditable coverage as described by the Health Insurance Portability and Accountability Act of 1996 includes, but is not limited to, group health plans or health insurance coverage consisting of medical care under any hospital or medical service policy, health maintenance organization, Medicare Part A or B, Medicaid, armed forces insurance, or state health risk pool. An individual who has creditable coverage shall not be eligible for coverage under the breast and cervical cancer treatment option of Medicaid.

“*Creditable coverage circumstances*” means those instances in which an individual has creditable coverage but is not actually covered for treatment of breast or cervical cancer.

1. When there is a preexisting-condition exclusion or when the annual or lifetime limit on benefits has been exhausted, an individual is not considered to have creditable coverage for this treatment.

2. If an individual has limited coverage, such as a high deductible, limited drug coverage, or a limited number of outpatient visits, the individual is still considered to have creditable coverage and is not eligible for coverage under the breast and cervical cancer treatment option of Medicaid.

3. If an individual has a policy with a limited scope of coverage, such as only dental, vision, or long-term care, or has a policy that covers only a specific disease or illness, the individual is not considered to have creditable coverage unless the policy provides coverage for breast and cervical cancer treatment.

4. For the purposes of this program, eligibility for Indian Health Services or tribal health care is not considered creditable coverage (according to P.L. 107-121, the Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001).

“*Cytology*” means the branch of biology that studies the structure and function of a cell.

“*Cytopathology*” means the branch of pathology that studies and diagnoses disease on the cellular level.

“*Cytotechnologist*” means a laboratory professional who studies cells and cellular abnormalities.

“*Department*” means the Iowa department of public health.

“*DHS*” or “*department of human services*” means the Iowa department of human services, a state agency that provides a wide range of services, including health care coverage for low-income uninsured individuals diagnosed with breast or cervical cancer or precancer and requiring treatment.

“*Diagnostic mammography*” means a radiological examination performed for clinical indications, such as breast mass(es), other breast signs or symptoms (spontaneous nipple discharge, skin changes), or special cases, such as a history of breast cancer with breast conservation or augmented breasts.

“*Facility*” means a place where health care is provided, including hospitals, clinics, outpatient care centers, laboratories, and specialized care centers that have completed enrollment paperwork with the IA CFY program.

“*Family planning clinic*” means a Title X family planning program site dedicated to the provision of family planning and related preventive health services to low-income and underserved populations.

“*FDA*” or “*Food and Drug Administration*” means the federal governmental body which certifies that a breast imaging facility meets minimum quality standards for personnel, equipment, and record keeping.

“*Follow-up*” means the IA CFY program component that ~~involves a system for seeking information about or reviewing an abnormal condition, rescreening, or recall for annual visits~~ ensures provision of timely and adequate services for participants who have abnormal screening results.

“*Gynecologist*” means a physician licensed to practice under Iowa Code chapter 148 who specializes in treating diseases of the female reproductive organs in women and providing well-woman health care that focuses primarily on the reproductive organs.

“*HbA1c*” or “*glycosylated hemoglobin*” means a clinical laboratory test for the purposes of diagnosing diabetes or determining control of diabetes over the past two to three months.

“*Health care provider*” means any physician, pharmacist, advanced registered nurse practitioner, or physician assistant who is authorized to practice by the state; who is performing within the scope of the practice as defined by state law; and who provides care to IA CFY program-enrolled individuals.

“*IA BCCEDP*” or “*Iowa breast and cervical cancer early detection program*” means a comprehensive breast and cervical cancer screening program established and funded under Title XV of the federal Public Health Service Act and administered by the Iowa department of public health, with the delegated responsibility of implementation and evaluation from the CDC, Division of Cancer Prevention and Control.

“*IA CFY program*” or “*Iowa care for yourself program*” means an integrated comprehensive breast and cervical cancer screening program and cardiovascular risk factor screening and intervention program administered by the Iowa department of public health.

“*IA WISEWOMAN*” or “*Iowa well-integrated screening and evaluation for women across the nation*” means a cardiovascular-related risk factor screening and intervention program to provide standard preventive screening services, including blood pressure measurements, cholesterol testing, blood glucose testing, and lifestyle interventions that target poor nutrition, physical inactivity, and

tobacco use. The program is authorized by the federal government and administered by the CDC to help reduce deaths and disability from cardiovascular disease and stroke.

