641—8.2(135) Components of the Iowa care for yourself (IA CFY) program. The IA CFY program shall include the following key components:

8.2(1) Program and fiscal management shall be conducted by ensuring strategic planning, implementation, coordination, integration, and evaluation of all programmatic activities and administrative systems, as well as the development of key communication channels and oversight mechanisms to aid in these processes. Program management shall ensure that infrastructure adequately supports service delivery.

8.2(2) Service delivery of specific and appropriate clinical procedures to detect breast and cervical abnormalities and cardiovascular disease or stroke risk factors for individuals enrolled in the IA CFY program shall be directly provided or provided through contractual arrangements.

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 whose facility has a cooperative agreement with the Iowa department of public 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) Physical examinations that include two blood pressure measurements in addition to one or more of the following screening services: CBE, pelvic examination, or Pap test;

(2) Height and weight measurements, when provided in conjunction with one or more of the screening services listed in subparagraph 8.2(2)*"a"*(1) above;

(3) Mammography (screening and diagnostic);

(4) Breast ultrasound, when used as an adjunct to mammography;

(5) Fine-needle aspiration of breast cysts;

(6) Breast biopsies, excisional and nonexcisional (physician charges only; hospital charges are not covered);

(7) Colposcopy of the cervix, with or without biopsy;

(8) Surgical consultations for diagnosis of breast and cervical cancer;

(9) Pathology charges for breast and cervical biopsies;

(10) Anesthesia for program-approved CPT and ICD-10 codes (health care provider charges only; hospital charges and supplies are not covered).

b. Breast and cervical cancer-related services not covered by the IA CFY program include, but are not limited to, the following:

(1) Services not related to breast or cervical cancer screening or diagnosis;

(2) Treatment procedures and services;

(3) Services provided by nonparticipating providers;

(4) Hospital charges for breast biopsies and anesthesia;

(5) Inpatient services.

c. The IA CFY program shall cover cardiovascular disease-related services for select participants enrolled for WISEWOMAN services for whom at least one breast or cervical cancer screening service was paid for using federal funds. Cardiovascular disease-related services shall include, but not be limited to, the following when a participating health care provider that has a cooperative agreement with the department provides those services. Payment shall be based on Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(1) Physical examinations that include two blood pressure measurements;

(2) Height and weight measurements;

(3) Fasting lipid panel that includes total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides; and

(4) Diabetes screening:

1. For an individual who has not been diagnosed with diabetes, fasting blood glucose; and

2. For an individual who has been diagnosed with diabetes, glycosylated hemoglobin (HbA1c).

d. Cardiovascular disease-related services not covered by the IA CFY program include, but are not limited to, the following:

(1) A follow-up diagnostic visit to a health care provider if one or more screening values are in the CDC-defined abnormal value range;

(2) Repeat laboratory testing;

(3) Any additional testing;

(4) Medication; and

(5) Treatment.

e. IA CFY program cardiovascular intervention shall be conducted as a component of the program for all individuals who are eligible and enrolled to receive WISEWOMAN services.

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

(1) The health care provider agrees that reimbursement of procedures and services provided shall not exceed the amount paid under Medicare Part B participating-provider rates as released annually at the beginning of each calendar year.

(2) A mammography health care provider shall ensure that the provider's facility has current FDA certification and ACR or state of Iowa accreditation and is a Medicare and Medicaid-approved facility utilizing BI-RADS and following ACR guidelines for mammography report content.

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

(4) The health care provider shall submit obtained cytology and pathology specimens to a CLIA-certified laboratory for processing. The laboratory shall provide cytological reading and analysis of cervical and vaginal Pap tests by certified/registered cytotechnologists. Cytology (Pap) test results shall be reported using current TBS terminology. The laboratory shall provide board-certified pathologists or experienced certified cytotechnologists to rescreen all analyses and readings of cervical and breast biopsies.

(5) The health care provider shall practice according to the current standards of medical care for breast and cervical cancer early detection, diagnosis, and treatment.

(6) Service delivery may be provided in a variety of settings. Service delivery, however, must include:

1. Providing screening services for specific geographic areas;

2. Providing a point of contact for scheduling appointments;

3. Providing age and income eligibility screening;

4. Providing breast and cervical cancer screening and cardiovascular disease and stroke screening to eligible individuals;

5. Providing referral and follow-up for individuals who have alert-value cardiovascular disease screening results;

6. Providing the required reporting system for screening and follow-up activities;

7. Providing population-based education, outreach, and recruitment activities;

8. Providing IA CFY program cardiovascular intervention as a component of the program for all individuals eligible for and enrolled to receive IA WISEWOMAN program services; and

9. Submitting data within 60 days of service date to establish screening documentation.

(7) The health care provider shall ensure compliance with this chapter and other terms and conditions included in the cooperative agreement.

8.2(3) Referral, tracking, and follow-up utilizing a data system to monitor each enrolled individual's receipt of screening/rescreening, diagnostic, and treatment procedures shall be conducted by the IA CFY program and contracted county board of health designated agency staff.

a. The enrolled individual shall be notified by contracted county board of health designated agency staff of the results of the service, whether the results are normal, benign, or abnormal.

b. The data system shall provide tracking of appropriate and timely clinical services following an abnormal test result or diagnosis of cancer.

c. If the enrolled individual has an abnormal Pap test or breast screening or an alert-value cardiovascular disease risk factor, the health care provider shall provide the individual with a comprehensive referral to appropriate diagnostic or treatment services.

d. The comprehensive referral shall be written. Follow-up shall be conducted to determine whether services were timely, completed, or met.

8.2(4) The IA CFY program and contracted county board of health designated agency staff shall provide case management and shall assist participants whose cancer or precancerous breast or cervical condition was diagnosed through the program in obtaining needed treatment services.

8.2(5) IA CFY program staff shall use quality assurance and improvement techniques including use of established standards, systems, policies and procedures to monitor, assess and identify practical methods for improvement of the program and its components.

a. Quality assurance tools shall include utilizing FDA and ACR minimum standards for mammography facilities and CLIA minimum standards for cytopathology and pathology laboratories.

b. Quality assurance measures shall contribute to the identification of corrective actions to be taken to remedy problems found as a result of investigating quality of care.

8.2(6) Professional development shall be provided by the IA CFY program and contracted county board of health designated agency staff through a variety of channels and activities that enable professionals to perform their jobs competently, identify needs and resources, and contribute to ensuring that health care delivery systems provide positive clinical outcomes.

8.2(7) Using a variety of methods and strategies to reach priority populations, the IA CFY program and contracted county board of health designated agency staff shall provide population-based public education and recruitment that involve the systematic design and delivery of clear and consistent messages about breast and cervical cancer and the benefits of early detection. Outreach activities should focus on individuals who have never or rarely been screened and should work toward the removal of barriers to care (i.e., the need for child care, respite care, interpreter services and transportation) through collaborative activities with other community organizations.

8.2(8) The IA CFY program may develop coalitions and partnerships to bring together groups and individuals that establish a reciprocal agreement for sharing resources and responsibilities to achieve the common goal of reducing breast and cervical cancer mortality and cardiovascular disease and stroke mortality.

8.2(9) The IA CFY program shall conduct surveillance utilizing continuous, proactive, timely and systematic collection, analysis, interpretation and dissemination of breast and cervical cancer screening and cardiovascular disease and stroke risk factor behaviors and incidence, prevalence, survival, and mortality rates. Epidemiological studies shall be conducted utilizing MDEs and other data sources to establish trends of disease, diagnosis, treatment, and research needs. Program planning, implementation, and evaluation shall be based on the epidemiological evidence.

8.2(10) Evaluation of the program shall be conducted through systematic documentation of the operations and outcomes of the program, compared to a set of explicit or implicit standards or objectives.

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