“*ICD-10*” or “*International Classification of Disease, 10th edition*” means a standardized classification of diseases, injuries, and reasons of death, by cause and anatomic localization, which is systematically put into a number of up to seven digits and which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both in the United States and internationally.

“*Infrastructure*” means the basic framework of sufficient staff and adequate support systems to plan, implement, and evaluate the components of the IA CFY program.

“*In need of treatment*” means that a medical or surgical intervention is required because of an abnormal finding of breast or cervical cancer or precancer that was determined as a result of a screening or diagnostic procedure for breast or cervical cancer/precancer.

“*Intervention*” means services that promote a cardiovascular-healthy diet and physical activity and that are based on screening results, which include blood pressure, cholesterol, blood glucose, weight, height, personal medical history, family medical history, and health behavior and readiness-to-change assessments.

“*MAB*” or “*medical advisory board*” means a body that may be utilized by the IA CFY program to offer knowledge and experience as related to the fields of expertise of the members of the board. Duties of the MAB may include, but are not limited to, the following:

1. Reviewing and making recommendations for clinical service expansion.
2. Reviewing program-developed clinical protocols.
3. Providing recommendations related to other clinical and participant-related issues.
4. Providing input related to quality assurance issues.
5. Reviewing program screening and diagnostic data.

“*MDEs*” or “*minimum data elements*” means a set of standardized data elements used to collect patient-level screening records demographic and clinical information on individuals served through the with NBCCEDP in order funds. The MDEs are reported to the CDC to evaluate whether programs are meeting clinical standards and programmatic priorities.

“*Medicaid*” means a health care program that assists low-income families or individuals in paying for doctor visits, hospital stays, long-term medical care, custodial care costs and more; the program is financed by federal and state payment sources and authorized by Title XIX of the Social Security Act and administered by the Iowa department of human services.

“*Medicare*” means the program of federal payment source for health benefits, especially for the aged, which is authorized by Title XVIII of the Social Security Act. Medicare is administered by CMS.

“*MRI*” or “*magnetic resonance imaging*” means a medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body.

“*NBCCEDP*” or “*National Breast and Cervical Cancer Early Detection Program*” means a program established with the passage of the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). The law authorizes the CDC to establish a program of grants to states, tribes, and territories for increasing the early detection of breast and cervical cancer, particularly among low-income, uninsured, and underserved individuals.

“*Nonprofit organization*” means a group organized for purposes other than generating profit and in which no part of the organization’s income is distributed to its members, directors, or officers, except under limited circumstances.

“*Oncologist*” means a physician licensed to practice under Iowa Code chapter 148 who is a specialist in treating or studying the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment.

“*Outreach*” means the IA CFY program component that involves recruiting targeted populations or individuals who never or rarely utilize preventive health services.

“Pap test” or *“Papanicolaou screening test”* means the Papanicolaou screening test that collects a procedure to collect cells from the cervix for examination under a microscope. The Pap test can detect abnormal cells or precancerous cells before cancer develops.

“Pathologist” means a physician licensed to practice under Iowa Code chapter 148 who is a specialist in identifying who interprets and diagnoses the changes caused by diseases by studying cells and tissues under a microscope in tissues and body fluids.

“Patient navigation” means an IA CFY program component that assists individuals in overcoming health care system barriers and facilitates timely access to quality screening and diagnostics as well as initiation of breast or cervical cancer treatment services.

“Pharmacist” means an individual licensed to practice under Iowa Code chapter 155A who is able to receive or process prescription drug orders in accordance with the pharmacy laws.

“Physician” means an individual licensed to practice medicine and surgery or osteopathic medicine and surgery under Iowa Code chapter 148.

“Physician assistant” means an individual who has successfully completed an approved program and passed an examination approved by the board or is otherwise found by the board to be qualified to perform medical services under the supervision of a physician and is licensed to practice under Iowa Code chapter 148C.

“Precancerous” means a condition or lesion involving abnormal cells that are associated with an increased risk of developing into cancer.

“Program and fiscal management” means the IA CFY program component that includes planning, organizing, directing, coordinating, managing, budgeting for, and evaluating program activities.

“Quitline Iowa” means a toll-free, statewide smoking tobacco cessation telephone counseling hotline through which trained counselors provide assistance in making an individualized tobacco use quit plan and provide ongoing support through optional follow-up calls.

“Radiologist” means a physician licensed to practice under Iowa Code chapter 148 who specializes in the branch of medicine that diagnoses injuries and diseases using medical imaging procedures such as X-rays, sound waves, or other types of energy.

“Rarely or never been screened” means, as defined for the NBCCEDP, that an individual has not had cervical cancer screening within the last five years 3,469 days (9.5 years) or has never been screened for cervical cancer.

“Recruitment” means the IA CFY program component that involves enrolling targeted populations or individuals finding new individuals to enroll in the IA CFY program for preventive breast and cervical health services.

“Referral” means the IA CFY program component that involves directing individuals with abnormal/alert screening results or barriers to services to appropriate resources for follow-up action.

“Screening mammography” means the use of X-ray of the breasts of asymptomatic individuals in an attempt to detect abnormal lesions of the breast when they are small, nonpalpable, and confined to the breast.

“Service delivery” means providing, either directly or through contractual arrangements, comprehensive breast and cervical cancer screening and cardiovascular disease and stroke risk factor screening, diagnosis, and treatment services through tracking of screening intervals, timeliness of diagnosis, and timeliness of treatment of individuals.

“Surgeon” means a physician licensed to practice under Iowa Code chapter 148 who treats disease, injury, or deformity by physical operation or manipulation.

“Surveillance” means the IA CFY program component that involves the systematic collection, analysis, and interpretation of health data.

“TBS” or *“the Bethesda system”* means a system for reporting cervical or vaginal cytologic diagnoses, used for reporting Pap test results.

“Triglycerides” means a type of fat that is carried in the blood by very low density lipoproteins. Excess calories, alcohol, or sugar in the body are converted into triglycerides and stored in fat cells throughout the body.

ITEM 2. Amend paragraph **8.2(2)“a”** as follows:

a. The IA CFY program shall cover breast and cervical cancer screening and diagnostic services including, but not limited to, the following when those services are provided by a participating health care provider ~~who~~ whose facility has a cooperative agreement with the Iowa department of public ~~health~~ health’s IA CFY program. Payment shall be based on Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(1) to (10) No change.

ITEM 3. Amend paragraph **8.2(2)“f”** as follows:

f. A health care provider ~~that~~ whose facility has a cooperative agreement with the IA CFY program shall be subject to the following:

(1) to (7) No change.

ITEM 4. Adopt the following new paragraph **8.3(1)“f”**:

f. If the applicant is 21 through 39 years of age and asymptomatic for breast cancer, the applicant may receive an office visit for a cervical cancer screening according to IA CFY protocol. If the applicant is determined to be at high risk for developing breast cancer using a risk assessment model that relies on family history, the applicant may receive breast services, including a mammogram and an MRI, in accordance with IA CFY protocols. EXCEPTION: This categorized group is not eligible for cardiovascular services under this program.

ITEM 5. Amend paragraph **8.3(3)“c”** as follows:

c. Individuals who have creditable coverage, Medicaid, or Medicare Part B are eligible for patient navigation if declaring a barrier to services.

ITEM 6. Amend subrule 8.3(5) as follows:

8.3(5) Ineligible. The IA CFY program does not provide coverage for: men.

~~a. Men.~~

~~b. Individuals 39 years of age and younger unless they have symptoms of breast cancer.~~

ITEM 7. Adopt the following new paragraph **8.5(1)“e”**:

e. Fifth priority shall be given to individuals 21 through 39 years of age.

ITEM 8. Amend paragraph **8.7(1)“a”** as follows:

a. The individual was enrolled in the IA CFY program when diagnosed; has had at least one of the screening services (Pap test, screening mammogram, CBE or MRI) or diagnostic procedures paid for by the IA CFY program or with funds from family planning centers, community health centers, or nonprofit organizations; and must be in need of treatment for breast or cervical cancer or precancerous conditions; or